

Section 1: 10-Q (10-Q)

[Table of Contents](#)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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
(State or other jurisdiction of
incorporation or organization)

47-2569713
(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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

The number of outstanding common shares of the registrant, no par value per share, as of October 31, 2019 was 39,387,339

[Table of Contents](#)

ZYMEWORKS INC.
QUARTERLY REPORT ON FORM 10-Q
For the Quarter Ended September 30, 2019
Table of Contents

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	1
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	37
Item 3. Quantitative and Qualitative Disclosures About Market Risk	51
Item 4. Controls and Procedures	52
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	53
Item 1A. Risk Factors	53
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	97
Item 3. Defaults upon Senior Securities	97
Item 4. Mine Safety Disclosures	97
Item 5. Other Information	97
Item 6. Exhibits	98

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; and
- our ability to predict and manage government regulation.

All forward-looking statements, including, without limitation, 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;
- 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;

Table of Contents

- delays with respect to the development and commercialization of our product candidates, which may cause increased costs or delay receipt of product revenue;
- our, or any of our partners', ability to enroll subjects in clinical trials and thereby complete trials on a timely basis;
- the design or our execution of clinical trials may not support regulatory approval, including where clinical trials are conducted outside the United States;
- our 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;

Table of Contents

- 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;
- 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 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 U.S. Food and Drug Administration (“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;

Table of Contents

- our ability to retain key executives and attract and retain qualified personnel;
- our ability to manage organizational growth;
- additional costs and expenses related to the change from foreign private issuer to U.S. domestic issuer status and 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.

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Zymeworks Inc.

Index to Interim Condensed Consolidated Financial Statements (unaudited)

As of and for the three and nine months ended September 30, 2019

	<u>Page</u>
Condensed Consolidated Balance Sheets	2
Condensed Consolidated Statements of Loss and Comprehensive Loss	3
Condensed Consolidated Statement of Changes in Shareholders' Equity	4
Condensed Consolidated Statements of Cash Flows	6
Notes to the Condensed Consolidated Financial Statements	7

Table of Contents

ZYMEWORKS INC.

Consolidated Balance Sheets

(Expressed in thousands of U.S. dollars except share data)

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 250,844	\$ 42,205
Short-term investments (note 4)	84,259	157,959
SR&ED receivables	95	997
Accounts receivables	3,325	358
Prepaid expenses and other current assets	6,788	2,850
Total current assets	345,311	204,369
Deferred financing fees	—	265
Acquired in-process research and development (note 5)	17,628	18,396
Goodwill (note 5)	12,016	12,016
Long-term prepaid assets	2,278	1,135
Property and equipment, net	10,148	6,484
Operating lease right-of-use assets	5,443	—
Intangible assets, net	6,958	1,614
Deferred tax assets	255	84
Total assets	<u>\$ 400,037</u>	<u>\$ 244,363</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (note 6)	\$ 26,922	\$ 13,403
Fair value of liability classified options	22,846	12,603
Current portion of operating lease liability (note 9)	912	—
Current portion of deferred revenue (note 8)	—	3,530
Other current liabilities (note 6)	9	450
Total current liabilities	50,689	29,986
Long-term portion of operating lease liability (note 9)	5,843	—
Long-term portion of deferred revenue (note 8)	32,941	32,941
Other long-term liabilities (note 6)	1,039	946
Total liabilities	90,512	63,873
Shareholders' equity:		
Common shares, no par value; unlimited authorized shares at September 30, 2019 and December 31, 2018, respectively; 39,335,992 and 31,977,668 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively (note 7a)	444,439	320,074
Additional paid-in capital	90,210	12,347
Accumulated other comprehensive loss	(6,659)	(6,659)
Accumulated deficit	(218,465)	(145,272)
Total shareholders' equity	309,525	180,490
Total liabilities and shareholders' equity	<u>\$ 400,037</u>	<u>\$ 244,363</u>
Research collaboration and licensing agreements (note 8)		
Commitments and contingencies (note 10)		

The accompanying notes are an integral part of these financial statements

[Table of Contents](#)

ZYMEWORKS INC.

Consolidated Statements of Loss and Comprehensive Loss

(Expressed in thousands of U.S. dollars except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue				
Research and development collaborations (note 8)	\$ 7,860	\$ 2,054	\$ 27,667	\$ 24,094
Operating expenses:				
Research and development	29,251	14,195	70,511	42,648
General and administrative	12,173	7,447	33,937	23,161
Impairment on acquired IPR&D (note 5)	—	—	768	—
Total operating expenses	41,424	21,642	105,216	65,809
Loss from operations	(33,564)	(19,588)	(77,549)	(41,715)
Other income (expense):				
Interest and other expense	(33)	(166)	(90)	(166)
Change in fair value of warrant liabilities	—	—	—	(3,565)
Interest and other income	2,097	1,131	4,566	1,648
Foreign exchange (loss) gain	117	(79)	(200)	(205)
Total other income (expense), net	2,181	886	4,276	(2,288)
Loss before income taxes	(31,383)	(18,702)	(73,273)	(44,003)
Current income tax recovery (expense)	710	(168)	(171)	(2,000)
Deferred income tax recovery	198	119	251	174
Net loss and comprehensive loss	<u>\$ (30,475)</u>	<u>\$ (18,751)</u>	<u>\$ (73,193)</u>	<u>\$ (45,829)</u>
Net loss per common share (note 2):				
Basic	(0.70)	(0.59)	(2.03)	(1.63)
Diluted	(0.70)	(0.59)	(2.03)	(1.63)
Weighted-average common shares outstanding (note 2):				
Basic	43,445,379	31,959,206	36,143,113	28,119,872
Diluted	43,445,379	31,959,206	36,143,113	28,119,872

The accompanying notes are an integral part of these financial statements

[Table of Contents](#)

ZYMEWORKS INC.
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, 2019	31,977,668	\$ 320,074	\$ (145,272)	\$ (6,659)	\$ 12,347	\$ 180,490
Issuance of common shares on exercise of options	52,130	549	—	—	(130)	419
Issuance of common shares through employee share 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 options	115,298	2,285	—	—	(241)	2,044
Stock-based compensation	—	—	—	—	3,038	3,038
Issuance of common shares and warrants in connection with public offering (note 1 and 7c)	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
Issuance of common shares on exercise of options	133,696	2,827	—	—	(592)	2,235
Issuance of common shares through employee share purchase plan	24,627	438	—	—	—	438
Stock-based compensation	—	—	—	—	3,310	3,310
Net Loss	—	—	(30,475)	—	—	(30,475)
Balance at September 30, 2019	39,335,992	\$ 444,439	\$ (218,465)	\$ (6,659)	\$ 90,210	\$ 309,525

The accompanying notes are an integral part of these financial statements

[Table of Contents](#)

ZYMEWORKS INC.
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, 2018	25,444,006	\$ 222,991	\$ (108,716)	\$ (6,659)	\$ 8,812	\$ 116,428
Issuance of common shares on exercise of options	7,207	56	—	—	(22)	34
Issuance of common shares through employee share purchase plan	13,247	100	—	—	—	100
Stock-based compensation	—	—	—	—	(830)	(830)
Net loss	—	—	(21,204)	—	—	(21,204)
Balance at March 31, 2018	25,464,460	\$ 223,147	\$ (129,920)	\$ (6,659)	\$ 7,960	\$ 94,528
Issuance of common shares on exercise of options	69,620	874	—	—	(272)	602
Stock-based compensation	—	—	—	—	1,517	1,517
Issuance of common shares on exercise of warrants	206,361	4,913	—	—	—	4,913
Issuance of common shares in connection with public offering	6,210,000	90,779	—	—	—	90,779
Net Loss	—	—	(5,874)	—	—	(5,874)
Balance at June 30, 2018	31,950,441	\$ 319,713	\$ (135,794)	\$ (6,659)	\$ 9,205	\$ 186,465
Issuance of common shares on exercise of options	2,997	52	—	—	(5)	47
Issuance of common shares through employee share purchase plan	9,242	152	—	—	—	152
Stock-based compensation	—	—	—	—	1,784	1,784
Share issue costs in connection with public offering	—	(27)	—	—	—	(27)
Net Loss	—	—	(18,751)	—	—	(18,751)
Balance at September 30, 2018	31,962,680	\$ 319,890	\$ (154,545)	\$ (6,659)	\$ 10,984	\$ 169,670

The accompanying notes are an integral part of these financial statements

[Table of Contents](#)

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Loss for the period	\$ (73,193)	\$ (45,829)
Items not involving cash:		
Depreciation and amortization of property and equipment	1,573	1,400
Amortization of intangible assets	2,156	1,094
Impairment of acquired IPR&D	768	—
Stock-based compensation	20,965	11,943
Amortization of operating lease right-of-use assets	1,019	—
Deferred income tax expense (recovery)	(171)	(174)
Change in fair value of warrant liabilities	—	3,565
Change in fair value of contingent consideration	285	53
Unrealized foreign exchange loss	152	254
Changes in non-cash operating working capital:		
Accounts receivable	(2,967)	(15)
SR&ED receivables	902	1,088
Prepaid expenses and other current assets	(5,567)	(280)
Accounts payable and accrued liabilities	12,449	1,018
Operating lease liabilities	(41)	—
Deferred revenue	(3,530)	—
Income taxes payable	(299)	(45)
Net cash used in operating activities	(45,499)	(25,928)
Cash flows from financing activities:		
Proceeds from public offering, net of issuance costs (note 1 and 7c)	188,231	90,752
Issuance of common shares on exercise of options (note 7d)	2,687	581
Issuance of common shares through employee share purchase plan	598	252
Finance lease payments	(13)	(8)
Net cash from financing activities	191,503	91,577
Cash flows from investing activities:		
Short-term investments	74,286	(69,881)
Acquisition of property and equipment	(4,181)	(544)
Acquisition of intangible assets	(7,500)	(2,607)
Net cash from (used in) investing activities	62,605	(73,032)
Effect of exchange rate changes on cash and cash equivalents	30	(188)
Net change in cash and cash equivalents	208,639	(7,571)
Cash and cash equivalents, beginning of period	42,205	35,946
Cash and cash equivalents, end of period	\$ 250,844	\$ 28,375
<i>Supplemental disclosure of non-cash investing and finance items:</i>		
Leased assets obtained in exchange for operating lease liabilities	6,682	—
Share issue costs and deferred financing fees in accounts payable and accrued liabilities	—	153
Acquisition of property and equipment in accounts payable and accrued liabilities	1,056	63
Cashless exercise of warrants	—	4,913

The accompanying notes are an integral part of these financial statements

Table of Contents

ZYMEWORKS INC.

Notes to the Interim Condensed Consolidated Financial Statements (unaudited)

1. Nature of Operations

Zymeworks (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, 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.

Public Offering

On January 31, 2019, the Company’s U.S. shelf registration statement on Form S-3 (File No. 333-228782) was declared effective by the SEC and a final base shelf prospectus was filed with the securities commissions or similar securities regulatory authorities in each of the provinces and territories of Canada. The U.S. shelf registration statement and Canadian base shelf prospectus allow Zymeworks to issue securities with a total aggregate offering price of up to \$250 million pursuant to prospectus supplements.

On June 18, 2019, the Company filed with the SEC, as well as with the securities commissions or similar securities regulatory authorities in each of the provinces and territories of Canada, a preliminary prospectus supplement to complete an underwritten public offering of its common shares and pre-funded warrants (the “Warrants”) (note 7c) in lieu of common shares plus an over-allotment option for the underwriters to purchase additional common shares (the “Offering”). On June 20, 2019, the Company filed a final prospectus supplement relating to the Offering with the SEC, as well as with the securities commissions or similar securities regulatory authorities in each of the provinces and territories of Canada, setting forth an offering price of \$18.00 per common share and \$17.9999 per pre-funded warrant.

The Offering closed on June 24, 2019 pursuant to which the Company sold 7,013,892 shares of common shares including the sale of 1,458,336 shares of common shares to the underwriters upon their full exercise of their over-allotment option and 4,166,690 pre-funded warrants in lieu of common shares. Net proceeds were approximately \$188.0 million, after underwriting discounts, commissions and offering expenses.

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 financial statements and notes for the year ended December 31, 2018.

These unaudited interim financial statements reflect all adjustments, consisting solely of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods presented. The results of operations for the three and nine months ended September 30, 2019 and 2018 are not necessarily indicative of results that can be expected for a full year. These unaudited interim financial statements follow the same significant accounting policies as those described in the notes to the audited financial

Table of Contents

statements of the Company for the year ended December 31, 2018, except for the new accounting guidance adopted during the period (note 3). Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

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 per share data and where otherwise indicated. References to "\$" are to U.S. dollars and references to "C\$" are to Canadian dollars.

Use of Estimates

The preparation of the 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. In preparing these interim condensed consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, some of which are those related to revenue recognition including estimated timing of completion of performance obligations required to meet revenue recognition criteria, Scientific Research and Experimental Development ("SR&ED") Program, stock-based compensation, warrants, accrual of expenses, preclinical study accruals, valuation allowance for deferred taxes, other contingencies and valuation of assets acquired in a business combination. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

Fair Value Measurements

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

To determine the fair value, the Company uses the fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use to value an asset or liability and are developed based on market data obtained from independent sources. Unobservable inputs are inputs based on assumptions about the factors market participants would use to value an asset or liability. The three levels of inputs that may be used to measure fair value are as follows:

- Level 1 inputs are quoted market prices for identical instruments available in active markets.
- Level 2 inputs are inputs other than Level 1 prices, such as prices for 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 assumptions 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 investments, amounts receivable, accounts payable and accrued liabilities, finance and operating lease obligations, liability classified options and other long-term liabilities.

