UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

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: 001-38419

Arcus Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-3898435**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3928 Point Eden Way
Hayward, CA 94545
(Address of principal executive offices)

Registrant's telephone number, including area code: (510) 694-6200

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of August 1, 2018, the registrant had 44,456,659 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCI AL INFORMATION

Item 1. Financial Statements.

ARCUS BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	June 30, 2018	December 31, 2017*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 169,998	$ 98,426
Short-term investments	95,700	77,277
Prepaid expenses and other current assets	1,550	1,141
Amounts owed by a related party	193	25
Total current assets	267,441	176,869
Long-term investments	11,792	—
Property, plant and equipment-net	12,513	11,230
Equity investment in related party	1,711	682
Restricted cash	203	203
Other long-term assets	205	1,502
Total assets	$ 293,865	$ 190,486
LIABILITIES		
Current liabilities		
Accounts payable	$ 5,388	$ 3,820
Accrued liabilities	4,342	3,137
Deferred revenue, current	5,000	5,000
Other current liabilities	1,650	769
Total current liabilities	16,380	12,726
Deferred revenue, noncurrent	16,087	18,587
Deferred rent	4,516	4,740
Other long-term liabilities	2,308	565
Total liabilities	39,291	36,618
Convertible preferred stock, $0.0001 par value, no shares and 120,958,867 shares authorized as of June 30, 2018 and December 31, 2017, respectively; no shares and 30,459,574 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of 226,725, as of December 31, 2017	—	226,196
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value, 10,000,000 shares and no shares authorized as of June 30, 2018 and December 31, 2017, respectively; no shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	—
Common stock; $0.0001 par value; 400,000,000 and 153,993,227 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 44,456,659 and 4,090,898 shares issued and outstanding as of June 30, 2018 and December 31, 2017 respectively	4	—
Additional paid-in capital	354,375	948
Accumulated deficit	(99,722)	(73,234)
Accumulated other comprehensive loss	(83)	(42)
Total stockholders' equity (deficit)	254,574	(72,328)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 293,865	$ 190,486

The accompanying notes are an integral part of these condensed consolidated financial statements.
*The Condensed Consolidated Balance Sheet as of December 31, 2017 has been derived from the audited financial statements as of that date.

ARCUS BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration and license revenue	$ 1,250	$ —	$ 2,500	$ —
Operation expenses:				
Research and development	13,699	7,834	25,352	13,637
General and administrative	3,450	1,830	6,379	3,327
Total operating expenses	17,149	9,664	31,731	16,964
Loss from operations	(15,899)	(9,664)	(29,231)	(16,964)
Interest and other income, net	2,366	114	2,743	214
Net loss	(13,533)	(9,550)	(26,488)	(16,750)
Other comprehensive income (loss)	14	11	(41)	3
Comprehensive loss	$ (13,519)	$ (9,539)	$ (26,529)	$ (16,747)
Net loss per share, basic and diluted	$ (0.32)	$ (5.64)	$ (1.01)	$ (10.66)
Weighted-average number of shares used to compute basic and diluted net loss per share	42,533,641	1,693,150	26,236,007	1,571,905

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

ARCUS BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Cash flow from operating activities		
Net loss	$ (26,488)	$ (16,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,772	203
Depreciation and amortization	1,743	1,114
Share of loss from equity method investee	377	141
Gain on deemed sale from equity method investee	(1,229)	—
Other non-operating income	(177)	(53)
Changes in operating assets and liabilities		
Amounts owed by a related party	(168)	384
Prepaid expenses and other current assets	(409)	(366)
Accounts payable	1,347	(1,610)
Accrued liabilities	1,812	821
Other current liabilities	20	20
Deferred revenue	(2,500)	—
Deferred rent	(224)	(316)
Net cash used in operating activities	(24,124)	(16,412)
Cash flow from investing activities		
Purchases of short-term and long-term investments	(90,671)	(31,440)
Proceeds from maturities of short-term investments	60,415	16,085
Purchases of property and equipment	(2,358)	(4,381)
Net cash used in investing activities	(32,614)	(19,736)
Cash flow from financing activities		
Proceeds from initial public offering, net of issuance costs	125,114	—
Proceeds from issuance of common stock upon exercise of stock options, net of repurchases	3,331	608
Payment of preferred stock issuance costs	(135)	—
Net cash provided by financing activities	128,310	608
Net decrease in cash and cash equivalents	71,572	(35,540)
Cash and cash equivalents at beginning of period	98,426	65,160
Cash and cash equivalents at end of period	$ 169,998	$ 29,620
Non-cash investing and financing activities:		
Unpaid portion of property and equipment purchases included in accounts payable and accrued liabilities	1,007	495
Vesting of early exercised stock options and restricted stock	$ 647	$ 86

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

Note 1. Organization

Description of Business

Arcus Biosciences, Inc. (Company or the Company) is a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies by leveraging underexploited biological opportunities. Specifically, the Company targets well-characterized biological pathways with significant scientific data supporting their importance in regulating the immune response against cancer and for which either there are no molecules in development or those that exist have suboptimal profiles. To exploit these pathways, the Company has built a robust and highly efficient discovery capability to create and optimize highly differentiated small-molecule immuno-oncology product candidates. Since its inception in 2015, the Company has built a broad portfolio of small molecule and antibody product candidates that it plans to develop together as intra-portfolio combinations.

Initial Public Offering

On March 21, 2018, the Company completed its initial public offering (IPO) pursuant to which the Company issued 9,200,000 shares of common stock, including the exercise of the underwriters' overallotment option to purchase 1,200,000 shares of common stock, at an offering price at $15.00 per share. The Company received aggregate net proceeds of approximately $124.7 million after deducting underwriting discounts and other offering related costs. In addition, in connection with the completion of the Company's IPO, all outstanding shares of convertible preferred stock were converted into 30,459,574 shares of common stock and the Company amended and restated its certificate of incorporation and bylaws, which, among other things, changed the authorized capital stock to 400,000,000 shares of common stock and 10,000,000 shares of preferred stock, each with a par value of $0.0001 per share.

Liquidity and Capital Resources

As of June 30, 2018, the Company had cash and investments of $277.5 million, of which $265.7 million are cash, cash equivalents, and short-term investments which the Company believes will be sufficient to fund its planned operations for a period of at least twelve months following the filing date of this report.

Note 2. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the Company's opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

Operating results for the three and six month periods ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018 or for any future period. The balance sheet as of December 31, 2017 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2017 included in our Prospectus.

There have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2018 as compared to the significant accounting policies described in the Company's audited financial statements for the year ended December 31, 2017 included in the prospectus dated March 14, 2018 filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1993, as amended.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condense d consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. The Company will remain an emerging growth company until the earliest of (1) the last day of its first fiscal year (a) following the fifth anniversary of the completion o f our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Principles of Consolidation

During 2017, the Company established a wholly-owned subsidiary in Australia. The condensed consolidated financial statements include the Company's accounts and those of its wholly-owned subsidiary. All intercompany accounts, transactions and balances have been eliminated.

Reverse Stock Split

On March 9, 2018, the Company effected a reverse split of all shares of its common and preferred stock at a ratio of 1-for-3.96 (the Reverse Split). The par values and the authorized shares of the common and preferred stock were not adjusted as a result of the Reverse Split. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these condensed consolidated financial statements and notes to the condensed consolidated financial statements have been adjusted within the condensed consolidated financial statements, on a retroactive basis, to reflect the Reverse Split .

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as related disclosure of contingent assets and liabilities. Estimates were used to determine the fair value of common stock prior to the IPO and are used to determine stock-based awards and other issuances, accruals for research and development costs, useful lives of long-lived assets, and uncertain tax positions. Actual results could differ materially from the Company's estimates.

Cash Equivalents, Short-Term and Long-Term Investments

Cash equivalents include marketable securities having an original maturity of three months or less at the time of purchase. Short-term investments have maturities of greater than three months at the time of purchase. Long-term investments have maturities greater than 12 months at the time of purchase. Collectively, cash equivalents, short-term and long-term investments are considered available-for-sale and are recorded at fair value. Unrealized gains and losses are recorded in accumulated other comprehensive loss. Realized gains and losses are included in interest and other income, net in the condensed consolidated statements of operations and comprehensive loss.

Restricted Cash

Restricted cash at June 30, 2018 and December 31, 2017, comprises cash balances primarily held as security in connection with the Company's facility lease agreement and is included in long-term assets in the condensed consolidated balance sheets.

Concentration of Credit Risk

Cash equivalents, short-term and long-term investments are financial instruments that potentially subject the Company to concentrations of credit risk. The Company invests in money market funds, treasury bills and notes, government bonds, commercial paper and corporate notes. The Company limits its credit risk associated with cash equivalents, short-term and long-term investments by placing them with banks and institutions it believes are highly credit worthy and in highly rated investments.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, filing and other fees directly related to the Company's IPO, are capitalized. The deferred offering costs, which totaled $3.6 million, were reclassified to additional paid-in capital upon the effectiveness of the IPO in March 2018. As of December 31, 2017, $1.3 million of deferred offering costs were capitalized and included in other long-term assets in the condensed consolidated balance sheet.