The carrying values of cash and cash equivalents, short-term investments, amounts receivable and accounts payable and accrued liabilities approximate their fair values due to the immediate or short-term maturity of these

Table of Contents

financial instruments. As quoted prices for the liability classified stock options are not readily available, the Company has used 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 adjusted quarterly for changes in its 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 indicates the fair value hierarchy of the valuation techniques used to determine such fair value:

	<u>September 30, 2019</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities				
Liability classified stock options	\$ 22,846	\$ —	\$ —	\$ 22,846
Liability for contingent consideration (note 10)	992	—	—	992
Total	<u>\$ 23,838</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 23,838</u>

	<u>December 31, 2018</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Liabilities				
Liability classified stock options	\$ 12,603	\$ —	\$ —	\$ 12,603
Liability for contingent consideration (note 10)	707	—	—	707
Total	<u>\$ 13,310</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 13,310</u>

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

	<u>Liability at beginning of the period</u>	<u>Reclassification to liabilities from equity</u>	<u>Increase (decrease) in fair value of liability classified stock options</u>	<u>Exercise of options</u>	<u>Unrealized foreign currency loss (gain)</u>	<u>Liability at end of the period</u>
Three months ended September 30, 2019	\$ 20,127	\$ —	\$ 3,687	\$ (796)	\$ (172)	\$ 22,846
Nine months ended September 30, 2019	\$ 12,603	\$ 119	\$ 11,850	\$ (2,009)	\$ 283	\$ 22,846

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

	<u>Liability at the beginning of the period</u>	<u>Increase (decrease) in fair value of liability for contingent consideration</u>	<u>Liability at end of the period</u>
Three months ended September 30, 2019	\$ 992	\$ —	\$ 992
Nine months ended September 30, 2019	\$ 707	\$ 285	\$ 992

Table of Contents

Net loss per share

Basic net loss per share attributable to common shareholders is computed by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to common shareholders is computed by adjusting net loss attributable to common shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including stock options and warrants. Diluted net loss per share attributable to common shareholders is computed by dividing the diluted net loss attributable to common shareholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding instruments. ASC 260 “Earnings Per Share” requires an adjustment to the numerator for any income or loss related to ASC 815 liability classified warrants and stock options, if dilutive, if they are presumed to be share settled. The stock options outstanding were excluded from the calculation of diluted loss per share because their inclusion would have been anti-dilutive.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Numerator:				
Net loss attributable to common shareholders:				
Basic	\$ (30,475)	\$ (18,751)	\$ (73,193)	\$ (45,829)
Diluted	\$ (30,475)	\$ (18,751)	\$ (73,193)	\$ (45,829)
Denominator:				
Weighted-average common shares outstanding:				
Basic (*)	43,445,379	31,959,206	36,143,113	28,119,872
Diluted	43,445,379	31,959,206	36,143,113	28,119,872
Net loss per common share—basic	\$ (0.70)	\$ (0.59)	\$ (2.03)	\$ (1.63)
Net loss per common share—diluted	\$ (0.70)	\$ (0.59)	\$ (2.03)	\$ (1.63)

(*): Weighted average number of common shares used in the basic earnings per share calculation for the three and nine months ended September 30, 2019 includes the pre-funded warrants issued in connection with the Company’s June 2019 offering as the warrants are exercisable at any time and for nominal cash consideration.

3. Recent Accounting Pronouncements

Initial adoption of new accounting pronouncements

Adoption of Topic 842 (Leases)

On January 1, 2019 the Company adopted Topic 842 using the modified retrospective approach with a cumulative-effect adjustment to accumulated deficit as of January 1, 2019 in accordance with ASU No. 2018-11, *Leases (Topic 842) — Targeted Improvements*. Results for the three and nine months ended September 30, 2019 are presented under Topic 842. Prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under previous lease guidance, ASC Topic 840: *Leases* (“Topic 840”). The Company elected certain practical expedients permitted under the transition guidance within the new standard, including not to separate non-lease components in determining operating lease liability.

Table of Contents

The impact of the adoption of Topic 842 on the accompanying Condensed Consolidated Balance Sheet as of January 1, 2019 was as follows:

	December 31, 2018	Adjustments Due to the Adoption of Topic 842	January 1, 2019
Operating lease right-of-use assets ⁽¹⁾	\$ —	\$ 3,222	\$ 3,222
Total lease inducements ⁽²⁾	333	(333)	—
Total operating lease liabilities ⁽³⁾	—	3,561	3,561

(1) Right-of-use assets include operating leases. Right-of-use assets for finance leases are included in property and equipment

(2) Included in current and long-term other liabilities (note 6)

(3) Includes current and non-current operating lease liabilities

The adjustments due to the adoption of Topic 842 primarily related to the recognition of operating lease right-of-use assets and operating lease liabilities. No adjustment was made to accumulated deficit as of January 1, 2019.

The Company evaluated its facility leases and determined that, effective upon the adoption of Topic 842, they were all operating leases. The Company performed an evaluation of its other contracts with customers and suppliers in accordance with Topic 842 and determined that, except for the facility and equipment leases described above, none of its contracts contain a lease. The impact of the adoption of Topic 842 on the accompanying Condensed Consolidated Statements of Operations for three and nine months ended September 30, 2019 were as follows:

	As reported	Effect of Adoption of Topic 842 Higher / (Lower)	Balances Without the Adoption of Topic 842
Operating expenses for the three months ended September 30, 2019	\$ 41,424	\$ 158	\$ 41,266
Operating expenses for the nine months ended September 30, 2019	\$ 105,216	\$ 408	\$ 104,808

See “note 9. Leases” in these consolidated financial statements for additional disclosures.

Adoption of other pronouncements

In June 2018, the FASB issued ASU 2018–07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. This new guidance is effective for the Company in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this standard as of January 1, 2019. Adoption of this new accounting standard did not have any significant impact on the Company’s consolidated financial statements.

Recent accounting pronouncements not yet adopted

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. Early adoption is permitted. The Company is currently assessing the impact the adoption of the standard will have on its consolidated financial statements.

Table of Contents

In August 2018, the FASB issued ASU 2018-15, Intangibles — Goodwill and Other — Internal Use Software (Subtopic 350-40). This ASU addresses customer's accounting for implementation costs incurred 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 hosting 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. Early adoption is permitted. The amendments in this ASU can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is evaluating the effect of adopting this new accounting guidance but does not expect adoption will have a material impact on the Company's consolidated financial statements.

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

4. Short-Term Investments

Short-term investments consist of guaranteed investment certificates ("GICs") and term deposits held at financial institutions in accordance with the Company's treasury policy. These GICs and term deposits bear interest rates of 2%-3% per annum with a maturity up to 12 months. The Company may redeem GIC investments 30 days after deposit without penalty.

5. IPR&D and Goodwill

Acquired IPR&D

All in-process research and development assets ("IPR&D") acquired in the Kairos Therapeutics Inc. ("Kairos") business combination is classified as indefinite-lived and is not currently being amortized. IPR&D becomes definite-lived upon the completion of the associated research and development efforts and will be amortized from that time over an estimated useful life based on respective patent terms. The Company evaluates the recoverable amount of intangible assets on an annual basis and performs an annual evaluation of goodwill as of December 31 each year, unless there is an event or change in the business that could indicate impairment, in which case earlier testing is performed.

During the nine months ended September 30, 2019, the Company recorded an impairment charge of \$768 related to the fair value of IPR&D recognized in relation to collaboration efforts with VAR2 Pharmaceuticals ApS ("VAR2") as parties jointly decided not to pursue opportunities for the co-development and collaboration for antibody-based therapies. The corresponding decrease in deferred tax liability and increase in valuation allowance against deferred tax asset balances of \$207 were also recorded. The following table summarizes the carrying value of IPR&D, net of impairment:

	Acquired IPR&D	Accumulated Impairment	Net
Balance at December 31, 2018	\$ 20,700	\$ (2,304)	\$ 18,396
Change during the period	—	(768)	(768)
Balance at September 30, 2019	<u>\$ 20,700</u>	<u>\$ (3,072)</u>	<u>\$ 17,628</u>

The Company concluded that there were no further impairment indicators related to IPR&D as of September 30, 2019.

Goodwill

The Company concluded that there were no impairment indicators related to goodwill as of September 30, 2019.

Table of Contents

6. Liabilities

Accounts payable and accrued expenses consisted of the following:

	September 30, 2019	December 31, 2018
Trade payables	\$ 8,040	\$ 2,599
Accrued research expenses	13,589	6,633
Employee compensation and vacation accruals	3,430	2,926
Accrued legal and professional fees	1,036	556
Other	827	689
Total	<u>\$ 26,922</u>	<u>\$ 13,403</u>

Other current liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Current income tax liability	\$ —	\$ 299
Current portion of lease inducements	—	136
Current portion of finance lease liability (note 9)	9	15
Total	<u>\$ 9</u>	<u>\$ 450</u>

Other long-term liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Liability for contingent consideration (note 10)	\$ 992	\$ 707
Lease inducements	—	197
Finance lease liability (note 9)	47	42
Total	<u>\$ 1,039</u>	<u>\$ 946</u>

7. Redeemable Convertible Class A Preferred Shares, and Shareholders' Equity

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

a. Authorized

On May 2, 2017, the Company's new Articles of Incorporation were issued under which the Company has an unlimited number of voting Common Shares and Preferred Shares without par value.

Under the Company's former Articles of Incorporation dated December 21, 2015, the Company had 6,413,265 authorized Redeemable Convertible Class A Preferred Shares.

b. Preferred Shares

As of September 30, 2019 and December 31, 2018, no preferred shares were issued or outstanding, respectively.

The rights and preferences of the unissued preferred shares are as follows:

Holders of Preferred Shares will be entitled to preference with respect to payment of dividends over the common shares and any other shares ranking junior to the preferred shares with respect to payment of dividends.

In the event of the liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, or any other distribution of the assets of the Company among its shareholders for the purpose of winding up its

Table of Contents

affairs, the holders of the preferred shares will be entitled to preference over the common shares and any other shares ranking junior to the preferred shares with respect to the repayment of capital paid up on and the payment of unpaid dividends accrued on the preferred shares.

The preferred shares may also be given such other preferences over the common shares and any other shares ranking junior to the preferred shares as may be fixed by directors' resolution as to the respective series authorized to be issued.

c. 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 as well as issued pre-funded warrants at a price of \$17.9999 per pre-funded warrant (the "Warrants") which granted holders of warrants to purchase up to 4,166,690 common shares of the Company ("Warrant Share"), at an exercise price of \$0.0001 per share (the "Exercise Price"). The Warrants are exercisable by the holders at any time on or after the original issue date. The Warrants do not expire unless they are exercised or settled in accordance with the warrant agreement.

As the Warrants meet the conditions for equity classification, proceeds from issuance of the Warrants, net of any transaction costs, are recorded in the additional paid-in capital. Upon exercise of the Warrants, the historical costs recorded in additional paid-in capital along with the Exercise Price collected from holders will be recorded in common shares.

d. Stock-Based Compensation

Original Stock Option Plan:

On July 14, 2006, the shareholders 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 are denominated in Canadian dollars. The U.S. dollar amounts have been translated using the period end rate or the average 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 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 allowed for the grant of options to directors, officers, employees and consultants in U.S. or Canadian dollars, and also permitted the Company to grant incentive stock options ("ISOs"), within the meaning of Section 422 of the 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 includes an article that allows the Company to grant restricted shares,

Table of Contents

restricted share units (“RSU”) and other share-based awards, in addition to options. All restricted share, RSU or other share-based award terms and conditions will be specified in future grant agreements. To date, no restricted shares, RSUs or other share-based awards have been granted.

The maximum number of common shares reserved for issuance under the New Plan is 5,686,097, which includes 3,985,768 shares issuable upon exercise of options outstanding as of December 31, 2018. Beginning in 2019 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.

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 currency into United States currency 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, 2018	2,445,990	14.66	10.74	6.99	14,421	10,571
Granted	322,800	21.34	15.91			
Exercised	(241,906)	10.60	7.97			
Forfeited	(37,906)	17.45	13.18			
Outstanding, September 30, 2019	2,488,978	15.88	11.99	6.86	42,215	31,883

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, 2018	1,539,778	11.67	9.02	4,876
Granted	1,210,050	17.07		
Exercised	(59,218)	12.94		
Forfeited	(30,261)	15.52		
Outstanding, September 30, 2019	2,660,349	14.05	8.79	28,659

During the nine months ended September 30, 2019, the Company received cash proceeds of \$2,686 (C\$3,267) from stock options exercised.

Table of Contents

The stock options expire at various dates from September 30, 2019 to September 16, 2029.

The estimated fair value of options granted to officers, directors, employees and consultants is amortized over the vesting period. 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 2), is recorded in research and development expenses, general and administration expenses and finance expense (income) as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development expenses:				
Stock-based compensation for equity classified instruments	\$ 1,690	\$ 691	\$ 4,324	\$ 1,724
Change in fair value of liability classified equity instruments	888	496	2,856	1,966
	<u>\$ 2,578</u>	<u>\$ 1,187</u>	<u>\$ 7,180</u>	<u>\$ 3,690</u>
General and administrative expenses:				
Stock-based compensation for equity classified instruments	\$ 1,721	\$ 1,093	\$ 4,791	\$ 2,758
Change in fair value of liability classified equity instruments	2,781	1,304	8,908	5,342
	<u>\$ 4,502</u>	<u>\$ 2,397</u>	<u>\$ 13,699</u>	<u>\$ 8,100</u>
Finance expenses:				
Stock-based compensation for equity classified instruments	\$ —	\$ —	\$ —	\$ 1
Change in fair value of liability classified equity instruments	18	39	86	152
	<u>\$ 18</u>	<u>\$ 39</u>	<u>\$ 86</u>	<u>\$ 153</u>

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:

	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
Dividend yield	0%	0%
Expected volatility	73.74%	66.0%
Risk-free interest rate	1.46%	2.17%
Expected average life of options	6.05 years	5.91 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:

	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
Dividend yield	0%	0%
Expected volatility	72.91%	66.0%
Risk-free interest rate	2.36%	2.64%
Expected average life of options	6.02 years	5.87 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.