Re venue Recognition

The Company generates revenue from its option and license agreement for the development and commercialization of its product candidates. Option and license agreements may include non-refundable upfront research and development fees, option fees to obtain development and commercialization licenses for the Company's products, milestone payments based on achievement of defined development, regulatory and sales targets, and royalties on sales of commercialized products. To date, the Company has not recognized revenue from sales of its product candidates.

The Company recognizes revenue when all four of the following criteria have been met: (i) collectability is reasonably assured; (ii) delivery has occurred or services have been rendered; (iii) persuasive evidence of an arrangement exists; and (iv) the fee is fixed or determinable. Revenue under option and license arrangements is recognized based on evaluation of the performance obligations of the contract. Collectability is assessed based on evaluation of payment criteria as stated in the contract as well as the creditworthiness of the customer. Determination of whether delivery has occurred, or services rendered are based on management's evaluation of the performance obligations as stated in the contract and progress made against those obligations. Evidence of arrangement is deemed to exist upon execution of the contract. Fees are considered fixed and determinable when the amount payable to the Company is no longer subject to any acceptance, refund rights or other contingencies that would alter the fixed nature of the fees charged for the deliverables.

Option and license agreements may contain multiple elements as evaluated under Accounting Standards Codification (ASC) 605-25, *Revenue Recognition-Multiple-Element Arrangements,* including agreements to provide research and development services, participation in development and/or steering committees, manufacturing services, sharing of know-how and other information, and grants of licenses to develop and commercialize product candidates. Each deliverable under the agreement is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has standalone value to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the following hierarchy: (i) vendor-specific objective evidence of the fair value of the deliverable, if it exists; (ii) third-party evidence of selling price, if vendor-specific objective evidence is not available; or (iii) the best estimate of selling price if neither vendor-specific objective evidence or third-party evidence is available.

A delivered item or items that do not qualify as a separate unit of accounting within the arrangement are combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue is then determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees are recognized as performance obligations related to the final deliverable are completed. In the case of research and development services, performance would generally be expected to be ratable over the estimated performance period unless the Company determines there is a discernible pattern of performance other than straight-line, in which case the Company uses a proportionate performance method to recognize the revenue over the estimated performance period. Amounts received in advance of performance are recorded as deferred revenue. If any of the initial deliverables are determined to have standalone value separate from the research and development services, then the allocated consideration is recorded as revenue when those items are delivered.

Option and license agreements may also contain milestone payments that become due upon the achievement of certain milestones. The Company applies ASC 605-28, *Revenue Recognition—Milestone Method.* Under the milestone method, payments that are contingent upon achievement of a substantive milestone are recognized in the period in which the milestone is achieved. Milestones are defined as an event that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, for the milestone to be considered substantive, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables, and the consideration must be commensurate with the Company's performance to achieve the milestone. Non-substantive milestone payments are recognized as revenue over the estimated period of any remaining performance obligations.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of personnel costs for the Company's research and product development employees. Also included are non-personnel costs such as professional fees payable to third parties for preclinical and clinical studies and research services, laboratory supplies and equipment maintenance, product licenses, and other consulting costs.

The Company estimates preclinical and clinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical and clinical studies and research services on its behalf. The Company estimates these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

Rec ently Issued Accounting Standards or Updates Not Yet Effective

In January 2016, the FASB issued ASU *No. 2016-01 (Subtopic 825-10), Financial Instruments (ASU 2016-01)* . ASU 2016-01 requires management to measure equity investments at fair value with changes in fair value recognized in net income or loss. ASU 2016-01 will impact the disclosure and presentation of financial assets and liabilities. ASU 2016-01 was effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-01 will be effective for the Company for the year ended December 31, 2019, and all interim periods thereafter. Early adoption is not permitted. We are currently in the process of evaluating the impact of adoption of this standard on our consolidated financial statements.

In November 2016, the FASB issued ASU *No. 2016-18 (Topic 230), Restricted Cash, Statement of Cash Flows (ASU 2016-18)* . ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash and, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the condensed consolidated statement of cash flows. ASU 2016-18 was effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-18 will be effective for the Company for the year ended December 31, 2019, and all interim periods thereafter. Early adoption is permitted. The amendments in this ASU should be applied using a retrospective transition method to each period presented. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09). In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date* , which delayed the effective date of ASU 2014-09 by one year. ASU 2014-09, as amended, became effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2014-09 will be effective for the Company for the year ended December 31, 2019, and all interim periods thereafter. Early adoption is permitted. ASU 2014-09 also permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method).

The core principle of ASU 2014-09 is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. generally accepted accounting pronouncements. The Company is still in the process of evaluating the effect that this guidance will have on revenue recognition for our option and license agreement with Taiho Pharmaceutical Co., Ltd. (Taiho), specifically as it pertains to the non-refundable, non-creditable cash payments to the Company totaling $35.0 million and the future contingent payments the Company may become entitled to. The Company expects its evaluation to be completed during 2018.

In February 2016, the FASB issued ASU *No. 2016-02 (Topic 842), Leases (ASU 2016-02).* ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-02 is effective for the Company for the year ended December 31, 2020, and all interim periods thereafter. Early adoption is permitted. The Company has not yet determined the potential effects of this ASU on its condensed consolidated financial statements.

In June 2018, the FASB issued ASU *No. 2018-07 (Topic 718), Compensation – Stock Compensation (ASU 2018-07).* ASU 2018-07 requires an entity to expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. For public entities, ASU 2018-07 is effective for fiscal years beginning after December 15, 2018. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2018-07 is effective for the Company for the year ended December 31, 2020, and all interim periods thereafter. Early adoption is permitted. The Company has not yet determined the potential effects of this ASU on its condensed consolidated financial statements.

Note 3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy as of June 30, 2018 and December 31, 2017. The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at June 30, 2018			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 104,286	$ 104,286	$ —	$ —
Overnight repurchase agreements	40,000	—	40,000	—
U.S. government agency obligations	46,755	—	46,755	—
Corporate securities and commercial paper	86,449	—	86,449	—
	$ 277,490	$ 104,286	$ 173,204	$ —

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 66,478	$ 66,478	$ —	$ —
U.S. government agency obligations	57,153	—	57,153	—
Corporate securities and commercial paper	52,072	—	52,072	—
	$ 175,703	$ 66,478	$ 109,225	$ —

Classified as (with contractual maturities):

	June 30, 2018	December 31, 2017
Cash and Cash equivalents (due within 90 days)	$ 169,998	$ 98,426
Short-term investments (due within one year)	95,700	77,277
Long-term investments (due between one and two years)	11,792	—
	$ 277,490	$ 175,703

The investments are classified as available-for-sale marketable securities. At June 30, 2018 and December 31, 2017, the balance in the Company's accumulated other comprehensive loss comprised activity related to the Company's available-for-sale marketable securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale marketable securities as of June 30, 2018 and December 31, 2017, and as a result, the Company did not reclassify any amounts out of accumulated othe r comprehensive loss for the periods then ended. The Company has a limited number of available-for-sale marketable securities in loss positions as of June 30, 2018, which the Company does not intend to sell and has concluded it will not be required to sell before recovery of the amortized cost for the investment at maturity (in thousands).

	Fair Value Measurements at June 30, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 104,286	$ —	$ —	$ 104,286
Overnight repurchase agreements	40,000		—	40,000
U.S. government agency obligations	46,779		(24)	46,755
Corporate securities and commercial paper	86,509	—	(60)	86,449
	$ 277,574	$ —	$ (84)	$ 277,490

	Fair Value Measurements at December 31, 2017			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 66,478	$ —	$ —	$ 66,478
U.S. government agency obligations	57,183	—	(30)	57,153
Corporate securities and commercial paper	52,084	—	(12)	52,072
	$ 175,745	$ —	$ (42)	$ 175,703

Note 4: Equity Investment

In September 2016, the Company purchased approximately 3.6 million shares of common stock of PACT Pharma, Inc. (PACT Pharma), a privately funded, early-stage biopharmaceutical company focused on adoptive cell therapy. The Company determined the fair value of such investment to be insignificant to the Company's 2016 financial statements given the start-up nature of operations of PACT Pharma, and it was recorded at a nominal amount. In December 2016, the Company and PACT Pharma entered into a Master Services Agreement (the PACT Agreement) under which the Company provided PACT Pharma with general administrative support, including finance, human resources, legal, and other operational support. The Company also received certain warrants to purchase PACT Pharma common stock exercisable upon PACT Pharma's achievement of certain valuation thresholds pursuant to the PACT Agreement. Also, in December 2016, the Company purchased 1.0 million shares of Series A preferred stock of PACT Pharma for $1.0 million. The Company determined PACT Pharma to be a variable interest entity, and that the Company has a variable interest in PACT. However, because the Company is not the primary beneficiary of PACT Pharma, it is not consolidating the results of operations of PACT Pharma in its condensed consolidated financial statements.

The Company's investment in PACT Pharma is accounted for as an equity method investment, and as a result the Company records its share of PACT Pharma's operating results in interest and other income, net, in its condensed consolidated statement of operations and comprehensive loss.