Table of Contents

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:

	September 30, 2019	September 30, 2018
Dividend yield	0%	0%
Expected volatility	72.8%	66.5%
Risk-free interest rate	1.47%	1.55%
Expected average option term	3.56 years	5.89 years
Number of liability classified stock options outstanding	1,327,334	1,441,163

At September 30, 2019, the unamortized compensation expense related to unvested options was \$14,276 (C\$18,905). The remaining unamortized compensation expense as of September 30, 2019 will be recognized over a weighted-average period of 1.74 years.

e. Employee Stock Purchase Plan:

On April 10, 2017, the employee stock purchase plan, (ESPP), was approved by the shareholders of the Company and became effective immediately prior to the consummation of the 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 ESPP is implemented through a series of offerings under which eligible employees are granted rights to purchase the Company's common shares at the end of specified purchase periods at a discounted purchase price. 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. The first six-month purchase period commenced on July 1, 2017.

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 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.

Table of Contents

Common shares purchased under the ESPP will be issued from treasury at a purchase price equal to 85% of the applicable market price of a common share, all in accordance with applicable laws and the terms and conditions of the ESPP. For the purposes of the ESPP, the market price of a common share is defined as the closing sale price of a share on such 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 number of common shares reserved for issuance under the ESPP shall not exceed 272,350 common shares, plus the number of common shares that are automatically added on January 1st of each year, commencing on (and including) January 1, 2018 and ending on (and including) January 1, 2027, in an amount equal to the lesser of (i) 1% of the total number of common shares issued and outstanding on December 31st of the preceding calendar year, and (ii) 419,000 common shares. As this plan is considered compensatory, a charge of \$232 has been recorded to research and development expense and general and administrative expense accounts. As of September 30, 2019, total amount contributed by the ESPP participants is \$223.

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.

8. Research, Collaboration and Licensing Agreements

In accordance with ASC 606, the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised deliverables in the contract; (ii) determination of whether the promised deliverables are performance obligations including whether they are distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on the stand-alone selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration that it is entitled to in exchange for the goods and services transferred to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of Topic 606, to identify distinct performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements ("ASC 808"), the Company applies the revenue recognition model under ASC 606 to part or all of the arrangement, when deemed appropriate.

The Company has entered into a number of collaboration and licensing agreements. Promised deliverables within these agreements may include: (i) grants of licenses, or options to obtain licenses, to the Company's intellectual property, (ii) research and development services, (iii) drug product manufacturing, and (iv) participation on joint research and/or development committees. The terms of these agreements typically include one or more of the following types of payments to the Company:

- non-refundable, upfront license and platform technology access fees;
- research, development and regulatory milestone payments;
- commercial milestone payments; and
- royalties on net sales of licensed products.

Licenses of intellectual property including platform technology access: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the

Table of Contents

arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.

Milestone payments: At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment. The probability of successfully achieving the criteria for the milestone payments is highly uncertain. Consequently, there is a significant risk that the Company may not earn all of the milestone payments from each of its strategic partners.

Research and development milestones in the Company's collaboration agreements may include some, but not necessarily all, of the following types of events:

- completion of preclinical research and development work leading to selection of product candidates;
- initiation of Phase 1, Phase 2 and Phase 3 clinical trials; and
- achievement of certain other technical, scientific or development criteria.

Regulatory milestone payments may include the following types of events:

- filing of regulatory applications for marketing approval in the United States, Europe or Japan, including Investigational New Drug ("IND") applications and Biologics License Application ("BLA"); and
- marketing approval in major markets, such as the United States, Europe or Japan.

Royalties and commercial milestones: For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee. Since inception to date, the Company has not recognized any royalty revenue or commercial milestone from any of its out-licensing arrangements.

Research support payments: Payments by the licensees in exchange for research activities performed by the Company on behalf of the licensee are recognized upon performance of such activities at rates consistent with prevailing market rates.

If the expectation at contract inception is such that the period between payment by the licensee and the completion of related performance obligations will be one year or less, the Company assumes that the contract does not have a significant financing component.

Table of Contents

Strategic Partnership Revenue

The following table presents summarized revenue recognized from the Company's strategic partnerships.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
BeiGene:				
Recognition of upfront fee	\$ —	\$ —	\$ 3,530	\$ —
Lilly:				
Milestone revenue	—	2,000	8,000	2,000
Daiichi Sankyo:				
Upfront technology access fee	—	—	—	18,000
Commercial license option fee	—	—	3,500	—
LEO:				
Research support payments	336	—	1,108	—
Celgene:				
Option exercise fee	7,500	—	7,500	4,000
Merck:				
Milestone revenue	—	—	2,000	—
Iconic:				
Milestone revenue	—	—	1,000	—
Research support and supplies payments	24	—	1,029	—
Other:				
Research support payments	—	54	—	94
	<u>\$ 7,860</u>	<u>\$ 2,054</u>	<u>\$ 27,667</u>	<u>\$ 24,094</u>

As at September 30, 2019 and December 31, 2018, contract assets from research, collaboration and licensing agreements were \$nil. Contract liabilities are comprised of \$32,941 deferred revenue from BeiGene as of September 30, 2019 (December 31, 2018: \$36,471) as disclosed below.

Research and License Agreement with Merck Sharp & Dohme Research Ltd. ("Merck")

On August 22, 2011, the Company entered into a Research and License Agreement with Merck providing Merck a worldwide license to develop and commercialize novel bispecific antibodies generated through use of the Company's Azymetric platform toward certain exclusive therapeutic targets. Both companies will collaborate to advance the therapeutic platforms, with Merck working to progress the bispecific therapeutic antibody candidates through clinical development and commercialization. No joint development activities to advance the therapeutic platforms have occurred since inception and Merck no longer has a right to such joint activities. In 2013, Merck was also provided with a limited, non-exclusive license to EFECT, to be used together with the Azymetric platform for developing products.

On December 3, 2014, the Company and Merck jointly amended the agreement, including amending certain terms and exclusivities contained therein. Under the terms of the amended agreement, the Company receives funding for certain internal and external research costs incurred in the project. Additionally, the amendment removed a \$2.0 million research milestone from the total milestones the Company would be eligible to receive over the life of the agreement. The new research funding terms were priced at market rate, and the Company concluded that the original agreement was not materially modified. Accordingly, the amendments did not impact the determination of units of accounting or the allocation of the arrangement consideration.

Upon the execution of the agreement, the Company received a one-time, non-refundable upfront payment of \$1.25 million. Over the life of the agreement, the Company is eligible to receive payments up to \$190.75 million,

Table of Contents

comprised of the \$1.25 million upfront payment, \$3.5 million for research phase successes, up to \$6.0 million for completion of IND-enabling studies, up to \$66.0 million for development milestones and up to \$114.0 million for commercial milestones. In addition, the Company is eligible to receive tiered royalty payments on sales of products. Merck will have exclusive worldwide commercialization rights to products derived from the agreement. The events and conditions resulting in payments for research, development and commercial milestones solely depend on Merck's performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Merck, is a customer. The Company identified the following promised goods and services at the inception of the Merck agreement: (1) the research license, (2) the commercial license, (3) the transfer of the Company's platform technology (Azymetric) (4) research services and technical assistance in connection with the transfer of platform technology to Merck, and (5) research activities to be performed on behalf of Merck. The Company concluded that the licenses and platform technologies together are distinct. Accordingly, the deliverables (1) through (4) were considered as a single performance obligation and the upfront payment of \$1.25 million has been allocated to this performance obligation. The upfront payment was recorded as deferred revenue and recognized into revenue on a straight-line basis from October 1, 2011 through June 30, 2012, the period over which the Company performed the procedures for transferring the Company's know-how and technology and related technical assistance during the transfer process. The research activities to be performed on behalf of Merck after the transfer of the technology are also determined to have stand-alone value as Merck or another third party could provide these services without the Company's assistance. The revenue from this deliverable is recognized upon performance of such activities at rates consistent with prevailing market rates.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements. The best estimate of selling price for the other deliverables was estimated using internal estimates of cost to perform the specific services plus a normal profit margin for providing the services.

At execution, the transaction price included only the \$1.25 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Merck and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The consideration otherwise allocable to delivered units is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions. Consequently, the arrangement consideration related to the research activities to be performed on behalf of Merck after the transfer of the technology was excluded from the allocation arrangement consideration because the consideration and performance are contingent upon Merck requesting performance of the services and these services are priced at an estimated fair value.

The Company received and recorded non-refundable milestone payments from Merck in the amounts of \$2.0 million, \$1.5 million and \$2.0 million on September 20, 2012, April 22, 2013 and May 28, 2019, respectively. These milestone payments were received upon the achievement of certain development activities during the course of the research program and were recorded as revenue upon achievement of the milestone as the Company had no remaining performance obligations under the arrangement. No additional milestone payments or royalties have been received to date.

Table of Contents

During the nine months September 30, 2019, the Company recorded \$nil (2018: \$nil) in research support payments from Merck, under the terms of the amended agreement.

Licensing and Collaboration Agreement with Eli Lilly and Company (“Lilly”)

On December 17, 2013, the Company entered into a Licensing and Collaboration Agreement with Lilly to develop novel bispecific antibody therapeutics using the Company’s proprietary Azymetric platform. The Company will apply its Azymetric platform in combination with Lilly’s proprietary targets to create novel bispecific antibodies which Lilly will have the right to develop and commercialize worldwide.

Upon the execution of the agreement, the Company received a one-time, non-refundable upfront payment of \$1.0 million. Over the life of the agreement, the Company will receive funding for internal and external research costs incurred on behalf of Lilly on the project, and is eligible to receive potential milestone payments for each product, comprised of \$1.0 million for research phase success, \$2.0 million for IND submission, \$8.0 million for development milestones and up to \$40.0 million for commercial milestones. In addition, the Company is eligible to receive tiered royalty payments on the sale of products. Lilly will have exclusive worldwide commercialization rights to products derived from the collaboration. The Company determined that other than the research milestone, the events and conditions resulting in payments for development and commercial milestones solely depend on Lilly’s performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Lilly, is a customer. The Company identified the following promised goods and services at the inception of the Lilly agreement: (1) the research license, (2) the commercial license, (3) the transfer of the Company’s platform technology (Azymetric), (4) the research services and technical assistance to be provided by the Company in connection with the transfer of intellectual property to Lilly, and (5) research activities to be performed on behalf of Lilly. The Company concluded that the licenses and platform technology together are distinct. Accordingly, the deliverables (1) through (4) were considered as a single performance obligation and the upfront payment of \$1.0 million has been allocated to this performance obligation. The payment was recorded as deferred revenue and recognized into revenue on a straight-line basis from December 31, 2013 to June 30, 2014, the period over which the Company performed the procedures for transferring the Company’s know-how and technology and related technical assistance during the transfer process. The research activities to be performed on behalf of Lilly after the transfer of the technology are also determined to be distinct as Lilly or another third party could provide these services without the Company’s assistance. The revenue from this deliverable is recognized upon performance of such activities at rates consistent with prevailing market rates.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company’s best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements. The best estimate of selling price for the other deliverables was estimated using internal estimates of cost to perform the specific services plus a normal profit margin for providing the services.

At execution, the transaction price included only the \$1.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee’s efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Lilly and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Table of Contents

The consideration otherwise allocable to delivered units is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions. Consequently, the arrangement consideration related to the research activities to be performed on behalf of Lilly after the transfer of the technology was excluded from the allocation arrangement consideration because the consideration and performance are contingent upon Lilly requesting performance of the services and these services are priced at an estimated fair value.

On December 11, 2015, the Company recorded non-refundable substantive research milestone revenue from Lilly in the amount of \$1.0 million upon the achievement of certain research activities during the course of the research program. Subsequently, on August 31, 2018, the Company recorded a non-refundable fee of \$2.0 million which was received upon Lilly's filing of IND application to the FDA for a bispecific antibody enabled by the Azymetric platform.

During the nine months September 30, 2019, the Company recorded \$nil (2018: \$nil) in research support revenue from Lilly. Lilly was a related party during 2018 but was not considered a related party as of December 31, 2018 and thereafter.

Licensing and Collaboration Agreement with Lilly

On October 22, 2014, the Company entered into a second Licensing and Collaboration Agreement with Lilly to develop novel bispecific antibody therapeutics using the Company's proprietary Azymetric platform. This agreement did not alter or amend the initial agreement entered into on December 17, 2013. Under the terms of this agreement, the Company will apply its Azymetric platform in combination with Lilly's proprietary targets to create novel bispecific antibodies which Lilly will develop and commercialize. In 2017 Lilly nominated a bispecific antibody from this agreement for preclinical development and discontinued the research of two other bispecific antibodies due to strategic portfolio realignment in those particular disease areas. Each of the two agreements with Lilly were negotiated independently and the deliverables covered by the respective contracts are unrelated to one another as they cover different product candidates. Accordingly, the second Licensing and Collaboration Agreement with Lilly has been accounted for as a new arrangement.

The Company is eligible to receive potential milestone payments totaling up to \$125.0 million, comprised of up to \$2.0 million for research success milestone, up to \$8.0 million for IND submission milestones, up to \$20.0 million for development milestones and up to \$95.0 million for commercial milestones. In addition, the Company is eligible to receive tiered royalty payments on the sale of products. Lilly will have exclusive worldwide commercialization rights to products derived from the collaboration. No license, research, development and commercial milestones or royalty payments have been received to date. The Company determined that other than the research milestone, the events and conditions resulting in payments for development and commercial milestones solely depend on Lilly's performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Lilly, is a customer. At execution, there was no upfront fee received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Lilly and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

On December 1, 2016, the Company recorded a non-refundable fee of \$2.0 million which was received upon achievement of a critical success criteria point milestone under the research plan. Subsequently, on January 16,

Table of Contents

2019, the Company recorded a non-refundable fee of \$8.0 million which was received upon Lilly's filing of IND application to the FDA for a bispecific antibody enabled by the Azymetric platform.

No other research, development or commercial milestone payments or royalties have been received to date.

Licensing and Collaboration Agreement with Celgene Corporation & Celgene Alpine Investment Co. LLC ("Celgene")

On December 23, 2014, the Company entered into an agreement with Celgene to develop novel bispecific antibody therapeutics using the Company's proprietary Azymetric platform. The Company will apply its Azymetric platform in combination with Celgene's proprietary targets to create novel bispecific antibodies for which Celgene has an option to develop and commercialize a certain number of products ("Commercial License Option").

Upon the execution of the Agreement, the Company received a one-time, non-refundable payment of \$8.0 million. Over the life of the agreement, the Company is eligible to receive potential milestone payments totaling up to \$164.0 million per each therapeutic candidate, comprised of a payment of \$7.5 million upon Celgene exercising a Commercial License Option, up to \$101.5 million for development milestones and up to \$55.0 million for commercial milestones. In addition, the Company is eligible to receive tiered royalties calculated upon the global net sales of the resulting products. Celgene will have exclusive worldwide commercialization rights to products derived from the agreement if Celgene elects to exercise a Commercial License Option for each product. The Company determined that, the events and conditions resulting in payments for research, development and commercial milestones solely depend on Celgene's performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Celgene, is a customer. The Company identified the following promised goods and services at the inception of the Celgene agreement: (1) the non-exclusive research license, (2) the transfer of the Company's platform technology (Azymetric) and relevant know-how, and (3) technical assistance if required by Celgene in connection with the transfer of technology. The Company concluded that the license and platform technology together are distinct. Accordingly, all the deliverables are considered a single performance obligation and the upfront payment of \$8.0 million has been allocated to this performance obligation. The upfront payment was recognized as revenue ratably over the six-month period ended June 30, 2015, the period during which the Company transferred its technical know-how and technology to Celgene.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price included only the \$8.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Celgene and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company concluded that, at the inception of the agreement, Celgene's option to obtain a Commercial License did not represent a deliverable because it is a substantive option and does not contain a significant or incremental discount.

Table of Contents

On April 22, 2018, Celgene exercised its right to increase the number of potential products it can develop and commercialize from eight to ten and extended the research program term by 24 months until April 2020, for which the Company received an expansion fee of \$4.0 million and is eligible to receive up to \$164.0 million per additional product in development and commercial milestones plus royalties on worldwide sales in accordance with the terms of the licensing and collaboration agreement. The research period extension commenced on April 22, 2018. In July 2019, the Company recorded \$7.5 million on exercise of a Commercial License Option.

No development or commercial milestone payments or royalties have been received to date.

Collaboration and License Agreement with GlaxoSmithKline Intellectual Property Development Ltd. (“GSK”)

On December 1, 2015, the Company entered into a Collaboration and License Agreement with GSK for the research, development, and commercialization of novel Fc-engineered monoclonal and bispecific antibody therapeutics, which have been optimized for specific therapeutic effects. The Company and GSK will collaborate to further develop the Company’s Effector Function Enhancement and Control Technology (EFECT) platform through the design, engineering, and testing of novel engineered Fc domains tailored to induce specific antibody-mediated immune responses.

At the conclusion of the research collaboration, both GSK and the Company will have the right to develop and commercialize monoclonal and bispecific antibody candidates that incorporate the Company’s optimized immune-modulating Fc domains.

Under the terms of the agreement, GSK will have the right to develop a minimum of four products across multiple disease areas, and the Company will be eligible to receive research, development, and commercial milestones of up to \$110.0 million for each product. In addition, the Company is eligible to receive tiered sales royalties. Under the terms of the agreement, each party is liable for their own internal and external research costs incurred in the project. Furthermore, the Company will have the right to develop up to four products with the intellectual property arising from the collaboration without any royalty or milestone payment to GSK. The Company determined that, the events and conditions resulting in payments for research, development and commercial milestones solely depend on GSK’s performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. At execution, there was no upfront fee received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee’s efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No development or commercial milestone payments or royalties have been received to date.

Platform Technology Transfer and License Agreement with GSK

On April 21, 2016, the Company entered into a Platform Technology Transfer and License Agreement with GSK for the research, development, and commercialization of novel bispecific antibodies enabled using the Company’s Azymetric platform. Each of the two agreements with GSK were negotiated independently and the deliverables covered by the respective contracts utilize different therapeutic platforms and are unrelated to one another. Accordingly, the Platform Technology and License Agreement with GSK has been accounted for as a new arrangement. In May 2019, this agreement was expanded to provide GSK access to Zymeworks’ unique heavy-light chain pairing technology under the Azymetric platform. This may include bispecific antibodies incorporating new engineered Fc regions generated under the 2015 GSK agreement.

Table of Contents

Upon execution of the agreement, the Company received a technology access fee of \$6.0 million on May 3, 2016. The Company is also eligible to receive up to \$37.5 million in research milestone payments; up to \$183.5 million in development milestone payments; and up to \$867.0 million in commercial sales milestone payments. In addition, the Company is entitled to receive tiered royalties on potential sales. The Company determined that, the events and conditions resulting in payments for research, development and commercial milestones solely depend on GSK's performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. The Company identified the following promised goods and services at the inception of the GSK agreement: (1) the non-exclusive research license, (2) commercial license (3) transfer of the Company's platform technology (Azymetric) and relevant know-how, (4) technical assistance if required by GSK in connection with the transfer of technology, and (5) the obligation to provide future technology improvement and updates, when and if available. The Company concluded that the licenses and platform technologies together are distinct. Accordingly, deliverables (1) through (4) were considered as a single performance obligation and the technology access fee of \$6.0 million has been allocated to this performance obligation and has been recognized as revenue upon completion of the transfer of the Company's technology and technical know-how to GSK.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements. The Company concluded that the best estimate of selling price for the obligation to deliver future technology improvements and updates was a nominal amount, as the Company has no intention of performing and has made no commitment to perform or provide additional update work on the applicable technology platform. Accordingly, no arrangement consideration was allocated to this deliverable.

At execution, the transaction price included only the \$6.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No research, development or commercial milestone payments or royalties have been received to date.

Collaboration and Cross License Agreement with Daiichi Sankyo, Co., Ltd. ("Daiichi Sankyo")

On September 26, 2016, the Company entered into a Collaboration and Cross License Agreement with Daiichi Sankyo for the research, development, and commercialization of novel bispecific antibodies enabled using the Company's Azymetric and EFECT platforms. Additionally, the Company will license immuno-oncology antibodies from Daiichi Sankyo, with the right to research, develop and commercialize multiple products globally in exchange for royalties on product sales. Under the agreement, Daiichi Sankyo will have the option to develop and commercialize a single bispecific immuno-oncology therapeutic.

Upon execution of the agreement, the Company received a technology access fee of \$2.0 million. The Company is also eligible to receive up to \$67.9 million in research and development milestone payments and commercial license option; and up to \$80.0 million in commercial sales milestone payments. In addition, the Company is

Table of Contents

eligible to receive tiered royalties on potential product sales. The Company determined that other than a research milestone for \$1.0 million, the events and conditions resulting in payments for research, development and commercial milestones solely depend on Daiichi Sankyo's performance. In April 2019, the Company recognized \$3.5 million revenue on Daiichi Sankyo's exercise of its option to obtain a commercial license with respect to its first Azymetric lead product candidate.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Daiichi Sankyo, is a customer. The Company identified the following promised goods and services at the inception of the Daiichi Sankyo agreement: (1) the research license, (2) the transfer of the Company's platform technologies (Azymetric and EFECT) and relevant know-how, and (3) research activities to be performed on behalf of Daiichi Sankyo. The Company concluded that the licenses and platform technologies together are distinct and the licenses are functional intellectual property because the Company's platform technologies are not expected to substantively change during the licensing period. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation and the technology access fee of \$2.0 million was allocated to this performance obligation and was recognized as revenue at a point in time upon delivery of the licenses and transfer of the relevant technology. The research activities to be performed on behalf of Daiichi Sankyo after the transfer of the technology are also determined to be distinct as Daiichi Sankyo or another third party could provide these services without the Company's assistance. The revenue to be received from Daiichi Sankyo from delivery of these services is recognized upon performance of such activities at rates consistent with prevailing market rates. The Company concluded that, at the inception of the agreement, Daiichi Sankyo's option to obtain a Commercial License did not represent a deliverable because it is a substantive option and did not contain a significant or incremental discount.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements. The best estimate of selling price for the other deliverables was estimated using internal estimates of cost to perform the specific services plus a normal profit margin for providing the services.

At execution, the transaction price included only the \$2.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Daiichi Sankyo and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The consideration otherwise allocable to delivered units is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions. Consequently, the arrangement consideration related to the research activities to be performed on behalf of Daiichi Sankyo after the transfer of the technology was excluded from the allocation arrangement consideration because the consideration and performance are contingent upon Daiichi Sankyo requesting performance of the services and these services are priced at an estimated fair value.

On June 26, 2017, the Company recorded non-refundable milestone revenue from Daiichi Sankyo in the amount of \$1.0 million upon the achievement of a research milestone.

During the nine months ended September 30, 2019, the Company recorded \$nil in research support revenue from Daiichi Sankyo (2018: \$nil).

Table of Contents

Second License Agreement with Daiichi Sankyo

In May 2018, the Company entered into a second license agreement with Daiichi Sankyo to research, develop and commercialize two bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Under the terms of the agreement, the Company granted Daiichi Sankyo a worldwide, royalty-bearing, antibody sequence pair-specific, exclusive license to research, develop and commercialize certain products. Under the agreement, Daiichi Sankyo will be solely responsible for the research, development, manufacturing and commercialization of the products.

Upon execution of the agreement, the Company received a non-refundable upfront technology access fee of \$18.0 million. The Company is also eligible to receive up to \$126.7 million in development milestone payments and up to \$340.0 million in commercial milestone payments. In addition, the Company is eligible to receive tiered royalties ranging from the low single digits up to 10% on product sales, with the royalty term being, on a product-by-product and country-by-country basis, either (i) for as long as there is Zymeworks platform patent coverage on products, or (ii) for 10 years beginning from the first commercial sale, whichever period is longer. If there is no Zymeworks patent coverage on products, royalty rates may be reduced.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Daiichi Sankyo, is a customer. The Company identified the following promised goods and services at the inception of the Daiichi agreement: (1) the research and commercial license, (2) the transfer of the Company's platform technologies (Azymetric and EFECT) and relevant know-how. The Company concluded that the licenses and platform technologies together are distinct. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation and the upfront fee of \$18.0 million was allocated to this performance obligation and was recognized as revenue upon delivery of the licenses and transfer of the relevant technology.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price included only the \$18.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Daiichi Sanyo and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No development or commercial milestone payments or royalties have been received to date.

Collaboration and License Agreement with Janssen Biotech, Inc. ("Janssen")

On November 13, 2017, the Company entered into a Collaboration and License Agreement with Janssen to research, develop and commercialize up to six bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Under the terms of the agreement, the Company granted Janssen a worldwide, royalty-bearing, antibody sequence pair-specific exclusive license to research, develop and commercialize certain products. Janssen also has the option to develop two additional bispecific antibodies under this agreement subject to a future option payment. Under the agreement, Janssen will be solely responsible for the research, development, manufacturing and commercialization of the products.

Table of Contents

Upon execution of the agreement, the Company received a non-refundable upfront fee of \$50.0 million. The Company is also eligible to receive up to \$282.0 million in development milestone payments and up to \$1,119.0 million in commercial milestone payments. In addition, Company is eligible to receive tiered royalties in the mid-single digits on product sales, with the royalty term being, on a product-by-product and country-by-country basis, either (i) for as long as there is Zymeworks platform patent coverage on products, or (ii) for 10 years, beginning from the first commercial sale, whichever period is longer. If there is no Zymeworks patent coverage on products, royalty rates may be potentially reduced. Janssen has the right, prior to the first dosing of a patient in a Phase 3 clinical trial for a product, to buy down the royalty relating to such product by one percentage point with a payment of \$10.0 million. The Company determined that, the events and conditions resulting in payments for research, development and commercial milestones solely depend on Janssen's performance.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Janssen, is a customer. The Company identified the following promised goods and services at the inception of the Janssen agreement: (1) the research and commercial license, (2) the transfer of the Company's platform technologies (Azymetric and EFECT) and relevant know-how. The Company concluded that the licenses and platform technologies together are distinct. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation and the upfront fee of \$50.0 million was allocated to this performance obligation and was recognized as revenue upon delivery of the licenses and transfer of the relevant technology.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price included only the \$50.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No research, development or commercial milestone payments or royalties have been received to date.

Research and License Agreement with LEO Pharma A/S ("LEO")

On October 23, 2018, the Company entered into a collaboration agreement with LEO. The Company granted LEO a worldwide, royalty-bearing, antibody sequence pair-specific exclusive license to research, develop and commercialize two bispecific antibodies, generated through the use of the Azymetric and EFECT platforms, for dermatologic indications. Zymeworks will retain rights to develop antibodies resulting from this collaboration in all other therapeutic areas. Zymeworks and LEO are jointly responsible for certain research activities, with Zymeworks' cost to be fully reimbursed by LEO. Each party is solely responsible for the development, manufacturing, and commercialization of their own products.