For the three and six month periods ended June 30, 2018, the Company recorded $0.2 million and $0.4 million, respectively, and for the three and six month periods ended June 30, 2017, the Company recorded $70,000 and $0.1 million, respectively relating to its share of PACT Pharma's operating losses. As of June 30, 2018 and December 31, 2017, the Company had a $0.2 million and $25,000 receivable from PACT Pharma, respectively, for expenses the Company paid for on its behalf.

In May 2018, PACT Pharma closed its Series B convertible preferred stock financing. The Company did not participate in this financing and therefore its equity ownership percentage in PACT Pharma decreased. As a result of the dilution in its equity ownership percentage and an increase in PACT Pharma's estimated fair value per share, the Company recorded a gain of $1.2 million in interest and other income, net, for the three-month period ended June 30, 2018 and an increase in the fair value of the investment balance in the condensed consolidated balance sheet as of June 30, 2018 by the same amount. The PACT Agreement also expired in accordance with its terms at the closing of PACT Pharma's Series B convertible preferred stock financing.

The Company monitors the investment for events or circumstances indicative of potential other-than-temporary impairment and makes appropriate reductions in carrying values if it is determined that an impairment charge is required. As of June 30, 2018 and 2017, no impairment charge was recorded. As of and for the six-month period ended June 30, 2018 and for the year ended December 31, 2017, the Company also determined the fair value of the warrants to be insignificant to the condensed consolidated financial statements.

Note 5. Lice nse and Collaboration Agreements

Taiho Pharmaceutical Co., Ltd

In September 2017, the Company and Taiho entered into an option and license agreement (the Taiho Agreement) to collaborate on the potential development and commercialization of certain product candidates from the Company's portfolio in Japan and certain other territories in Asia (excluding China) (the Taiho Territory). The Taiho Agreement provides Taiho with exclusive options, over a five-year period (the Option Period), to obtain an exclusive development and commercialization license to clinical stage product candidates from the Company's programs (each, an Arcus Program).

In consideration for the exclusive options and other rights contained in the Taiho Agreement, Taiho will make non-refundable, non-creditable cash payments to the Company totaling $35.0 million, of which the Company received $25.0 million during 2017. An additional $5.0 million is payable by Taiho and expected to be received in both October 2018 and 2019.

In the event that the Company has not initiated IND enabling studies for at least five Arcus Programs prior to the expiration of the Option Period, Taiho may elect to extend the Option Period, up to a maximum of seven years for the Option Period, subject to an extension fee. If Taiho elects to exercise an option they will be obligated to make an exercise option payment for each option exercise of between $3.0 million to $15.0 million, dependent on the development stage of the applicable Arcus Program for which the option is exercised. In addition, the Taiho Agreement provides that the Company is eligible to receive additional clinical and regulatory milestones totaling up to $130.0 million per Arcus Program, and it will be eligible to receive contingent payments of up to $145.0 million per Arcus Program associated with the achievement of specified levels of Taiho net sales in the Taiho Territory.

In addition, the Company will receive royalties ranging from high single-digits to mid-teens on net sales of licensed products in the Taiho Territory. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis during the period of time commencing on the first commercial sale of a licensed product in a country and ending upon the later of: (a) ten (10) years from the date of first commercial sale of such licensed product in such country; and (b) expiration of the last-to-expire valid claim of the Company's patents covering the manufacture, use or sale or exploitation of such licensed product in such country (the Royalty Term).

The Taiho Agreement contains multiple elements, and the deliverables under the Taiho Agreement consist of (1) the research and development services, in which the Company will use commercially reasonable efforts to initiate IND enabling studies for at least five Arcus Programs, as well as further develop such Arcus Programs during the term of the Agreement, and (2) the obligation to participate on the joint steering committee. These deliverables are non-contingent in nature. The Company determined that the obligation to participate in the joint steering committee does not have stand-alone value to Taiho because the committee's primary purpose is to monitor and govern the research and development activities and, hence, it is inseparable from the research and development services. The Company also concluded that, at the inception of the agreement, Taiho's exclusive options are contingent deliverables as the exclusive options have significant uncertainty and are outside of the control of the Company, since Taiho has sole discretion to determine whether or not to exercise such options. Further, the Company concluded that the exclusive options do not contain a significant and incremental discount. As of June 30, 2018, Taiho had not exercised any exclusive option. In July 2018, Taiho exercised its first option and is obligated to make an exercise payment of $3.0 million.

The Company determined that the level of effort required for it to meet its obligations under the Taiho Agreement is not expected to vary significantly over the Company's performance period. Accordingly, the Company combined these deliverables into a single unit of accounting and allocated the entire arrangement consideration to that combined unit of accounting. As a result, the $25.0 million non-refundable, non-creditable cash payments received by the Company are being recognized ratably over the estimated performance period of five years, and the remaining $10.0 million of non-refundable, non-creditable cash payments will be recognized ratably over the estimated remaining performance period as they become due and payable by Taiho. During the three and six month periods ended June 30, 2018, the Company recognized $1.3 million and $2.5 million, respectively, of revenue under the Taiho Agreement. As of June 30, 2018, the Company recorded deferred revenue, current and deferred revenue, noncurrent of $5.0 million and $16.1 million, respectively, in its condensed consolidated balance sheet. As of December 31, 2017, the Company recorded as deferred revenue, current and deferred revenue, noncurrent of $5.0 million and $18.6 million, respectively, in its consolidated balance sheet.

The Company determined that the clinical and regulatory milestone payments under the Taiho Agreement do not constitute substantive milestones and, therefore, will not b e accounted for under the milestone method of revenue recognition. The events leading to these payments do not meet the definition of a substantive milestone because the achievement of these events depends primarily on Taiho's performance. Accordingly, any revenue from these payments would be recognized over the remaining period of the performance obligations, if any, relating to this arrangement. If there are no remaining performance obligations under the arrangement at the time the milestone payment is tr iggered, then such milestone payment will be recognized as revenue in full upon the triggering event being achieved. The Company considers the contingent payments due from Taiho upon the achievement of specified sales volumes to be similar to royalty payme nts. The Company will recognize royalty payments as revenue in the period when such royalty payments are earned, i.e. in the period when sales of the licensed products in Taiho Territory occur. The Taiho Agreement shall remain in effect until (a) expiratio n of the last exercise period if Taiho has not exercised any of its exclusive options prior to such expiration or (b) if Taiho has exercised any of its exclusive options prior to the expiration of the applicable exercise period, expiry of all Royalty Terms for the licensed products, in each case subject to certain exceptions.

WuXi Biologics License Agreement

In August 2017, the Company entered into a license agreement (the WuXi Agreement) with WuXi Biologics (Cayman) Inc. (WuXi Biologics) in which it obtained an exclusive license to develop, use, manufacture, and commercialize products including an anti-PD-1 antibody in North America, Europe, Japan and certain other territories. The Company paid upfront and milestone payments of $18.5 million during the second half of 2017 which were recorded within research and development expenses, as the products have not reached technological feasibility and do not have alternate commercial use. No milestone payments were made during the three and six month periods ended June 30, 2018. The WuXi Agreement also provides for clinical and regulatory milestone payments, commercialization milestone payments of up to $375.0 million, and tiered royalty payments to be made to WuXi Biologics that range from the high single-digits to low teens of net sales by the Company of licensed products.

Abmuno License Agreement

In December 2016, the Company entered into a license agreement (the Abmuno Agreement) with Abmuno Therapeutics LLC (Abmuno) in which it obtained a worldwide exclusive license to develop, use, manufacture, and commercialize products that include an anti-TIGIT antibody. The Company made milestone payments of zero and $0.8 million for the three and six month periods ended June 30, 2018, respectively, and upfront and milestone payments of zero and $3.8 million for the three and six month periods ended June 30, 2017, respectively, which were recorded within research and development expenses, as the products have not reached technological feasibility and do not have alternate commercial use and are expensed as incurred. In addition, a $2.0 million milestone was reached and recorded within research and development expenses in June 2018 and paid in July 2018. The Abmuno Agreement also provides for additional clinical, regulatory and commercialization milestone payments up to $101.0 million which reflects the payment of $2.0 million in milestone payment made in July 2018.

Note 6: Stock-Based Compensation

In March 2018, the Company adopted the 2018 Equity Incentive Plan (2018 Plan). The 2018 Plan replaced the 2015 Plan and 3,570,000 shares were reserved under the 2018 Plan, along with any shares remaining available for issuance under our 2015 Plan or outstanding awards under our 2015 Plan that subsequently expire, lapse unexercised or are forfeited to or repurchased by the Company.

Total stock-based compensation expense was recognized in our condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three months ended June,		Six months ended June 30,	
	2018	2017	2018	2017
Research and development	701	$ 67	1,041	$ 108
General and administrative	415	64	731	95
Total stock-based compensation	$ 1,116	$ 131	$ 1,772	$ 203

The Company granted 210,808 and 1,396,989 stock options for the three and six month periods ended June 30, 2018, respectively, and 190,145 and 866,582 for the three and six month periods ended June 30, 2017, respectively. These options had a weighted average grant-date fair value of $11.23 and $7.29 per share for the three and six month periods ended June 30, 2018, respectively, and $1.76 and $1.75 for the three and six month periods ended June 30, 2017, respectively.