Pursuant to this agreement, the Company received an upfront payment of \$5.0 million. In addition, (i) for the first therapeutic candidate, the Company is eligible to receive preclinical and development milestone payments of up to \$74.0 million and commercial milestone payments of up to \$157.0 million together with tiered royalties on

Table of Contents

future sales of up to 20% in the United States and up to high single digits elsewhere, and (ii) for the second therapeutic candidate, the Company is eligible to receive preclinical and development milestone payments of up to \$86.5 million and commercial milestone payments of up to \$157.0 million together with tiered royalties on future sales of up to low double digits globally. For products developed by Zymeworks outside of dermatology, LEO is eligible to receive commercial milestone payments and up to single-digit royalties on future sales. No development or commercial milestone payments or royalties have been received to date.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, LEO, is a customer. The Company identified the following promised goods and services at the inception of the LEO agreement: (1) the research and commercial license, (2) the transfer of the Company's platform technologies (Azymetric and EFECT) and relevant know-how (3) participation in the Joint Steering Committee ("JSC"), and (4) performance of research activities under the Research Program. The Company concluded that the licenses and platform technologies together are distinct while the Company's participation to the JSC is a protective right. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation and the upfront fee of \$5.0 million was allocated to this performance obligation and was recognized as revenue upon delivery of the licenses and transfer of the relevant technology. The research activities to be performed on behalf of LEO after the transfer of the technology are also determined to be distinct as LEO or another third party could provide these services without the Company's assistance. The revenue to be received from LEO from delivery of these services is recognized upon performance of such activities at rates consistent with prevailing market rates

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price included only the \$5.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to LEO and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The consideration otherwise allocable to delivered units is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions. Consequently, the arrangement consideration related to the research activities to be performed on behalf of LEO after the transfer of the technology was excluded from the allocation arrangement consideration because the consideration and performance are contingent upon LEO requesting performance of the services and these services are priced at an estimated fair value.

During the nine months ended September 30, 2019, the Company recorded \$1,108 in research support revenue from LEO (2018: \$nil).

Collaboration and License Agreements with BeiGene, Ltd. ("BeiGene")

On November 26, 2018, the Company entered into three concurrent agreements with BeiGene whereby the Company granted BeiGene royalty-bearing exclusive licenses for the research, development and commercialization of its bispecific therapeutic candidates, ZW25 ("ZW25 Agreement") and ZW49 ("ZW49

Table of Contents

Agreement”) in Asia (excluding Japan but including the People’s Republic of China, South Korea and other countries), Australia and New Zealand. In addition, the Company also granted BeiGene a worldwide, royalty-bearing, antibody sequence pair-specific license to research, develop and commercialize globally three bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Pursuant to these agreements, Zymeworks received an upfront payment of \$60.0 million in 2018 for the totality of the rights described. The Company considered the fair value of performance obligations based on the Company’s best estimate of their relative stand-alone selling prices, and allocated \$40.0 million of transaction price to the License and Collaboration Agreements for ZW25 and ZW49 while \$20.0 million has been allocated to the Company’s performance obligations under the Research and Licensing Agreement for Azymetric and EFECT Platforms.

License and Collaboration Agreements for ZW25 and ZW49

The Company is also eligible to receive development and commercial milestone payments of up to \$390 million, together with tiered royalties from high single digits and up to 20% on future sales of the products. No development or commercial milestone payments or royalties have been received to date. Under the agreements, Zymeworks and BeiGene are collaborating on certain global clinical studies and both Zymeworks and BeiGene will be independently conducting clinical studies in their own respective territories. Each of Zymeworks and BeiGene are responsible for all the development and commercialization costs in their own territories.

The Company assessed the ZW25 and ZW49 agreements in accordance with ASC 606 and ASC 808, as certain performance obligations for research and development activities of these agreements fall under ASC 808. ASC 808 does not address recognition or measurement matters. Pursuant to ASU 2018-18 which clarified the interaction between ASC 808 and ASC 606, the Company applied ASC 606 to recognize revenue from such collaboration activities as BeiGene meets the definition of a customer.

In relation to the ZW25 Agreement, the Company identified the following promised goods and services at the inception of the BeiGene agreement that are material: (1) development and commercial licenses, (2) initial transfer of the Company’s technologies and relevant know-how, (3) continuing technology transfer (4) participation in the Joint Steering Committee (“JSC”) and other sub-committees, (5) manufacturing technology transfer, (6) provision of development supply, (7) provision of commercial supply, and (8) transfer of future rights related to the development and commercial license. The Company concluded that the licenses and initial technology transfer are distinct together while the continuing technology transfer and the Company’s participation to the JSC and other sub-committees’ activities together are distinct. Manufacturing technology transfer, provisions of development supply and commercial supply, and the transfer of future rights related to the development and commercial license were individually determined to be distinct. Accordingly, performance obligations from the ZW25 were determined as described below.

The Company determined that at the inception of the development and commercial license and upon completion of the initial transfer of the Company’s technologies and relevant know-how (performance obligations (1) and (2)), BeiGene obtained control over certain initial rights, with control over future rights dependent upon the completion of certain collaborative activities.

With respect to the initial rights controlled by BeiGene, deliverables (1) and (2) were considered as a single performance obligation. BeiGene received control of the license and began to benefit from the initial rights at inception of the agreement. The consideration allocated to these performance obligations will be recognized as revenue over a two-month period which is the expected period to complete the delivery of the license and transfer of the relevant technology. Deliverables (3) and (4) together were considered as a single performance obligation and the consideration allocated to this performance obligation will be recognized as revenue over time as these performance obligations are completed. Deliverables (5), (6) and (7) are considered individually distinct and the revenue will be recognized as delivery occurs. Remaining deliverable (8) is considered individually distinct and the revenue will be recognized as the future rights are transferred to BeiGene.

Table of Contents

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated selling price of the deliverables based on comparable license and collaboration arrangements as well as using internal estimates of cost to perform the specific services plus a normal profit margin for providing the services. The Company allocated the transaction price for the ZW25 Agreement to performance obligations under deliverables (1) and (2), (3) and (4) and (8). Out of \$7.1 million which was allocated to deliverables (1) and (2) of the ZW25 Agreement, the Company recognized \$3.5 million for the nine months ended September 30, 2019.

In relation to the ZW49 Agreement, the Company identified the following promised goods and services at the inception of the BeiGene agreement that are material: (1) development and commercial licenses, (2) initial transfer of the Company's technologies and relevant know-how, (3) continuing technology transfer, (4) participation in the Joint Steering Committee ("JSC") and other sub-committees, (5) manufacturing technology transfer, (6) provision of development supply, (7) provision of commercial supply, and (8) transfer of future rights related to the development and commercial license. The Company concluded that the licenses and initial technology transfer together are distinct together while the continuing technology transfer and the Company's participation to the JSC and other sub-committees' activities together are distinct. Manufacturing technology transfer, provisions of development supply and commercial supply were individually determined to be distinct. Accordingly, performance obligations from the ZW49 were determined as below:

Deliverables (1) and (2) were considered as a single performance obligation while deliverables (3) and (4) together were considered as a single performance obligation. Remaining deliverables of (5), (6) and (7) were considered individually distinct. Deliverable (8) is considered individually distinct and will be recognized as the future rights are transferred to BeiGene. No performance obligations were completed by the Company as of December 31, 2018 as the initial transfer of technologies and relevant know-how is not going to start until the completion of the Company's Phase-1 clinical studies for ZW49. Accordingly, no revenue was recognized from the ZW49 Agreement to date.

As of September 30, 2019, \$32,941 of upfront fees from the ZW25 and ZW49 agreements was recorded as deferred revenue on the Company's consolidated financial statements (December 31, 2018: \$36,471). Amounts not expected to be recognized as revenue within the next twelve months of the consolidated balance sheet date are classified as long-term deferred revenue.

Research and Licensing Agreement for Azymetric and EFECT Platforms

For the development and commercialization licenses of up to three bispecific antibody therapeutics using the Azymetric and EFECT platforms, the Company received an upfront payment of \$20.0 million. The Company is also eligible to receive development and commercial milestone payments of up to \$702.0 million. In addition, the Company is eligible to receive tiered royalties in the mid-single digits on product sales. No development or commercial milestone payments or royalties have been received to date. BeiGene is solely responsible for the research, development, manufacturing, and commercialization of the products.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, BeiGene, is a customer. The Company identified the following promised goods and services at the inception of the BeiGene agreement: (1) the research and commercial license, (2) the transfer of the Company's platform technologies (Azymetric and EFECT) and relevant know-how, and (3) participation in the Information Sharing Committee ("ISC"). The Company concluded that the licenses and platform technologies together are distinct while the Company's participation to the ISC is a protective right. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation and the upfront fee of \$20.0 million was allocated to this performance obligation and was recognized as revenue upon delivery of the licenses and transfer of the relevant technology.

Table of Contents

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price included only the \$20.0 million upfront consideration received. None of the research and development milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to BeiGene and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

License Agreement with Iconic Therapeutics, Inc. ("Iconic")

On May 13, 2019, the Company entered into a license agreement with Iconic to develop and commercialize an antibody-drug conjugate (ICON-2) targeting tissue factor generated through the use of the ZymeLink platform. Under the terms of this agreement, the Company granted Iconic a worldwide, royalty-bearing, antibody sequence-specific, exclusive license to develop and commercialize certain products. Iconic is responsible for the development, manufacturing, and commercialization of the products.

Pursuant to this agreement, The Company is eligible to receive development and commercial milestone payments and tiered royalties on worldwide net sales. This agreement also provides the Company with co-promotion rights with increased royalties for products generated from this collaboration. If Iconic sublicenses the program, in lieu of co-promotion rights, the Company will receive a share of the revenue Iconic receives from any partners as well as tiered royalties on worldwide net sales.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Iconic, is a customer. The Company identified the following promised goods and services at the inception of the Iconic agreement: (1) the research and commercial license, (2) the transfer of the Company's platform technology (ZymeLink) and relevant know-how and assistance related to transfer (3) Manufacturing services to be provided upon Iconic's request and (4) support for application of technology and research materials upon Iconic's request. The Company concluded that the licenses and platform technology together are distinct. Accordingly, the deliverables (1) and (2) were considered as a single performance obligation. The manufacturing and support activities to be performed upon Iconic's request are also determined to be distinct as Iconic or another third party could provide these services without the Company's assistance. The revenue to be received from Iconic from delivery of these services will be recognized upon performance of such activities at rates consistent with prevailing market rates.

In order to evaluate the appropriate transaction price, the Company determined that the upfront amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. The Company estimated the best estimate of selling price of the licenses and technology platform based on comparable license and collaboration arrangements.

At execution, the transaction price is constrained to nil given the contract consideration only consists of milestone payments and tiered royalties. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based

Table of Contents

milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Iconic and therefore have also been excluded from the transaction price. Similarly, any revenue from partner revenue sharing payments upon sublicensing by Iconic will be recognized when such sub-licensing arrangements occur. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The consideration otherwise allocable to delivered units is limited to the amount that is not contingent on the delivery of additional items or fulfillment of other performance conditions. Consequently, the arrangement consideration related to the potential manufacturing activities after the transfer of the technology was excluded from the allocation arrangement consideration because the consideration and performance are contingent upon Iconic requesting performance of these services and these services are priced at an estimated fair value.

In June 2019 the Company recognized a development milestone revenue of \$1.0 million.

During the nine months ended September 30, 2019, the Company recorded \$1.0 million in support and supply payments from Iconic (2018: \$nil).

9. Leases

The Company leases office premises in Vancouver, British Columbia and Seattle, Washington that expire in August 2021 and February 2022, respectively. The Company has also entered into a lease for laboratory space in Vancouver, British Columbia that will expire in August 2021. The leases contain rent escalation clauses. The Company entered into a lease on January 25, 2019 in Vancouver to serve as the Company's future head office. The commencement date of this lease will be no later than September 21, 2021, and has an initial term of ten years, with two five-year extension options. Effective February 25, 2019, the Company also entered into a lease for office space in Seattle. The commencement date of this lease was July 30, 2019 for a portion of the space and will be no later than April 1, 2020 for the remaining portion of the space. The expiration date of the lease is April 30, 2025 with a five-year extension option. None of these 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:

	September 30, 2019	December 31, 2018
Operating lease liabilities:		
Current portion	\$ 912	\$ —
Long-term portion	5,843	—
Total operating lease liabilities	<u>6,755</u>	<u>\$ —</u>
Finance lease liabilities:		
Current portion included in other current liabilities	9	15
Long-term portion included in other long-term liabilities	47	42
Total finance lease liabilities	<u>56</u>	<u>57</u>
Total lease liabilities	<u>\$ 6,811</u>	<u>\$ 57</u>

Cash paid for amounts included in the measurement of operating lease liabilities for the nine months ended September 30, 2019 was \$1.2 million and was included in net cash provided by operating activities in the consolidated statements of cash flows.

Table of Contents

As of September 30, 2019, the maturities of the Company's operating lease liabilities were as follows:

	<u>Operating leases</u>
Within 1 year	\$ 1,307
1 to 2 years	2,253
2 to 3 years	1,131
3 to 4 years	982
4 to 5 years	1,010
Thereafter	604
Total operating lease payments	<u>7,287</u>
Less:	
Imputed interest	(532)
Operating lease liabilities	<u>\$ 6,755</u>

As of September 30, 2019, the weighted average remaining lease term is 4.3 years and the discount rate used to determine the operating lease liability was 4.6% for leases in Canadian dollar and 2.9% for leases in U.S. dollar.

During the three months ended September 30, 2019, the Company incurred total operating lease expenses of \$698, which included lease expenses associated with fixed lease payments of \$657, and variable payments associated with Common area maintenance and similar expenses of \$41.

The Company also leases office equipment under finance lease agreements. As of September 30, 2019, the maturities of the Company's finance lease liabilities were as follows:

	<u>Finance leases</u>
Within 1 year	\$ 27
1 to 2 years	22
2 to 3 years	6
3 to 4 years	4
4 to 5 years	2
Thereafter	—
Total finance lease payments	<u>61</u>
Less:	
Imputed interest	(5)
Finance lease liabilities	<u>\$ 56</u>

10. 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. This insurance 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 the Company 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.

Table of Contents

In August 2016, the Company entered into a license agreement with Innovative Targeting Solutions Inc., (“ITS”), to use ITS’ protein engineering technology for the development and commercialization of antibody and protein therapeutics. Pursuant to the agreement, the Company agreed to pay an aggregate of \$12.0 million in annual licensing fees to ITS over a five-year period, the full outstanding amount of which was paid in the period ended September 30, 2019 in accordance with the prepayment terms thereunder. As a result, as of September 30, 2019, we have no further licensing fee payment obligations under the agreement. Licensing fees paid to ITS are recorded in intangible assets and are amortized over useful lives. The Company may also be required to make payments to ITS upon the achievement of certain development and commercial milestones, as well as royalty payments on net sales. No liabilities have been recorded for any amounts payable as of September 30, 2019.

In connection with the Kairos acquisition, the Company may be required to make future payments to 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 September 30, 2019, the contingent consideration had an estimated fair value of approximately \$992, which has been recorded within Other long-term liabilities (note 6) (2018: \$707). 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 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.

Table of Contents

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, 2018 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 6, 2019 and with the securities commissions in all provinces and territories of Canada on March 6, 2019. 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.

Description of Business and Products

Our lead product candidate, ZW25, is a novel bispecific (dual-targeting) antibody which targets two distinct domains of the human epidermal growth factor receptor 2 ("HER2"). The unique mechanism of action of ZW25 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 ZW25, and ZW25 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 standard of care, including multiple HER2-targeted regimens. In 2019 we initiated a global multicenter Phase 2 clinical trial evaluating ZW25 in combination with standard of care chemotherapy for the first-line treatment of HER2-positive metastatic gastric, gastroesophageal junction and esophageal adenocarcinomas. In addition, ZW25 continues to be evaluated in multiple expansion cohorts in the ongoing Phase 1 trial as a single agent in several niche indications including biliary tract, colorectal, gynecological and other HER2-expressing cancers. Our second product candidate, ZW49, capitalizes on the unique design of ZW25 and is a bispecific antibody-drug conjugate ("ADC") based on the same antibody framework as ZW25 but armed with our proprietary ZymeLink-cytotoxic (potent cancer cell-killing) payload. 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. In addition to our robust pipeline, 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 ("Celgene"), GlaxoSmithKline Intellectual Property Development Limited ("GSK"), Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), Janssen

Table of Contents

Biotech, Inc. (“Janssen”), LEO Pharma A/S (“LEO”), BeiGene, Ltd. (“BeiGene”) and Iconic Therapeutics, Inc. (“Iconic”).

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 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 which comprises multiple cytotoxic payloads and the linker technology used to couple these payloads 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
- **EFFECT**, 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.

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 and 2019. From inception through September 30, 2019, we received approximately \$421.5 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. 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.

Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our existing cash and cash equivalents and short-term investments as of September 30, 2019, combined with the collaboration payments we anticipate receiving, will enable us to fund our planned operations into 2021 and potentially beyond.

Through September 30, 2019, we had an accumulated deficit of \$218.5 million. We reported a net loss of \$73.2 million for the nine months ended September 30, 2019. 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.

We voluntarily delisted our common shares from the Toronto Stock Exchange (“TSX”) as of the close of business on October 1, 2019. Prior to the voluntary delisting, our common shares traded on the TSX under the

Table of Contents

symbol “ZYME”. We continue to be listed on the New York Stock Exchange (the “NYSE”) under the symbol “ZYME”.

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 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. These strategic partnerships have provided us with non-dilutive funding as well as access to proprietary therapeutic assets, which increase our ability to rapidly advance our product candidates while maintaining commercial rights to our own therapeutic pipeline. To date, we have received \$185.8 million in the form of non-refundable upfront payments and milestone payments and are additionally eligible to receive up to \$2.4 billion in preclinical and development milestone payments and \$5.5 billion in commercial milestone payments available 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. Our strategic partnerships include the following:

Research and License Agreement with Merck

In August 2011, we entered into a research and license agreement with Merck, which was amended and restated in December 2014, to develop and commercialize three bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Under the terms of the agreement, we granted Merck a worldwide, royalty-bearing antibody sequence pair exclusive license to research, develop and commercialize certain licensed products. We are eligible to receive up to \$190.75 million, including an upfront payment (\$1.25 million received in 2011), research milestone payments totaling \$3.5 million (\$2.0 million and \$1.5 million received in 2012 and 2013, respectively), payments for completion of IND-enabling studies of up to \$6.0 million (\$2.0 million received in 2019), development milestone payments of up to \$66.0 million and commercial milestone payments of up to \$114.0 million. In addition, we are eligible to receive tiered royalties in the low to mid-single digits on product sales. Merck is solely responsible for the further research, development, manufacturing and commercialization of the products.

Licensing and Collaboration Agreement with Lilly

In December 2013, we entered into a licensing and collaboration agreement with Lilly, under which Lilly has the right to research, develop and commercialize one bispecific antibody generated through the use of the Azymetric platform. Under the terms of the agreement, we granted Lilly a worldwide, royalty-bearing antibody target pair-specific exclusive license to research, develop and commercialize certain licensed products. We are eligible to receive up to \$52.0 million, including an upfront payment (\$1.0 million received in 2013) and per product potential milestone payments, comprised of research milestone payments totaling \$1.0 million (received in 2015), investigational new drug (“IND”) application submission milestone payments of \$2.0 million (received in 2018), development milestone payments of \$8.0 million and commercial milestone payments of \$40.0 million. In addition, we are eligible to receive tiered royalties in the low to mid-single digits on product sales. Lilly is solely responsible for the further research, development, manufacturing, and commercialization of the products.

Second Licensing and Collaboration Agreement with Lilly

In October 2014, we entered into a second licensing and collaboration agreement with Lilly to research, develop and commercialize one bispecific antibody generated through the use of the Azymetric platform. This agreement

Table of Contents

did not alter or amend the initial 2013 agreement. Under the terms of this 2014 agreement, we granted Lilly a worldwide, royalty-bearing antibody sequence pair-specific license to research, develop and commercialize certain licensed products. In 2019 Lilly filed an IND for a bispecific candidate from this agreement for clinical development. We are currently eligible to receive up to \$125.0 million, comprised of research milestone payments of up to \$2.0 million (received in 2016), IND submission milestone payments of up to \$8.0 million (\$8.0 million received in 2019), development milestone payments of up to \$20.0 million and commercial milestone payments of up to \$95.0 million. In addition, we are eligible to receive tiered royalties in the low to mid-single digits on product sales. Lilly is solely responsible for the research, development, manufacturing and commercialization of the products.

Licensing and Collaboration Agreement with Celgene

In December 2014, we entered into a collaboration agreement with Celgene to research, develop and commercialize bispecific antibodies generated through the use of the Azymetric platform. This agreement was expanded in 2018 to increase the number of programs from eight to ten and to extend Celgene's research period. Under the terms of the agreement, we granted Celgene a right to exercise options to worldwide, royalty-bearing, antibody sequence pair-specific exclusive licenses to research, develop and commercialize certain licensed products. We received an upfront payment (\$8.0 million received in 2014) and an expansion fee of \$4.0 million (received in 2018). Celgene has the right to exercise options on up to ten programs and if Celgene opts in on a program, we are eligible to receive up to \$164.0 million per product candidate (up to \$1.64 billion for all ten programs), comprised of a commercial license option payment of \$7.5 million, development milestone payments of up to \$101.5 million and commercial milestone payments of up to \$55.0 million. In July 2019, Celgene exercised an option on the first program and we received an option payment of \$7.5 million. No development or commercial milestone payments or royalties have been received to date. After conclusion of Celgene's research period, Celgene will be solely responsible for the research, development, manufacturing and commercialization of the products.

Licensing and Collaboration Agreement with GSK

In December 2015, we entered into a collaboration and license agreement with GSK to research, develop and commercialize up to ten Fc-engineered monoclonal and bispecific antibodies generated through the use of the EFECT and Azymetric platforms. Under the terms of the agreement, we granted GSK a worldwide, royalty-bearing antibody target-exclusive license to new intellectual property generated to the EFECT platform under this collaboration and a non-exclusive license to the Azymetric platform to research, develop and commercialize future licensed products. We are eligible to receive up to \$1.1 billion, including research, development and commercial milestone payments of up to \$110.0 million for each product. In addition, we are eligible to receive tiered royalties in the low single digits on net sales of products. No development or commercial milestone payments or royalties have been received to date. We retained the right to develop up to four products, free of royalties, using the new intellectual property generated in this collaboration, and after a period of time, to grant licenses to such intellectual property for development of additional products by third parties.

Under this agreement, we are sharing certain research and development responsibilities with GSK to generate new Fc-engineered antibodies. Each party will bear its own costs for the responsibilities assigned to it during the research period. After the conclusion of the research period, each party will be solely responsible for the further research, development, manufacturing and commercialization of its own respective products.

Second Licensing and Collaboration Agreement with GSK

In April 2016, we entered into a licensing agreement with GSK to research, develop and commercialize up to six bispecific antibodies generated through the use of the Azymetric platform. This may include bispecific antibodies incorporating new engineered Fc regions generated under the 2015 GSK agreement. Under the terms of this 2016 agreement, we granted GSK a worldwide, royalty-bearing antibody sequence pair-specific exclusive license to

Table of Contents

research, develop and commercialize licensed products. In May 2019, this agreement was expanded to provide GSK access to Zymeworks' unique heavy-light chain pairing technology under the Azymetric platform. Under the expanded agreement, we are eligible to receive up to \$1.1 billion, including an upfront payment as a technology access fee (\$6.0 million received in 2016), research milestone payments of up to \$37.5 million, development milestone payments of up to \$183.5 million and commercial milestone payments of up to \$867.0 million. In addition, we are eligible to receive tiered royalties in the low to mid-single digits on product sales. GSK bears all responsibility and costs associated with research, development and commercialization of products generated using the Azymetric platform.

Collaboration and Cross-License Agreement with Daiichi Sankyo

In September 2016, we entered into a collaboration and cross-license agreement with Daiichi Sankyo to research, develop and commercialize one bispecific antibody generated through the use of the Azymetric and EFECT platforms. Under the terms of the agreement, we granted Daiichi Sankyo a worldwide, royalty-bearing antibody sequence pair-specific exclusive license to research, develop and commercialize certain licensed products. We are eligible to receive up to \$149.9 million, including an upfront payment as a technology access fee of \$2.0 million (received in 2016), research (\$1.0 million received in 2017) and development milestone payments and a commercial option payment totaling up to \$67.9 million (\$3.5 million commercial option payment received in 2019), and commercial milestone payments of up to \$80.0 million. In addition, we are eligible to receive tiered royalties ranging from the low single digits up to 10% on product sales. We also gained non-exclusive rights to develop and commercialize up to three products using Daiichi Sankyo's proprietary immune-oncology antibodies, with royalties in the low single digits to be paid to Daiichi Sankyo on sales of such products. Daiichi Sankyo is solely responsible for the research, development, manufacturing and commercialization of the products. Under the non-exclusive immunology antibody license to Zymeworks, we are solely responsible for all research, development and commercialization of the resulting products.

Second Licensing Agreement with Daiichi Sankyo

In May 2018, we entered into a new license agreement with Daiichi Sankyo to research, develop and commercialize two bispecific antibodies generated through the use of the Azymetric and EFECT platforms. This agreement did not alter or amend the initial 2016 agreement. Under the terms of this 2018 agreement, we granted Daiichi Sankyo a worldwide, royalty-bearing, antibody sequence pair-specific, exclusive license to research, develop and commercialize certain products. We are eligible to receive up to \$484.7 million, including an upfront technology access fee payment of \$18.0 million (received in 2018), development milestone payments totaling up to \$126.7 million and commercial milestone payments of up to \$340.0 million. In addition, we are eligible to receive tiered royalties ranging from the low single digits up to 10% on product sales. Daiichi Sankyo is solely responsible for the research, development, manufacturing and commercialization of the products.

Licensing and Collaboration Agreement with Janssen

In November 2017, we entered into a collaboration agreement with Janssen to research, develop and commercialize up to six bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Under the terms of the agreement, we granted Janssen a worldwide, royalty-bearing, antibody sequence pair-specific exclusive license to research, develop and commercialize certain products. We are eligible to receive up to \$1.45 billion, including an upfront payment of \$50.0 million (received in 2017), development milestone payments of up to \$282.0 million and commercial milestone payments of up to \$1.12 billion. In addition, we are eligible to receive tiered royalties in the mid-single digits on product sales. Janssen has the option to develop two additional bispecific antibodies under this agreement subject to a future option payment. Janssen is solely responsible for the research, development, manufacturing and commercialization of the products.

Research and License Agreement with LEO

In October 2018, we entered into a collaboration agreement with LEO whereby we granted LEO a worldwide, royalty-bearing, antibody sequence pair-specific exclusive license to research, develop and commercialize two

Table of Contents

bispecific antibodies, generated through the use of the Azymetric and EFECT platforms, for dermatologic indications. Zymeworks will retain rights to develop antibodies resulting from this collaboration in all other therapeutic areas. Pursuant to this agreement, we received an upfront payment of \$5.0 million in 2018. In addition, (i) for the first therapeutic candidate, we are eligible to receive preclinical and development milestone payments of up to \$74.0 million and commercial milestone payments of up to \$157.0 million together with tiered royalties on future sales of up to 20% in the United States and up to high single digits elsewhere, and (ii) for the second therapeutic candidate, we are eligible to receive preclinical and development milestone payments of up to \$86.5 million and commercial milestone payments of up to \$157.0 million together with tiered royalties on future sales of up to low double digits globally. For products developed by Zymeworks outside of dermatology, LEO is eligible to receive commercial milestone payments and up to single-digit royalties on future sales. No development or commercial milestone payments or royalties have been received to date. Zymeworks and LEO are jointly responsible for certain research activities, with Zymeworks' cost to be fully reimbursed by LEO. Each party is solely responsible for the development, manufacturing, and commercialization of its own products.