As a result of stock issuances under the Company's stock plans, the Company issued 5,171 and 713,931 shares of our common stock for the three and six month periods ended June 30, 2018, respectively, a nd 240,407 and 519,059 for the three and six month periods ended June 30, 2017, respectively.

As a result of early exercises under the 2015 Plan, approximately 1,181,717 and 812,769 shares had not vested and were subject to repurchase as of June 30, 2018 and December 31, 2017, respectively. The Company treats cash received from the exercise of unvested options as a refundable deposit and classifies such amounts as a liability in its condensed consolidated balance sheets. As of June 30, 2018 and December 31, 2017, the Company included cash received from the early exercise of unvested options of $3.5 million and $0.9 million, in its other current and long-term liabilities, respectively based on the timing of their expected vesting. Amounts included in liabilities are transferred into common stock and additional paid-in capital as the shares vest, which is generally over a period of 48 months.

Note 7. Condensed Consolidated Balance Sheet Components

Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	As of June 30, 2018	As of December 31, 2017
Scientific equipment	$ 6,197	$ 5,053
Furniture and equipment	730	625
Capitalized software	146	131
Leasehold improvements	10,824	9,280
Construction in progress	338	119
Total	18,235	15,208
Less: Accumulated depreciation and amortization	(5,722)	(3,978)
Property and equipment, net	$ 12,513	$ 11,230

Depreciation and amortization expense was $0.9 million and $1.7 million for the three and six month periods ended June 30, 2018, respectively, and $0.6 million and $1.1 million for the three and six month periods ended June 30, 2017, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of June 30, 2018	As of December 31, 2017
Accrued personnel expenses	$ 1,902	$ 1,026
Accrued research and development expenses	2,082	1,193
Professional fees	100	706
Other	258	212
Total	$ 4,342	$ 3,137

Note 8. Net Loss per Share

Effective as of the completion of the IPO, all of the Company's preferred stock was converted to common stock. For purposes of calculating net loss per share for the three and six month periods ended June 30, 2018, the preferred stock converted to common stock was included in the net loss per common share calculation on a post-conversion basis based on the conversion date.

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (13,533)	$ (9,550)	$ (26,488)	$ (16,750)
Denominator:				
Weighted-average common shares outstanding	44,450,312	3,900,271	28,248,337	3,725,487
Less: weighted-average common shares subject to repurchase	(1,916,671)	(2,207,121)	(2,012,330)	(2,153,582)
Weighted-average common shares used to compute basic and diluted net loss per share	42,533,641	1,693,150	26,236,007	1,571,905
Net loss per share: basic and diluted	$ (0.32)	$ (5.64)	$ (1.01)	$ (10.66)

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	Six Months Ended June 30,	
	2018	2017
Convertible preferred stock	—	21,307,645
Common stock options issued and outstanding	1,221,862	471,891
Unvested restricted common stock	636,574	1,331,018
Unvested early exercised common stock options	1,181,717	867,958
Total	3,040,153	23,978,512

Note 9. Subsequent Event

In July 2018, Taiho exercised its option under the Option and License Agreement entered into in September 2017 to obtain an exclusive development and commercialization license to the Company's adenosine receptor antagonist program, which includes AB928 and back-up compounds, in Japan and certain other territories in Asia (excluding China). Taiho is obligated to make the $3.0 million option exercise payment in August 2018.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and notes thereto in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto for the year ended December 31, 2017, included in our prospectus dated March 14, 2018, filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (Prospectus). This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies by leveraging underexploited biological opportunities. Specifically, we target well-characterized biological pathways with significant scientific data supporting their importance in regulating the immune response against cancer and for which either there are no molecules in development or those that exist have suboptimal profiles. To exploit these pathways, we have built a robust and highly efficient discovery capability to create and optimize highly differentiated small-molecule immuno-oncology product candidates. Since our inception in 2015, we have built a broad portfolio of small-molecule and antibody product candidates that we plan to develop together as intra-portfolio combinations. Our most advanced small-molecule product candidate, AB928, is in a Phase 1/1b program to evaluate it in combination with chemotherapy and with our anti-PD-1 antibody, AB122. We expect to report dose-escalation data for these combinations in the first half of 2019. We have also initiated clinical trials for our two antibody product candidates, AB122 and AB154 (our anti-TIGIT antibody) and expect to advance our fourth product candidate, AB680 (a small molecule CD73 inhibitor) into a clinical trial by the end of 2018. Members of the Arcus team have worked together for more than 10 years discovering innovative small-molecule product candidates while at companies such as Tularik Inc., Amgen, Inc. and Flexus Biosciences, Inc.

Components of Operating Results

Collaboration and License Revenue

We recognize revenue from our option and license agreement (Taiho Agreement) with Taiho Pharmaceutical Co., Ltd. (Taiho) for research and development services provided pursuant to our collaboration with Taiho on the development of certain product candidates.

Operating Expenses

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the research and development of our research programs. These expenses include payroll and personnel expenses including stock-based compensation for our research and product development employees, laboratory supplies, product licenses, consulting costs, contract research, pre-clinical and clinical expenses, and depreciation. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as an expense as the related services are performed.

We do not allocate our costs by product candidates, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, and external costs neither of which are tracked by product candidate. In particular, with respect to internal costs several of our departments support multiple product candidate research and development programs, and we do not allocate those costs by product candidate.

We expect our research and development expenses to increase substantially during the next few years as we seek to complete existing and initiate additional clinical trials, pursue regulatory approval of AB928 and AB122, and advance other programs including AB154 and AB680 into the clinic. Over the next few years, we expect our preclinical, clinical, and contract manufacturing expenses to increase significantly relative to what we have incurred to date. In addition, under the license agreement entered into in August 2017 (the WuXi Agreement) with WuXi Biologics (Cayman) Inc. (WuXi Biologics), we may be required to pay additional clinical and regulatory milestone payments based on the development progress of AB122. Predicting the timing or the final cost to complete our clinical program or validation of our manufacturing and supply processes is difficult and delays may occur because of many factors.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs including payroll and stock-based compensation for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, and accounting services, rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase substantially during the next few years as a result of staff expansion and additional occupancy costs, as well as costs associated with being a public company, including higher legal and accounting fees, investor relations costs, higher insurance premiums and other compliance costs associated with being a public company.

Interest and Other Income, Net

Interest and other income, net consists primarily of interest earned on our investments including corporate notes and government agency notes, and equity method investment accounting transactions related to our investment in PACT Pharma, Inc. (PACT Pharma), including recognition of our share of losses and any gains and losses related to a dilution of our investment.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies relating to revenue recognition, clinical trial accruals and stock-based compensation reflect the more significant estimates and assumptions used in the preparation of our condensed consolidated financial statements.

There have been no significant changes in our critical accounting policies and estimates during the six-month period ended June 30, 2018, as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Prospectus and more fully described in Note 2 of the accompanying condensed consolidated financial statements.

Results of Operations

Three Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the periods indicated (in thousands)

	Three Months Ended June 30,		Change	
	2018	2017	$	%
Collaboration and license revenue	$ 1,250	$ —	$ 1,250	100%
Operating expenses:				
Research and development	13,699	7,834	5,865	75%
General and administrative	3,450	1,830	1,620	89%
Loss from operations	(15,899)	(9,664)	(6,235)	65%
Interest and other income, net	2,366	114	2,252	*
Net loss	$ (13,533)	$ (9,550)	$ (3,983)	42%

** Not Meaningful*

Collaboration and License Revenue

Collaboration and license revenue of $1.3 million for the three months ended June 30, 2018 was entirely due to the revenue we recognized pursuant to the Taiho Agreement we entered into in September 2017. We had no collaboration and license revenue for the three months ended June 30, 2017.

Research and Development Expenses

Research and development expenses increased $5.9 million, or 75%, from $7.8 million for the three months ended June 30, 2017 to $13.7 million for the three months ended June 30, 2018. The increase in research and development expenses was primarily due to an increase of $1.8 million in manufacturing and clinical costs for our ongoing clinical trials on AB928 and AB122 and the manufacturing of AB154 and AB680, an increase of $1.5 million in product license costs resulting from a milestone reached in our Abmuno Agreement, an increase of $1.4 million in employee compensation costs, and an increase of $0.6 million in stock-based compensation.

General and Administrative Expenses

General and administrative expenses increased $1.6 million, or 89%, from $1.8 million for the three months ended June 30, 2017 to $3.5 million for the three months ended June 30, 2018. The increase in general and administrative expenses was primarily due to an increase of $0.5 million in employee compensation costs, an increase of $0.4 million in legal and accounting fees, an increase of $0.3 million in stock-based compensation, and an increase of $0.3 million in facilities and office related expenses.

Interest and Other Income, Net

Interest and other income, net increased $2.3 million from $0.1 million for the three months ended June 30, 2017 to $2.4 million for the three months ended June 30, 2018. The increase was primarily due to a $1.2 million gain related to the dilution of our equity method investment in PACT Pharma and an increase in interest income of $1.0 million resulting from higher cash and investment balances.

Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,		Change	
	2018	2017	$	%
Collaboration and license revenue	$ 2,500	$ —	$ 2,500	100%
Operating expenses:				
Research and development	25,352	13,637	11,715	86%
General and administrative	6,379	3,327	3,052	92%
Loss from operations	(29,231)	(16,964)	(12,267)	72%
Interest and other income, net	2,743	214	2,529	*
Net loss	$ (26,488)	$ (16,750)	$ (9,738)	58%

** Not Meaningful*

Collaboration and License Revenue

Collaboration and license revenue of $2.5 million for the six months ended June 30, 2018 was entirely due to the revenue we recognized pursuant to the Taiho Agreement we entered into in September 2017. We had no collaboration and license revenue for the six months ended June 30, 2017.

Research and Development Expenses

Research and development expenses increased $11.7 million, or 86%, from $13.6 million for the six months ended June 30, 2017 to $25.3 million for the six months ended June 30, 2018. The increase in research and development expenses was primarily due to an increase of $7.0 million in manufacturing and clinical costs for our ongoing clinical trials on AB928 and AB122 and the manufacturing of AB154 and AB680, an increase of $2.3 million in employee compensation costs, an increase of $0.9 million in stock-based compensation, and an increase of $0.4 million in depreciation expense related to increases in lab equipment.

General and Administrative Expenses

General and administrative expenses increased $3.1 million, or 92%, from $3.3 million for the six months ended June 30, 2017 to $6.4 million for the six months ended June 30, 2018. The increase in general and administrative expenses was primarily due to an increase of $0.8 million in legal and accounting fees, an increase of $0.7 million in employee compensation costs, an increase of $0.6 million in stock-based compensation, an increase of $0.4 million in facilities and office costs, and an increase of $0.2 million in depreciation expense.

Interest and Other Income, Net

Interest and other income, net increased $2.5 million from $0.2 million for the six months ended June 30, 2017 to $2.7 million for the six months ended June 30, 2018. The increase was primarily due to a $1.4 million increase in interest income resulting from higher cash and investment balances and a $1.2 million gain related to the dilution of our equity method investment in PACT Pharma.

Liquidity and Capital Resources

To date, we have financed our operations primarily through net proceeds of $226.2 million from private placements of convertible preferred stock, $25.0 million in proceeds from the Taiho Agreement, and net proceeds of $124.7 million from our IPO in March 2018, pursuant to which we issued 9,200,000 shares of our common stock. As of June 30, 2018, we had $277.5 million of cash and investments, of which $265.7 million are cash, cash equivalents, and short-term investments. Our cash and investments are held in a variety of interest-bearing instruments, including money market funds, and investments in corporate securities and government agency obligations.

Based on our existing business plan, we believe that our existing cash, cash investments, and short-term investments will be sufficient to fund our anticipated level of operations through at least the next 12 months following the filing date of this report.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the timing and amount of milestone payments we receive under the Taiho Agreement;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Condensed Consolidated Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Six Months Ended June 30,	
Net cash (used in) provided by:	**2018**	**2017**
Operating activities	$ (24,124)	$ (16,412)
Investing activities	(32,614)	(19,736)
Financing activities	128,310	608
Net increase (decrease) in cash and cash equivalents	$ 71,572	$ (35,540)

Cash Used in Operating Activities

Net cash used in operating activities was $24.1 million for the six months ended June 30, 2018 and $16.7 million for the six months ended June 30, 2017.

Cash used in operating activities for the six months ended June 30, 2018 was primarily due to our net loss for the period of $26.5 million, and was also affected by changes in operating assets and liabilities, including a decrease in deferred revenue of $2.5 million, an increase in accounts payable and accrued liabilities of $3.2 million, an increase in prepaid expenses of $0.4 million, a non-cash gain of $0.9 million relating to our equity method investee and non-cash charges relating to depreciation and amortization and stock-based compensation expense of $3.5 million.

Cash used in operating activities for the six months ended June 30, 2017 was primarily due to our net loss for the period of $16.8 million, and was also affected by changes in operating assets and liabilities, including a decrease in accounts payable and accrued liabilities of $0.8 million and non-cash depreciation and amortization and stock-based compensation expense of $1.3 million.

Cash Used in Investing Activities

Cash used in investing activities was $32.6 million for the six months ended June 30, 2018, primarily related to the net purchase of investments of $30.2 million, and purchases of property and equipment of $2.4 million.

Cash used in investing activities was $19.7 million for the six months ended June 30, 2017, primarily related to the net purchase of investments of $15.3 million and purchases of property and equipment of $4.4 million.

Cash Provided by Financing Activities

Cash provided by financing activities was $128.3 million for the six months ended June 30, 2018, which consisted primarily of net proceeds of $125.1 million from our IPO (approximately $0.4 million of IPO costs were paid in 2017) and net proceeds of $3.3 million from the exercise of our common stock options.

Cash provided by financing activities was $0.6 million for the six months ended June 30, 2017, which consisted primarily of net proceeds of $0.6 million from the exercise of our common stock options.

Contractual Obligations and Commitments

There have been no material changes outside the ordinary course of business to our contractual obligations during the three and six month periods ended June 30, 2018, as compared to those disclosed in our Prospectus.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 (the JOBS Act), permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to elect the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (1) the las t day of our first fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, w hich means the market value of our common stock that is held by non-affiliates exceeds $700.0 million of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year peri od.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (Exchange Act) reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the six-month period ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFO RMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Risks Related to our Limited Operating History, Financial Position and Capital Requirements

We are an early-stage immuno-oncology company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.

We are an early-stage immuno-oncology company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations have been limited to organizing and staffing our company, business planning, raising capital, identifying potential product candidates, establishing licensing arrangements and/or acquiring any necessary technology, and undertaking research and preclinical studies and clinical trials of our product candidates. All of our product candidates are in early development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the three and six month periods ended June 30, 2018, our net losses were $13.5 million and $26.5 million, respectively, and $9.6 million and $16.7 million for the three and six month periods ended June 30, 2017, respectively. As of June 30, 2018, we had an accumulated deficit of $99.7 million. We expect that it will be several years, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

To become and remain profitable, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that are significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2018, we had $277.5 million in cash and investments, which included $265.7 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund the clinical development of AB928 and AB122, including cohort expansion studies, into at least the fourth quarter of 2020, but not through regulatory approval. Accordingly, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the timing and amount of milestone payments we receive from Taiho Pharmaceuticals Co., Ltd. (Taiho) under our option and license agreement (the Taiho Agreement);
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval. In addition, our product candidates, if approved, may not achieve product sales or commercial success. We do not expect to have any products commercially available for sale for many years, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or fi nancial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectati ons of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, 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 funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Discovery and Development of our Product Candidates

Our product candidates are in the early stages of development. We only recently began clinical trials to test some of our product candidates in humans and, as a company, we have limited experience in this area.

We are early in our development efforts and our operations to date have been limited to drug discovery, preclinical studies and early-stage clinical trials. Our two lead product candidates entered Phase 1 clinical trials in November 2017 and we expect to have a total of four product candidates in Phase 1 clinical trials by the end of 2018. While our clinical trials to date have been conducted outside the United States, we are initiating several trials in the United States. As a result, we will need to expand our clinical operations, quality and regulatory capabilities to support these activities.

Our interactions with the FDA have been limited to the initiation of our Phase 1/1b program. Because of these limited interactions, we may subsequently learn of certain information or data that the FDA may request, which may necessitate conducting additional preclinical studies or generating such information at significant time and expense, including under a clinical hold imposed on an investigational new drug application (IND). Even if we conducted the additional studies or generated the additional information requested, the FDA could disagree that we have satisfied their requirements, all of which will cause significant delays to our programs.

In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on our ability to successfully complete the above activities and any other activities required for the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will further depend on factors such as:

- successful completion of preclinical studies;
- approval of IND or other regulatory applications for our planned clinical trials or future clinical trials;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing manufacturing capabilities or arrangements with third party manufacturers for clinical supply and, if and when approved, for commercial supply;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- developing and implementing marketing and reimbursement strategies;
- obtaining and maintaining third party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- maintaining a continued acceptable safety profile of any product following approval.

If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs and biological products is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain.

The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. Clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. In particular, results from uncontrolled trials, meaning there is no control group such as a placebo group, are inherently difficult to interpret. Clinical trials evaluating two or more investigational product candidates that have not yet been approved can compound these difficulties. As a key element of our strategy is the development of intra-portfolio combinations, many of our clinical trials will test more than one investigational product candidates in uncontrolled studies, such as the clinical trials in our Phase 1/1b program for AB928 where we are evaluating AB928 in combination with AB122, and the Phase 1 trial for AB154 which will evaluate AB154 in combination with AB122. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

We currently have three product candidates in clinical development and their risk of failure is high. We are unable to predict if these product candidates or any of our future product candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired.

A key element of our strategy is th e development of intra-portfolio combinations. If we are not successful in discovering, developing and commercializing product candidates that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of single agent s or other combination therapies, our ability to achieve our strategic objectives would be impaired.

A key element of our strategy is to build a broad portfolio of product candidates that will allow for the development of intra-portfolio combinations. We believe that by developing or licensing these product candidates, we can control the combinations we pursue and, if and when approved, maximize the commercial potential of these combinations.