Licensing and Collaboration Agreements with BeiGene

In November 2018, we entered into agreements with BeiGene whereby we granted BeiGene royalty-bearing exclusive licenses for the research, development and commercialization of ZW25 and ZW49 in Asia (excluding Japan but including the People's Republic of China, South Korea and other countries), Australia and New Zealand. In addition, we also granted BeiGene a worldwide, royalty-bearing, antibody sequence pair-specific license to research, develop and commercialize globally three bispecific antibodies generated through the use of the Azymetric and EFECT platforms. Zymeworks received an upfront payment of \$60.0 million in 2018 for the totality of the rights described.

ZW25 & ZW49

For the research, development and commercialization licenses to ZW25 and ZW49, we received an upfront payment of \$40.0 million in 2018. In aggregate for both ZW25 and ZW49, we are also eligible to receive development and commercial milestone payments of \$390.0 million, together with tiered royalties from high single digits and up to 20% on future sales of the products. No development or commercial milestone payments or royalties have been received to date.

Under the agreement, Zymeworks and BeiGene are collaborating on certain global clinical studies and both Zymeworks and BeiGene will independently conduct other clinical studies in their own respective territories. Each of Zymeworks and BeiGene are responsible for all of the development and commercialization costs in their own territories.

Azymetric & EFECT Platforms

For the development and commercialization licenses of up to three bispecific antibody therapeutics using the Azymetric and EFECT platforms, we received an upfront payment of \$20.0 million in 2018. We are also eligible to receive development and commercial milestone payments of up to an aggregate of \$702.0 million. In addition, we are eligible to receive tiered royalties in the mid-single digits on product sales. No development or commercial milestone payments or royalties have been received to date. BeiGene is solely responsible for the research, development, manufacturing, and commercialization of the products.

License Agreement with Iconic

In May 2019, we entered into a license agreement with Iconic to develop and commercialize its antibody-drug conjugate (ICON-2) targeting Tissue Factor, generated through the use of the ZymeLink platform. Under the terms of this agreement, we granted Iconic a worldwide, royalty-bearing, antibody sequence-specific, exclusive license to develop and commercialize certain products. We are eligible to receive development and commercial

Table of Contents

milestone payments and tiered royalties on worldwide net sales. In June 2019, we recognized a development milestone payment of \$1.0 million. This agreement also provides us with co-promotion rights with increased royalties for products generated from this collaboration. If Iconic outlicenses the program, in lieu of co-promotion rights, we will receive a share of the revenue Iconic receives from any partners as well as tiered royalties on worldwide net sales. Iconic is responsible for the development, manufacturing, and commercialization of the products.

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, 2018.

Our management's discussion and analysis of financial conditions and results of operations is based on our interim condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of the financial statements in accordance with U.S. GAAP requires us 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. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, SR&ED Program and Industrial Research Assistance Program ("IRAP"), share-based compensation, warrants, accrual of expenses, preclinical study accruals, valuation allowance for deferred taxes, other contingencies and valuation of assets acquired in a business combination. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2019 as compared to the critical accounting policies and estimates described in our most recent annual consolidated financial statements, except the adoption of ASU 2016-02, Leases (Topic 842), effective on January 1, 2019.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) and subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10 and ASU 2018-11 (collectively, Topic 842). We adopted the new standard effective January 1, 2019, as required, using the modified retrospective approach. The adoption of Topic 842 did not have a material impact on our consolidated financial position, results of operations, equity or cash flows as of the adoption date, and as of or for the nine months ended September 30, 2019 as described in notes to the consolidated financial statements. We have included the disclosures required by Topic 842.

A summary of recent accounting pronouncements is presented in note 3 of our interim condensed consolidated financial statements for the quarter ended September 30, 2019 within this Quarterly Report on Form 10-Q.

Financial Operations Overview

Revenue

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

[Table of Contents](#)

Research and Development Expense

Research and development expenses consist of expenses incurred in performing research and development activities. These expenses include conducting research experiments, preclinical 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:

- employee-related expenses such as salaries and benefits;
- employee-related overhead expenses such as facilities and other allocated items;
- share-based compensation expense related to employees and consultants engaged in research and development activities;
- depreciation of laboratory equipment, computers and leasehold improvements;
- 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 items; and
- amounts paid to vendors and suppliers for laboratory supplies.

It is difficult to determine with certainty the duration and completion costs of our current or future clinical trials and preclinical research and development programs, 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 business operations functions, as well as legal and professional fees, travel and other general office expenses. We expect to incur additional expenses related to supporting our ongoing research and development activities, operating as a public company and other administrative expenses.

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).

Results of Operations for the Three and Nine months Ended September 30, 2019 and 2018

Research and Development Revenue

The following represents a comparison of our research and development revenue for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase/ (Decrease)	
	2019	2018	(dollars in millions)	
Revenue from research and collaborations	\$ 7.9	\$ 2.1	\$ 5.8	276%

Table of Contents

Our revenue for each period presented is primarily comprised of non-recurring upfront fees, expansion payments or milestone payments from our licensing and collaboration agreements. Revenue for the three months ended September 30, 2019 includes \$7.5 million recognized upon Celgene's exercise of its commercial license option and \$0.4 million in research and support payments from our partners. Revenue in the same period in 2018 was primarily due to a \$2.0 million development milestone upon Lilly's submission of an IND application under the first licensing agreement with Lilly.

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2019	2018		
	(dollars in millions)			
Revenue from research and collaborations	\$ 27.7	\$ 24.1	\$ 3.6	15%

Revenue for the nine months ended September 30, 2019 includes an \$8.0 million development milestone received from Lilly upon Lilly's submission of an IND application, \$3.5 million in recognized deferred revenue from BeiGene in relation to the licensing and collaboration agreement for development of ZW25, a \$2.0 million payment received for the achievement of a development milestone upon Merck's completion of a GLP toxicology study for its first program, \$3.5 million recognized upon Daiichi Sankyo's exercise of a commercial license option, \$1.0 million recognized in relation to a development milestone from Iconic, \$7.5 million recognized upon Celgene's exercise of its commercial license option as well as \$2.2 million in research support payments from our partners. Revenue in the same period in 2018 was due to an \$18.0 million upfront technology access fee in relation to the second licensing agreement with Daiichi Sankyo, a \$4.0 million research program expansion fee from Celgene, a \$2.0 million development milestone from Lilly and \$0.1 million in research support payments.

Research and Development Expense

The following represents a comparison of our research and development expense for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase/ (Decrease)	
	2019	2018		
	(dollars in millions)			
ZW25	\$ 16.8	\$ 6.3	\$ 10.5	167%
ZW49	2.5	1.7	0.8	47%
Therapeutic platforms	1.6	1.6	-	0%
Other research activities	8.3	4.6	3.7	80%
Total research and development expense	\$ 29.2	\$ 14.2	\$ 15.0	106%

[Table of Contents](#)

During the three months ended September 30, 2019, our research and development expenditures increased by \$15.0 million, compared to the same period in 2018. This was primarily due to an increase in clinical trial activity and associated manufacturing costs for ZW25, as well as an increase in other research and discovery activities compared to the same period in 2018. Research and development expense included non-cash stock-based compensation expense of \$1.7 million from equity classified equity awards (2018 – \$0.7 million) and \$0.9 million expense related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (2018 – \$0.5 million).

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2019	2018		
	(dollars in millions)			
ZW25	\$ 38.4	\$ 19.3	\$ 19.1	99%
ZW49	5.8	4.8	1.0	21%
Therapeutic platforms	5.2	5.2	-	0%
Other research activities	21.1	13.3	7.8	59%
Total research and development expense	\$ 70.5	\$ 42.6	\$ 27.9	65%

During the nine months ended September 30, 2019, our research and development expenditures increased by \$27.9 million, compared to the same period in 2018. This was primarily due to an increase in clinical trial activity and associated manufacturing costs for ZW25, as well as an increase in other research and discovery activities compared to the same period in 2018. Research and development expense included non-cash stock-based compensation expense of \$4.3 million from equity classified equity awards (2018 – \$1.7 million) and \$2.9 million expense related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (2018 – \$2.0 million).

General and Administrative Expense

The following represents a comparison of our general and administrative expense for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase/ (Decrease)	
	2019	2018		
General and administrative expense	\$ 12.2	\$ 7.5	\$ 4.7	63%

General and administrative expense increased for the three months ended September 30, 2019 by \$4.7 million, compared to the same period in 2018, primarily due to an increase in employee compensation expenses relating to non-cash stock-based compensation, as well as increased head count in 2019 over 2018. General and administrative expense in 2019 includes non-cash stock-based compensation expense of \$1.7 million from equity classified equity awards (2018 – \$1.1 million) and \$2.8 million related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (2018 – \$1.3 million).

	Nine Months Ended September 30,		Increase/ (Decrease)	
	2019	2018		
General and administrative expense	\$ 33.9	\$ 23.2	\$ 10.7	46%

General and administrative expense increased for the nine months ended September 30, 2019 by \$10.7 million, compared to the same period in 2018, primarily due to an increase in employee compensation expenses relating to non-cash stock-based compensation, as well as increased head count in 2019 over 2018. General and administrative expense in 2019 includes non-cash stock-based compensation expense of \$4.8 million from equity

[Table of Contents](#)

classified equity awards (2018 – \$2.8 million) and \$8.9 million related to the non-cash mark-to-market revaluation of certain historical liability classified equity awards (2018 – \$5.3 million).

Other Income (Expense), net

	Three Months Ended		Increase/ (Decrease)	
	September 30,			
	2019	2018		
	(dollars in millions)			
Other income (expense), net	\$ 2.2	\$ 0.9	\$ 1.3	144%

Other net income increased for the three months ended September 30, 2019 by \$1.3 million compared to the same period in 2018. Net other income for 2019 primarily included \$2.1 million of net interest and other income and \$0.1 million net foreign exchange gain. Net other income for 2018 primarily included \$1.0 million of net interest and other income, which was offset by net foreign exchange loss and other expenses.

	Nine Months Ended		Increase/ (Decrease)	
	September 30,			
	2019	2018		
	(dollars in millions)			
Other income (expense), net	\$ 4.3	\$ (2.3)	\$ 6.6	287%

Other net income increased for the nine months ended September 30, 2019 by \$6.6 million compared to the same period in 2018. Net other income for 2019 primarily included \$4.6 million of net interest and other income, which was partially offset by a \$0.2 million net foreign exchange loss. Net other expense for 2018 primarily included a \$3.6 million loss due to an increase in fair value of warrant liabilities and a \$0.2 million net foreign exchange loss, which were partially offset by \$1.6 million of net interest and other income.

Liquidity and Capital Resources

Sources of Liquidity

Until the completion of our IPO in Q2 2017, we had financed our operations primarily through private equity placements of our common shares, the issuance of convertible debentures which subsequently converted into equity securities, and 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 approximately \$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. We received net cash proceeds of approximately \$188.0 million, after underwriting discounts, commissions and offering expenses.

In addition, our operations have been funded through upfront fees, milestone payments, research support payments from our strategic partners, government grants and SR&ED credits. As of September 30, 2019, we had \$335.1 million in cash and cash equivalents and short-term investments.

Table of Contents

In addition to our existing cash and cash equivalents, we expect to continue to receive additional milestone payments and research support payments from our existing and future research collaborations. However, our ability to receive future milestone payments is dependent upon the successful completion of specified research and development activities by Zymeworks and its collaborators and therefore is uncertain at this time.

Cash Flows

The following table represents a summary of our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine months Ended September 30	
	2019	2018
	(dollars in millions)	
Net cash provided by (used in):		
Operating activities	\$ (45.5)	\$ (25.9)
Investing activities	62.6	(73.0)
Financing activities	191.5	91.5
Effect of exchange rate changes on cash and cash equivalents	0.0	(0.2)
Net change in cash and cash equivalents	\$ 208.6	\$ (7.6)

Operating Activities

During the nine months ended September 30, 2019, cash used in operating activities was \$45.5 million, which consisted of a net loss of \$73.2 million, adjusted by non-cash charges of \$26.7 million and a net decrease of \$0.9 million in our net operating assets. The non-cash charges primarily consisted of \$21.0 million in stock-based compensation for liability and equity classified stock options, \$4.7 million in depreciation, amortization and non-cash lease expenses, \$0.8 million in impairment charges, \$0.3 million in increase of contingent consideration. The change in our net operating assets and liabilities was primarily attributable to an increase in accounts payable and accruals and income tax payable of \$12.2 million which was partially offset by an increase in prepaid assets of \$5.6 million, a decrease in deferred revenue of \$3.5 million and an increase in accounts receivable and SR&ED receivable of \$2.1 million.

During the nine months ended September 30, 2018, cash used in operating activities was \$25.9 million, which consisted of a net loss of \$45.8 million, adjusted by non-cash charges of \$18.1 million and a net increase of \$1.8 million in our net operating assets. The non-cash charges primarily consisted of \$11.9 million in stock-based compensation for liability and equity classified stock options, \$2.5 million in depreciation and amortization, \$3.6 million in increase in fair value of warrant liabilities and \$0.3 million in unrealized foreign currency loss, which were partially offset by a \$0.2 million income tax recovery. The change in our net operating assets and liabilities was primarily attributable to a decrease in our SR&ED and accounts receivable of \$1.1 million and an increase in our accounts payable and accrued liabilities and income taxes payable of \$1.0 million, which was partially offset by an increase in prepaid assets of \$0.3 million.