However, these combinations have not been tested before and may fail to demonstrate synergistic activity against immunological targets, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of the product candidates when used as monotherapy, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. In addition, it may be difficult to interpret the results of any uncontrolled trials we conduct with our intra-portfolio combinations, such as the clinical trials in our Phase 1/1b program for AB928 where we are evaluating AB928 in combination with AB122, and the Phase 1 trial for AB154 which will evaluate AB154 in combination with AB122.

We expect that our anti-PD-1 antibody, AB122, will form the backbone of many of our intra-portfolio combinations. In the event that AB122, which is currently in a Phase 1 trial, were to fail to demonstrate sufficient safety and efficacy, we would need to identify alternatives for accessing an anti-PD-1 antibody. In the event we are unable to do so, or are unable to do so on commercially reasonable terms, our business and prospects would be materially harmed. All of our product candidates are targeting mechanisms that other companies are pursuing as either monotherapy or combination products. As such, even if we are successful in developing combination therapies, competition from other product candidates in the same class which are either already approved or further along in development than ours may prevent us from realizing the commercial potential of our combination therapies and prevent us from achieving our strategic objectives.

Our intra-portfolio combination strategy relies on discovering, developing and commercializing highly differentiated small molecules. If we are not able to differentiate our small molecules from other products which are approved or in development, our business prospects would be materially adversely affected.

Our combination therapy strategy relies on discovering and developing differentiated small molecules with ideal pharmacologic properties for the targeted pathway to complement our antibody product candidates, which we believe will form the backbone of our combination therapies. We conduct in our laboratories those activities that we consider to be critical for creating a development candidate with optimal properties. These activities include medicinal chemistry, assay development, assessment of compound potency and selectivity, *in vitro* and *in vivo* pharmacokinetic profile evaluation, *in vivo* pharmacology and exploratory safety evaluation, among others. As such, we have invested heavily in these internal capabilities and over 80% of our current workforce is dedicated to research and development. If the small molecules that we discover and design do not have ideal pharmacologic properties, or are not differentiated from other product candidates in development, either through their efficacy or toxicity profile, our product development activities, business and prospects would be materially harmed.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

To date, we have only tested AB928 and AB122 in a limited number of oncology subjects. As we continue our development of these product candidates and initiate clinical trials of our additional product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our product candidates initially show promise in these early clinical trials, the side effects of drugs are frequently only detectable after they are tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occ urrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties investigating the same product candidates as us in different territories, which could adversely affect our development program.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties investigating the same product candidates as us in different territories. For example, we and Harbin Gloria Pharmaceuticals Co. Ltd. (Gloria Pharmaceuticals) each licensed our rights to the same anti-PD-1 antibody (which we refer to as AB122) from WuXi Biologics (Cayman) Inc. (WuXi Biologics). Gloria Pharmaceuticals refers to this antibody as GLS-010 and is conducting clinical trials with GLS-010 in China. We have no control over their clinical trials or development program, and lack of efficacy, adverse events or undesirable side effects experienced by subjects in their clinical trials could adversely affect our development of AB122 or even the viability of AB122 as a product candidate. We may be required to report Gloria Pharmaceuticals' adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of AB122. We may face similar risks if Taiho exercises its option to license development rights to any of our programs under the Taiho Agreement.

Enrollment and retention of subjects in clinical trials is expensive and time consuming, can be made more difficult or rendered impossible by competing treatments or clinical trials of competing product candidates in the same or other indications, and could result in significant delays and additional costs in our product development activities, or in the failure of such activities.

We may encounter delays in enrolling, or be unable to enroll and maintain, a sufficient number of subjects to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size of the patient population required for analysis of the trial's primary endpoints, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the product candidate, the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication, the proximity of subjects to clinical trial sites, the eligibility criteria for the clinical trial and our ability to obtain and maintain subject consents.

For example, enrollment of oncology subjects in our AB122 clinical trial may be hampered by nivolumab from Bristol-Myers Squibb and pembrolizumab from Merck, both of which are approved and on the market. Subjects may opt to be treated with an approved product with substantially more safety and efficacy data than is currently available for our anti-PD-1 antibody product candidate. Bristol-Myers Squibb and Merck may also be conducting clinical trials of these products in additional indications, and some of those clinical sites may also participate in our clinical trials, which could reduce the number of subjects available for our clinical trials at those sites.

Furthermore, any negative results that we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same product candidate. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Failures in planned subject enrollment or retention may result in increased costs or program delays and could render further development impossible.

Certain of our product candidates may require companion diagnostics in certain indications. Failure t o successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our product candidates.

Certain of our product candidates may require companion diagnostics to identify appropriate patients for those product candidates in certain indications. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization. We may rely on third parties for the design, development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory authorization, and the commercial supply of these companion diagnostics. If these parties are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected and we may not be able to obtain marketing authorization for these product candidates. Furthermore, our ability to market and sell, as well as the commercial success, of any of our product candidates that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization for a companion diagnostic and supply such companion diagnostic will harm our business, results of operations and financial condition.

The design or our execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing 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 with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. Furthermore, results from uncontrolled trials, meaning there is no control group such as a placebo group, are inherently difficult to interpret, especially where the clinical trial is evaluating two or more investigational product candidates that have not yet been approved. As a key element of our strategy is the development of intra-portfolio combinations, many of our clinical trials will test more than one investigational product candidates in uncontrolled studies, such as the clinical trials in our Phase 1/1b program for AB928 where we are evaluating AB928 in combination with AB122, and the Phase 1 trial for AB154 which will evaluate AB154 in combination with AB122. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing 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 registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or 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 or registrational clinical trial that has the potential to result in FDA or other comparable foreign regulatory authorities' 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 comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

To date, our clinical trials have been conducted outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

To date, our clinical trials have been conducted outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. 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. In general, 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. We cannot assure you that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from such clinical trials, 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 our product candidates.

We may expe nd 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 must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other 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 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 also 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 to such product candidate.

Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials in the United States for our product candidates, we must submit the results of preclinical testing to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls (CMC) and our proposed clinical trial protocol, as part of an IND. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- any interruptions or delays in the supply of our product candidates for our clinical trials;
- a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process or product specifications that may be necessary or desired;
- any failure or delay in reaching an agreement with contract research organizations (CROs) and clinical trial sites;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- one or more Institutional Review Boards (IRBs) refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- changes in regulatory requirements and policies, which may require us to amend clinical trial protocols to comply with these changes and resubmit our clinical trial protocols to IRBs for reexamination.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize the commercial prospects of our product candidates and our ability to commence product sales and generate revenue.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our product candidates will harm our commercial prospects and our ability to generate revenue.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

If we do not achieve our product development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and as a result our share price may decline.

Drug development is inherently risky and uncertain. We cannot be certain that we will be able to:

- complete IND-enabling preclinical studies or develop manufacturing processes and associated analytical methods that meet cGMP requirements in time to initiate clinical trials in the timeframes we announce;
- obtain sufficient clinical supply of our product candidates to support our ongoing or planned clinical trials;
- initiate our clinical trials within the timeframes we announce;
- enroll and maintain a sufficient number of subjects to complete any of our clinical trials; or
- analyze the data collected from any completed clinical trials in the timeframes we announce.

The actual timing of our development milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. If we are unable to achieve our goals within the timeframes we announce, the commercialization of our product candidates may be delayed and, as a result, the stock price of our common stock could fall and you may lose all of your investment.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. Most of our product candidates currently target mechanisms for which there are no currently approved products. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our medicines for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our ongoing Phase 1 clinical trials and any future clinical trials of our product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, Australian Therapeutic Goods Administration and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We contract with third parties for the manufacturing and supply of product candidates for use in preclinical testing and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary

documentation in support of a New Drug Application (NDA) or Biologics Licensing Application (BLA) on a timely basis and must adhere to the FDA's Good Laboratory Practi ce regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third-party contractor manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract m anufacturing partners for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of an existing or future collaborator, including option exercises by Taiho under the Taiho Agreement;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from conducting clinical trials and developing our product candidates.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

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

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as the product candidate's specifications, manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality 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 to commercialize our product candidates and generate revenue.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing 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 its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While the processes to implement the BPCIA have not yet been fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

AB122 and AB154 are biological products and we may develop additional biological products in the future. We believe that any of our current and future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive marketing approval, we may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

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

Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including n on-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, 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.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our medicines on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties, and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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 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 ability to realize the full market potential of our products will be harmed.

Risks Related to our In-Licenses and Other Strategic Agreements

We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these product candidates or both, which would adversely affect our business and prospects.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement and any other product candidates being developed or tested in combination. For example, we intend to test many of our small-molecule product candidates with AB122, which we in-licensed from WuXi Biologics. In the event we breach our license agreement with WuXi Biologics, and WuXi Biologics terminates our license agreement, we would be unable to test those combinations, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

In addition, the agreements under which we license intellectual property or technology to or from third parties are c omplex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellect ual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. M oreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected pro duct candidates.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research program or product candidate and our business, financial condition, results of operations and prospects could suffer.

We may not realize the benefits of any acquisitions, in-license or other collaborations or strategic alliances that we enter into.

We have entered into in-license agreements with multiple licensors and an option agreement to out-license certain of our product candidates in select markets and in the future may seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into collaboration agreements, strategic partnerships or license our products, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement. For example, the Taiho Agreement provides us with non-dilutive capital to fund our operations and a strategic development and commercialization partner for our product candidates in Japan and certain other territories in Asia (excluding China). If Taiho does not exercise its option to a development program, our capital requirements relating to such development program will significantly increase and we may need to seek a new partner in order to develop and commercialize our product candidates from such program in the territories optioned by Taiho. Failure to realize the benefits of any collaborations or strategic alliances may further cause us to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any planned 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 will 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 collaborations 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 and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization pl ans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We have entered into an option and license agreement with Taiho for the potential development and commercialization of our product candidates in Japan and certain other territories in Asia (excluding China). We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates in other countries or territories of the world. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the 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 or other rights, 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 collaborator 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. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations 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 collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Managing our obligations under our in-license agreements and our option agreement may divert management time and attention, causing delays or disruptions to our business.

We have entered into and may in the future enter into in-license agreements with multiple licensors and a strategic option agreement, which subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities.

Our in-license and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives.

Our operating activities may be res tricted by certain covenants in our license and other strategic agreements, which could limit our development and commercial opportunities.

In connection with certain of our acquisitions, in-license or other collaborations or strategic alliances, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to our in-license of anti-PD-1 antibodies from WuXi Biologics, we made certain covenants to not commercialize any anti-PD-1 antibody licensed or obtained by us after the date of the license agreement with WuXi Biologics other than anti-PD-1 antibodies licensed from WuXi Biologics, subject to certain exceptions as set forth in our license agreement with WuXi Biologics. Furthermore, we agreed in our license agreement that WuXi Biologics would be our exclusive manufacturer of anti-PD-1 antibodies licensed thereunder until a certain number of years has elapsed following commercialization of such an anti-PD-1 antibody and that we would utilize WuXi Biologics as our exclusive provider of CMC development services for our biologic product candidates for three years from the date of our license agreement, subject to certain exceptions in each case. These exclusivity provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other anti-PD-1 antibody product candidates and may materially harm our business, financial condition, results of operations and prospects.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued which protect our product candidates or their intended uses or which effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

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, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We have pending U.S. and foreign patent applications in our portfolio, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors,
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the U.S. Patent and Trademark Office (USPTO) or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- 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 not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. For example, we are aware of certain patents owned or exclusively licensed by Bristol-Myers Squibb (BMS) having claims directed broadly to treating cancer with anti-PD-1 antibodies (the BMS Patents), which expire in 2023 and 2024. The BMS Patents are currently the subject of litigation between BMS and several other parties. If the validity of the BMS Patents is upheld following all such challenges, and if we receive regulatory approval for AB122 prior to expiration of the BMS Patents, then we may need to delay our commercialization of AB122 or we may need to obtain a license from BMS, which license may not be available on commercially reasonable terms, or at all. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur

substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fee s if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we ha ve misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 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 a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using techn ologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our busin ess, results of operations and financial condition.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, 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. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, 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. In addition, certain developing countries, including China and India, 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 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.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act 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 a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application in clude, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our p roduct candidates, our competitive position would be adversely affected.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them 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 other third party, our competitive position would be harmed.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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. Such an outcome could have a material adverse effect on our business. 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 terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, 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. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to our Business Operations

We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President.

We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President. Although we have entered into employment agreements with them, they are not for a specific term and each of them may terminate their employment with us at any time, thou gh we are not aware of any present intention of either of these individuals to leave us. We maintain "key person" insurance on each of them, but not for any of our other executives or employees.

Drs. Rosen and Jaen have significant experience identifying and developing biopharmaceuticals. Drs. Rosen and Jaen were previously the founders of Flexus Biosciences, Inc., which was acquired by Bristol-Myers Squibb approximately 18 months after it was founded to access its IDO-1 enzyme inhibitor. Previously, Dr. Rosen was Vice President of Therapeutic Discovery at Amgen, overseeing large and small-molecule drug discovery efforts, and Dr. Jaen was Senior Vice President, Drug Discovery and Chief Scientific Officer at ChemoCentryx, having built a track record of efficiently moving quality product candidates from discovery into clinical development across a wide range of therapeutic areas, including oncology. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. However, the historical results, past performance and/or acquisitions of companies with which they were affiliated, including Flexus, do not necessarily predict or guarantee similar results for our company.

Drs. Rosen and Jaen have certain other business and personal commitments outside of serving as the Chief Executive Officer and President of Arcus, including serving on the boards of other companies and foundations. Drs. Rosen and Jaen are defendants in an ongoing litigation with Incyte Corporation related to their previous company, Flexus Biosciences, Inc., alleging misappropriation of trade secrets, which litigation our founders believe has no merit. While such litigation involves no claims against our company, our founders may be required to focus time on the defense of such litigation, and any adverse developments in the litigation could affect our company's reputation.

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As we advance our research and development programs, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as monotherapy and in combination with other intra-portfolio product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of our product candidates. We cannot assure you that the services of such third party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our product candidates. To obtain marketing approval in many foreign countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Some of the other products in the same class as our product candidates have already been approved or are further along in development. With respect to our dual adenosine receptor antagonist, AB928, AdoRx has a program to discover and develop a dual adenosine receptor antagonist, and we are aware of other companies that are developing selective adenosine receptor anta gonists, including AstraZeneca/MedImmune, Corvus, iTEOS and Novartis. For our small-molecule CD73 inhibitor, AB680, Peloton Therapeutics has a program to discover and develop a small-molecule against this same target, and Exscientia and Evotec have partner ed to discover and develop bispecific small molecules that target both A $_{2a}$ R and CD73, as well as small molecules that only target A $_{2a}$ R or CD73. We are also aware of several pharmaceutical companies developing antibodies against this target, including Astr aZeneca/MedImmune, Bristol-Myers Squibb, Corvus, Innate Pharma, Merck and Surface Oncology. Regarding our anti-PD-1 antibody, AB122, multiple large pharmaceutical companies have already received regulatory approvals for their anti-PD-1/PD-L1 antibodies, in cluding AstraZeneca, Bristol-Myers Squibb, Merck, Pfizer in partnership with Merck Kgaa, and Roche/Genentech, and there are also many other anti-PD-1 and anti-PD-L1 antibodies in clinical development. With respect to our anti-TIGIT antibody, AB154, we are aware of several pharmaceutical companies developing antibodies against this target, including Bristol-Myers Squibb, Compugen, Genentech, iTEOS, Merck, OncoMed, and Potenza in partnership with Astellas. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candid ates in those class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercia lization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or r eimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Many of our competitors, such as large pharmaceutical and biotechnology companies like AstraZeneca/MedImmune, Bristol-Myers Squibb, Merck, Novartis and Roche/Genentech, have longer operating histories and significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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 subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

The development and commercialization of AB122 may face strong competition from other anti-PD-1 antibodies that have already received marketing approval by larger companies with substantial resources and more experience developing, manufacturing and commercializing biologic compounds.

As discussed above, some companies, such as AstraZeneca, Bristol-Myers Squibb, Merck, Pfizer in partnership with Merck Kgaa and Roche/Genentech, have anti-PD-1/PD-L1 antibodies that are approved and on the market, and other companies are developing anti-PD-1/PD-L1 antibodies for various oncology indications that are further along in development than AB122. This competitive environment could limit our development opportunities for AB122 or compromise our ability to successfully enroll our ongoing and future clinical trials with AB122 by limiting the availability of clinical trial investigators, sites and/or subjects which could slow, delay or limit the progress of AB122's development. As a result of these or other problems and risks, we may never receive marketing approval for AB122, may not realize the full commercial potential of AB122 as monotherapy or in combination with our other product candidates, may never recoup our financial investment or may never generate significant value or revenue from this asset.

Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amount s of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service inter ruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrit y and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosur e of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our drug candidates could be delayed. While we have not experienced any such system failure, accident or sec urity breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product can didates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disru ptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or o ther intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of per sonal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mand atory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could pote ntially have an adverse effect on our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and main research facility are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

Unfavorable global economic and trade conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and global trade. To date, our clinical trials have been conducted outside of the United States, and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. In addition, proposed tariffs from President Trump have included a 25% tariff on raw ingredients for pharmaceuticals, such as the active pharmaceutical ingredient for our product candidates. Given our exclusive relationship with WuXi Biologics, located in China, for the manufacture of AB122 and AB154 and for biologics CMC development, these additional tariffs, if they were to be imposed, would have an adverse impact on our operating results and financial condition. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We conduct clinical development operations through our Australian wholly-owned subsidiary. If we do not effectively manage our operations in Australia, our business and results of operations may suffe r.

In September 2017, we formed a wholly-owned Australian subsidiary, Arcus Biosciences Australia Pty Ltd, to develop our product candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor any clinical trials we conduct in Australia nor the development of our product candidates in Australia.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses for the tax year ended December 31, 2017 and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused losses generated after December 31, 2017, under new tax legislation will not expire and may be carried forward indefinitely but will be only deductible to the extent of 80% of current year taxable income in any given year. In addition, both our current and our future unused losses may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. As a result, if we earn net taxable income our pre-2018 net operating loss carryforwards may expire prior to being used, our net operating loss carryforwards generated in 2018 and thereafter will be subject to a percentage limitation and, if we undergo an ownership change, our ability to use all of our pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

U.S. federal income tax reform could adversely affect us.