Investing Activities

Net cash provided by investing activities for the nine month periods ended September 30, 2019 and September 30, 2018 is primarily related to a change in short-term investments.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019 included net proceeds of \$188.0 million from our recent public offering of equity securities, \$2.7 million from stock option exercises and

Table of Contents

\$0.6 million from the issuance of common shares in relation to our employee stock purchase plan, whereas the same period in 2018 included net proceeds of \$90.8 million from our public offering of equity securities, \$0.6 million from stock option exercises and \$0.3 million from the issuance of common shares in relation to our employee stock purchase plan.

Funding Requirements

We have historically generated revenue from our strategic collaborations, licensing agreements and research support payments and 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 and short-term investments as of September 30, 2019, combined with certain anticipated milestone payments from our collaborations, will enable us to fund our operating expenses and capital expenditure requirements into 2021 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 Zymeworks 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 Item 1A, “Risk Factors – Risks Related to Our Dependence on Third Parties – We may not realize the anticipated benefits of our strategic partnerships”.

Contractual Obligations and Contingent Liabilities

Lease Commitments

We lease office premises in Vancouver, British Columbia and Seattle, Washington pursuant to leases that expire in August 2021 and February 2022, respectively. We also lease laboratory space in Vancouver, British Columbia pursuant to a lease that will expire in August 2021. The leases contain rent escalation clauses. We entered into a lease on January 25, 2019 for office and laboratory space in Vancouver to serve as our future head office. The commencement date of this lease will be no later than September 21, 2021 and has an initial term of ten years, with two five-year extension options. Effective February 25, 2019, we also entered into a lease for office space in Seattle. The commencement date of this lease was July 30, 2019 for a portion of the space and will be no later than April 1, 2020 for the remaining portion of the space. The expiration date of the lease is April 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 September 30, 2019 are as follows:

	Payments due by period					Total
	Less Than 1 Year	1 to 2 Years	2 to 3 Years	3 to 4 Years	Thereafter	
	(dollars in thousands)					
Capital lease obligations	\$ 27	\$ 22	\$ 6	\$ 4	\$ 2	\$ 61
Operating lease obligations	1,307	2,253	1,131	982	1,614	7,287
Total contractual obligations	\$ 1,334	\$ 2,275	\$ 1,137	\$ 986	\$ 1,616	\$ 7,348

Table of Contents

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 August 2016, we entered into a license agreement with Innovative Targeting Solutions Inc. (“ITS”) to use ITS’ protein engineering technology for the development and commercialization of antibody and protein therapeutics. Pursuant to the agreement, we agreed to pay an aggregate of \$12.0 million in annual licensing fees to ITS over a five-year period, the full outstanding amount of which was paid in the period ended September 30, 2019 in accordance with the prepayment terms thereunder. As a result, as of September 30, 2019, we have no further licensing fee payment obligations under the agreement. Licensing fees paid have been recorded in intangible assets and are being amortized over their useful lives. We may also be required to make future payments to ITS upon the achievement of certain development and commercial milestones, as well as royalty payments on net sales.

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 September 30, 2019, the development milestone payments had an estimated fair value of approximately \$992 thousand, which has been recorded as contingent consideration within other long-term liabilities (December 31, 2018: \$707 thousand). 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 discovery, development and commercialization of next-generation biotherapeutics.

[Table of Contents](#)

Outstanding Share Data

As of October 31, 2019, our authorized share capital consisted of an unlimited number of common shares, each without par value, of which 39,387,339 were issued and outstanding, and an unlimited number of preferred shares, each without par value, none of which were issued and outstanding. As of October 31, 2019, we had 4,166,690 common shares issuable pursuant to 4,166,690 pre-funded warrants, 2,338,347 common shares issuable pursuant to 2,338,347 exercisable outstanding stock options and 2,911,149 common shares issuable pursuant to 2,911,149 outstanding options that were not exercisable at that date.

Jumpstart Our Business Startups Act (the “JOBS Act”) Accounting Election

In April 2012, the JOBS Act was enacted. 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 U.S. Securities Act of 1933, as amended (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. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is 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. The 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

We had cash, cash equivalents and short-term investments of \$335.1 million and \$200.2 million at September 30, 2019 and December 31, 2018, respectively, consisting primarily of funds in cash and guaranteed investment certificates. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income 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 an immediate 10% increase in interest rates would have a material effect on the fair market value of our portfolio, 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

We undertake certain transactions in Canadian dollars and as such are subject to risk due to fluctuations in exchange rates. Canadian dollar denominated payables are paid at the converted rate as due. We do not use derivative instruments to hedge exposure to foreign exchange rate risk due to the low volume of transactions denominated in foreign currencies. At September 30, 2019, our net monetary assets denominated in Canadian dollars was \$5.8 million (C\$7.6 million).

Our operating results and financial position are reported in U.S. dollars in our financial statements. The fluctuation of the Canadian dollar in relation to the U.S. dollar will consequently have an impact upon our loss and may also affect the value of our assets and the amount of shareholders equity. A hypothetical 10% increase (decrease) in the value of the Canadian dollar would result in a foreign exchange gain (loss) of \$0.6 million being recorded in the Consolidated Statements of Loss and Comprehensive Loss on the translation of our Canadian dollar net monetary assets into our U.S. dollar functional currency.

Table of Contents

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial expenses. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As 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 (our principal executive officer and principal financial officer, respectively), evaluated the design and operating effectiveness of our disclosure controls and procedures. The term “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”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. As of September 30, 2019, 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.

Table of Contents

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 ZW25 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 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;

Table of Contents

- 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

Table of Contents

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.

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.

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

Table of Contents

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 ZW25 has been well tolerated in human clinical trials and ZW25 and ZW49 have demonstrated favorable safety profiles in animals; however, ZW25 and ZW49 continue to be evaluated in clinical trials. The results of these and future clinical trials may show that ZW25, 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 Phase 1 clinical trial 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.

Table of Contents

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 or develop bispecific antibodies. These companies include MacroGenics, Inc., Xencor, Inc., Daiichi Sankyo and F. Hoffmann-La Roche AG.

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 biological product or “reference product.” Manufacturers may not submit an application for a biosimilar to the FDA until four years following approval of the reference

Table of Contents

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 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 ZW25 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

Table of Contents

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 ZW25 for the treatment of gastric 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 ZW25, 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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

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, the interpretation and application of consumer, health-related and data protection laws in the United States, the EU, and elsewhere are often uncertain, contradictory and in flux. 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

Table of Contents

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.

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. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing or delaying penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance, delaying the implementation of certain PPACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

Other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Bipartisan Budget Act of 2018, among other things, amends 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 U.S. Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization

Table of Contents

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.

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;

Table of Contents

- regulatory changes and economic conditions leading up to and following the United Kingdom's expected 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; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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;

Table of Contents

- 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 which 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 pre-empted 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 non-compliance 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.

Table of Contents

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 which 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, 2017 and 2018 and for the nine months ended September 30, 2019 was \$10.4 million, \$36.6 million and \$73.2 million, respectively. As of September 30, 2019, our accumulated deficit was approximately \$218.5 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

Table of Contents

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 2021 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 1 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;

Table of Contents

- 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 the last decade, 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 another such disruption in credit and financial markets and deterioration of confidence in economic conditions 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.

Table of Contents

As of September 30, 2019, approximately 2.0% of our cash and cash equivalents and short-term investments was denominated in Canadian dollars. 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.

From time to time, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. For example, we maintain a natural currency hedge against fluctuations in the U.S./Canadian foreign exchange rate by matching the amount of U.S. dollar and Canadian dollar investments to the expected amount of future U.S. dollar and Canadian dollar obligations, respectively. 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, Celgene, 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;

Table of Contents

- 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, Celgene, GSK, Daiichi Sankyo, Janssen, LEO, BeiGene and Iconic may be terminated for convenience upon the completion of a specified notice period; and
- 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.

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

Table of Contents

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 its 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. Any failure by a third party with respect to these activities may 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.

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

Table of Contents

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.

The manufacture of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.

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 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.

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

Table of Contents

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

[Table of Contents](#)

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

Risks Related to Our Intellectual Property

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. For example, certain patents and patent applications held by third parties cover Fab and Fc region engineering methods for bispecific antibodies, and antibodies having mutations in Fab heavy and light chain regions and Fc regions to generate correctly paired bispecific antibodies. If our products or our strategic partners' products incorporate any Fab or Fc region mutations covered by any claims of these patents or patents that may issue from these applications and 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;

Table of Contents

- 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.

Table of Contents

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.

Table of Contents

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;

Table of Contents

- 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;

Table of Contents

- 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

Table of Contents

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

Table of Contents

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 which 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. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Further, 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 combination of events 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

Table of Contents

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 going forward 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

Table of Contents

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

Table of Contents

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; and
- submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

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

Table of Contents

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 pre-empted by HIPAA, thus complicating compliance efforts.

Additionally, the PPACA also included the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals 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.

Table of Contents

The change from foreign private issuer to U.S. domestic issuer status may result in additional costs and expenses to us.

As of June 30, 2018, we determined that we no longer qualify as a “foreign private issuer,” as such term is defined in Rule 405 under the Securities Act. As a result, as of January 1, 2019, we are no longer eligible to use the rules and forms designated for foreign private issuers and we are considered a U.S. domestic issuer. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than the costs incurred as a foreign private issuer. As a U.S. domestic issuer, we are required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are generally more detailed and extensive than the forms available to a foreign private issuer. In addition, we are required to comply with U.S. proxy requirements and Regulation FD (Fair Disclosure) and our officers, directors and principal shareholders are subject to the beneficial ownership reporting and short-swing profit recovery requirements in Section 16 of the Exchange Act. We are also no longer eligible to rely upon exemptions from corporate governance requirements that are available to foreign private issuers or to benefit from other accommodations for foreign private issuers under the rules of the SEC or the NYSE, which may involve additional costs.

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, Mr. Neil Klompas, our Executive Vice President, Business Operations and Chief Financial Officer, and other members of our senior management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We currently maintain “key person” insurance coverage for Dr. Tehrani (C\$5.0 million) and Mr. Neil Klompas (C\$2.0 million). 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 September 30, 2019, we had 226 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

Table of Contents

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 recently 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;

Table of Contents

- economic and other external factors or other disasters or crises;
- 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, 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 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

Table of Contents

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.

As a foreign private issuer, we were subject to different U.S. securities laws and rules than a U.S. domestic issuer, in particular, certain disclosure requirements, which may have limited the information publicly available to our shareholders.

As of June 30, 2018, we determined that we no longer qualify as a “foreign private issuer,” as such term is defined in Rule 405 under the Securities Act. However, we remained eligible to use the rules and forms designated for foreign private issuers until January 1, 2019, at which time we were considered a U.S. domestic issuer. As a foreign private issuer, we were not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act that apply to U.S. domestic issuers and, as such, there may be less publicly available information about us than if we had been a U.S. domestic issuer prior to January 1, 2019.

Effective December 31, 2019, we will no longer be an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies will 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 will be a large accelerated filer as of December 31, 2019 and will 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. However, we are not required to reflect the change in our smaller reporting company status until our first quarterly report in our next fiscal year (i.e., the quarterly report for the three-month period ended March 31, 2020).

As an emerging growth company and a smaller reporting company, we have 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 have 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 will increase our expenses and require significant management time. Investors may find our common shares less attractive because of the additional compliance costs. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

Table of Contents

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 disclosure controls and procedures annually. We have thus far elected to take advantage of certain exceptions from reporting requirements that are available to emerging growth companies under the JOBS Act and therefore have not previously delivered an auditor’s attestation report on the effectiveness of our internal control over financial reporting pursuant to Section 404.

As of December 31, 2018, our management performed an evaluation of the design and operating effectiveness of our internal control over financial reporting based on the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or 2013 COSO Framework. However, no independent assessment of the design and operating effectiveness of our internal controls was performed by our independent registered public accounting firm as of December 31, 2018 pursuant to certain exceptions under the JOBS Act, as described above. Had our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by our independent registered public accounting firm and those control deficiencies could have also represented one or more material weaknesses.

As of December 31, 2019, we will no longer qualify as an emerging growth company. As a result, our independent registered public accounting firm will be 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.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its 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.

Table of Contents

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 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. Certain of our directors and 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 directors, 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.

Table of Contents

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, 2018. 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 31.1% of our outstanding common shares as of September 30, 2019 (24.8% excluding the exercise of convertible securities). Our directors and named executive officers beneficially own, in the aggregate, approximately 3.6% of our outstanding common shares as of September 30, 2019. 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.

Table of Contents

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 nine months ended September 30, 2019, we (i) granted our Canadian employees, consultants and advisors options to purchase an aggregate of 847,800 common shares under our equity compensation plans at exercise prices ranging from C\$20.77 to C\$30.81 and ranging from \$15.23 to \$25.83 per share and (ii) made an aggregate of 26,368 common shares available to eligible Canadian employees for purchase under our employee stock purchase plan at purchase price of \$12.49 per share. Such options and shares 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.

Table of Contents

Item 6. Exhibits

<u>Exhibit No.</u>	<u>Description</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
4.1	<u>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).</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</u>
31.2	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</u>
32.1	<u>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.</u>
32.2	<u>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.</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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: November 5, 2019

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: November 5, 2019

[\(Back To Top\)](#)

Section 2: EX-31.1 (EX-31.1)

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: November 5, 2019

/s/ Ali Tehrani
Chief Executive Officer
([Back To Top](#))

Section 3: EX-31.2 (EX-31.2)

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: November 5, 2019

/s/ Neil Klompas
Chief Financial Officer
([Back To Top](#))

Section 4: EX-32.1 (EX-32.1)

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 September 30, 2019 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: November 5, 2019

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.

[\(Back To Top\)](#)

Section 5: EX-32.2 (EX-32.2)

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 September 30, 2019 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: November 5, 2019

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.

[\(Back To Top\)](#)