In December 2017, new legislation significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. We do not expect this tax legislation to have a material impact to our current projection of minimal cash taxes for the near future. However, we continue to examine the impact that this tax legislation may have on our business in the longer term. Accordingly, notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax legislation on holders of our common stock is also uncertain and could be adverse. We urge prospective investors to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Related to Our Industry

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;

- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our industry is highly regulated by the FDA and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for any of our product candidates.

Securing FDA or comparable foreign regulatory approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. It takes years to complete the testing of a new drug or biologic and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

- any preclinical study or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical study or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the facilities that we utilize, or the processes or facilities of third party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and
- we may encounter delays or rejections based on changes in FDA policies or the policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or preven t marketing approval at any stage of the approval process. For example, results from uncontrolled trials, meaning there is no control group such as a placebo group, are inherently difficult to interpret and may be made more difficult where a clinical trial is evaluating two or more investigational product candidates that have not yet been approved. As a key element of our strategy is the development of intra-portfolio combinations, many of our clinical trials will test multiple investigational product candidates in uncontrolled studies, such as the clinical trials in our Phase 1/1b program for AB928 where we are evaluating AB928 in combination with AB122, and the Phase 1 trial for AB154 which will evaluate AB154 in combination with AB122. Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all.

Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant a ddditional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Once marketing approval has been granted by the FDA and comparable foreign regulatory authorities, the approved product and those entities within the product's supply chain are subject to continual review by the applicable regulatory authorities. Any marketing approval that we receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up trials or surveillance to monitor the safety and efficacy of the product. In addition, if the FDA and comparable foreign regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements with regard to labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, recordkeeping and submission of safety and other post-market information. Manufacturers of our products and manufacturers' facilities are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation.

Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and other comparable regulatory authorities and to comply with requirements concerning advertising and promotion for our products. If we, any future collaboration partner or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the collaboration partner, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

The FDA as well as other comparable regulatory authorities closely regulate the post-approval marketing and promotion of therapeutic products to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA and other comparable regulatory authorities also impose stringent restrictions on communications regarding off-label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing. If we, our product candidates or the manufacturing facilities for our product candidates are not found to be in compliance with regulatory requirements of the FDA and comparable foreign regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters or untitled letters;
- mandated modifications to promotional materials or the required provision of corrective information to healthcare practitioners;
- restrictions imposed on the product or its manufacturers or manufacturing processes;
- restrictions imposed on the labeling or marketing of the product;
- restrictions imposed on product distribution or use;
- requirements for post-marketing clinical trials;
- suspension of any ongoing clinical trials;
- suspension of or withdrawal of marketing approval;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements;
- seizure or detention of our products;
- refusal to permit the import or export of our products;
- required entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- civil or criminal penalties; or
- injunctions.

Widely publicized events concerning the safety risk of certain products ha ve resulted in their withdrawal from the market, revisions to product labeling that further limit use of the products and the imposition by the FDA of REMS to ensure that the benefits of the product outweigh its risks. In addition, because of the serious p ublic health risks of high profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly REMS programs.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. 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 in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, will not be permitted to market our future products and our business will suffer.

In the European Union, various penalties and sanctions exist in different EU Member States for non-compliance with the EU marketing authorization procedure. The European Commission may also impose financial penalties on the holders of marketing authorizations if they fail to comply with certain obligations in connection with the authorizations. If we or our potential collaborators fail to comply with applicable EU, or other foreign jurisdictions, regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws also apply to health-related and other personal information obtained outside of the United States. Regulation (EU) 2016/679 (General Data Protection Regulation), which began to apply to companies on May 25, 2018 directly in all EU Member States, replacing Directive 95/46/EC (EU Data Protection Directive) and each EU Member State's implementing legislation, imposes even stricter obligations on the use of health-related and other personal information. These requirements include the obligation to appoint data protection officers in certain circumstances, new rights for individuals to be "forgotten" and rights to data portability, the principal of accountability and the obligation to make public notification of significant data breaches. Under the General Data Protection Regulation, data protection authorities can also impose administrative fines of up to 4% of our total worldwide turnover or up to €20 million (whichever is higher). In addition, the General Data Protection Regulation only permits exports of personal data to countries outside of the European Economic Area (EEA), like the United States, if there is a suitable data transfer solution in place to safeguard personal data. Some of the approved current data transfer mechanisms are under review in the EU courts and by the European Commission, which adds to the complexity of transferring personal data outside of the EEA. The General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we will be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Changes in healthcare law and implementing re gulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (vi) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (vii) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (viii) created a licensure framework for follow on biologic products; and (ix) established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the Affordable Care Act. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the Affordable Care Act for plans sold through such marketplaces. Furthermore, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the Affordable Care Act. While Congress has not passed repeal legislation, the newly enacted federal income tax law includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal and replace elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which will first affect physician payment in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over the manner in which dru g manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationshi p between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, in September 2 017, the California State Assembly approved SB17, which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16% over a two-ye ar period, and further requiring pharmaceutical companies to explain the reasons for such increase. Effective in 2016, Vermont passed a law requiring certain manufacturer identified by the state to justify their price increases.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. Also at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

We will be subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the False Claims Act (FCA) which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, providing consulting fees and other benefits to physicians to induce them to prescribe products, engaging in promotion for "off-label" uses, and submitting inflated best price information to the Medicaid Rebate Program;

- HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit progra m, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictit ious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by HITECH and its implementing regulations, which imposes privacy, security and breach reporting obligations with respect to 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. 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;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious con sequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws) prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous 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 in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Common Stock

The stock price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory, trade or legal developments in the United States and other countries, including changes in tariffs or other trade restrictions;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;

- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding c ommon stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. Of the 44,456,659 shares of our common stock outstanding as of June 30, 2018, a significant majority are currently restricted from resale as a result of market standoff and "lock-up" agreements. These shares will become available to be sold 181 days after the date of our initial public offering, which occurred in March 2018. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act), and various vesting agreements. Certain of our stockholders will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to market standoff and lockup agreements. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares can be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements.

Citigroup Global Markets Inc., Goldman Sachs & Co. LLC and Leerink Partners LLC may, in their discretion, permit our stockholders to sell shares prior to the expiration of the restrictive provisions contained in those lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively or in ways that increase the value of our share price.

We cannot specify with any certainty the particular uses of the net proceeds that we received from our initial public offering, but we currently expect such uses will include advancing our clinical product candidates into later-stage clinical trials and combination trials, advancing our research product candidates into clinical development, supporting our ongoing drug discovery efforts and supporting our growing infrastructure and needs in operating as a public company. We have broad discretion in the application of the net proceeds, including working capital and other general corporate purposes, and you and other stockholders may disagree with how we spend or invest these proceeds. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest the net proceeds from our initial public offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. To date, only a few securities analysts have published research on our company and if they were to downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts were to cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), or the other rules and regulations of the Securities and Exchange Commission (SEC) or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the New York Stock Exchange. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2019, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recently Adopted Accounting Standards" in our registration statement on Form S-1 which was declared effective on March 14, 2018.

In particular, in May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition* . The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. As an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act with respect to ASU 2014-09, which will result in ASU 2014-09 becoming applicable to us on January 1, 2019.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act) and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Based upon shares outstanding as of June 30, 2018, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 57.0% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 $2/3$ % of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affe ct the price of our common stock and limit opportunities for you to realize value in a corporate transaction. For information regarding these and other provisions, see "Description of Capital Stock."

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 2. Unre gistered Sales of Equity Securities and Use of Proceeds.

On March 14, 2018, our Registration Statements on Form S-1 (File Nos. 333-223086 and 333-223670) were declared effective by the SEC for our initial public offering of common stock, pursuant to which we sold an aggregate of 9,200,000 shares of our common stock at an initial public offering price of $15.00 per share. There has been no material change in the planned use of proceeds from our initial public offering as described in our Prospectus.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

None

Item 5. Other Information.

None

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	10-Q	001-38419	3.1	May 9, 2018
3.2	Amended and Restated Bylaws	10-Q	001-38419	3.2	May 9, 2018
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

† This certification is deemed not filed for purposes of section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

Company Name

Date: August 6, 2018

By: /s/ Terry Rosen

Terry Rosen, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 6, 2018

By: /s/ Jennifer Jarrett

Jennifer Jarrett
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terry Rosen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcus Biosciences, 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 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)) 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) 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

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

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

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

Date: August 6, 2018

By: /s/ Terry Rosen

Terry Rosen, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jennifer Jarrett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcus Biosciences, 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 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)) 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) 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

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

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

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

Date: August 6, 2018

By: /s/ Jennifer Jarrett

Jennifer Jarrett
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 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 result of operations of the Company.

Date: August 6, 2018

By: /s/ Terry Rosen

Terry Rosen, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, 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 result of operations of the Company.

Date: August 6, 2018

By: /s/ Jennifer Jarrett

Jennifer Jarrett
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)