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 September 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: 001-38682

KODIAK SCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**27-0476525** **(I.R.S. Employer Identification No.)**
2631 Hanover Street **Palo Alto, CA** **(Address of principal executive offices)**	**94304** **(Zip Code)**

Registrant's telephone number, including area code: (650) 281-0850

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

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

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

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

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

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

As of November 14, 2018, the registrant had 36,829,857 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. This Quarterly Report should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report. The statements contained in this Quarterly Report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the translation of our preclinical results and data and early clinical trial results into future clinical trials in humans;
- the number, size and design of clinical trials that regulatory authorities may require to obtain marketing approval, including whether our planned Phase 2 trial in wet AMD will be considered a pivotal trial by the U.S. Food and Drug Administration, or FDA;
- the timing or likelihood of regulatory filings and approvals;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- the success of competing products or platform technologies that are or may become available;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- existing regulations and regulatory developments in the United States and foreign countries;
- the expected potential benefits of strategic collaboration agreements and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- potential claims relating to our intellectual property and third-party intellectual property;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the pricing and reimbursement of our product candidates, if approved;
- our ability to attract and retain key managerial, scientific and medical personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of the proceeds from our initial public offering.

You should refer to the “Part II, Item 1A — Risk Factors” section of this Quarterly Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Quarterly Report and any documents that we reference in this Quarterly Report that we have filed with the Securities and Exchange Commission, or SEC, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Table of Contents

Item 1. Financial Statements (Unaudited).

Kodiak Sciences Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 11,590	$ 1,395
Prepaid expenses and other current assets	703	200
Total current assets	12,293	1,595
Restricted cash	140	140
Property and equipment, net	1,198	1,509
Deferred offering costs	3,484	—
Total assets	$ 17,115	$ 3,244
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,724	$ 3,356
Accrued and other current liabilities	3,659	5,802
Total current liabilities	5,383	9,158
Convertible notes (includes $18,487 and $7,937 at September 30, 2018 and December 31, 2017 due to related parties)	41,476	9,921
Redeemable convertible preferred stock warrant liability (includes $4,000 and $1,840 at September 30, 2018 and December 31, 2017 attributable to warrants held by related parties)	5,000	2,300
Derivative instrument (includes $2,467 at September 30, 2018 attributable to related parties)	8,517	—
Other liabilities	552	586
Total liabilities	60,928	21,965
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.0001 par value, 18,753,595 shares authorized at September 30, 2018 and December 31, 2017; 12,385,154 shares issued and outstanding at September 30, 2018 and December 31, 2017; liquidation value of $50,324 at September 30, 2018 and December 31, 2017	50,017	50,017
Stockholders' deficit:		
Common stock, $0.0001 par value, 28,500,000 shares authorized at September 30, 2018 and December 31, 2017; 8,011,734 shares issued and outstanding at September 30, 2018 and 7,936,434 shares issued and outstanding at December 31, 2017	1	1
Additional paid-in capital	2,273	584
Accumulated deficit	(96,104)	(69,323)
Total stockholders' deficit	(93,830)	(68,738)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 17,115	$ 3,244

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 4,709	$ 3,148	$ 11,942	$ 13,246
General and administrative	1,671	831	5,075	2,517
Total operating expenses	6,380	3,979	17,017	15,763
Loss from operations	(6,380)	(3,979)	(17,017)	(15,763)
Interest expense (includes $1,076 and $311 attributable to related parties for the three months ended September 30, 2018 and 2017 and $2,944 and $311 attributable to related parties for the nine months ended September 30, 2018 and 2017)	(1,982)	(395)	(5,329)	(407)
Other income (expense), net (includes $1,129 and $176 other expense attributable to related parties for the three months ended September 30, 2018 and 2017 and $2,714 and $176 other expense attributable to related parties for the nine months ended September 30, 2018 and 2017)	(2,090)	(209)	(4,435)	(196)
Net loss and comprehensive loss	$ (10,452)	$ (4,583)	$ (26,781)	$ (16,366)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.33)	$ (0.61)	$ (3.45)	$ (2.19)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,851,560	7,549,711	7,764,888	7,479,523

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (26,781)	$ (16,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	367	363
Non-cash interest expense and amortization of debt discount and issuance cost	5,295	392
Change in fair value of redeemable convertible preferred stock warrant liability	2,700	220
Change in fair value of derivative instrument	1,914	—
Stock-based compensation	1,549	207
Changes in assets and liabilities:		
Prepaid expense and other current assets	(503)	423
Accounts payable	(1,754)	2,015
Accrued and other current liabilities	(3,511)	(45)
Other liabilities	33	33
Net cash used in operating activities	(20,691)	(12,758)
Cash flows from investing activities		
Purchase of property and equipment	(56)	(159)
Net cash used in investing activities	(56)	(159)
Cash flows from financing activities		
Proceeds from issuance of convertible notes (includes $9,560 and $8,000 from related parties for the nine months ended September 30, 2018 and 2017)	33,000	10,000
Deferred offering costs	(1,815)	—
Debt issuance cost	(140)	(181)
Principal payments of capital lease	(81)	(70)
Proceeds from issuance of common stock	49	3
Principal payments of tenant improvement allowance payable	(71)	(65)
Net cash provided by financing activities	30,942	9,687
Net increase (decrease) in cash, cash equivalents and restricted cash	10,195	(3,230)
Cash, cash equivalents and restricted cash, at beginning of period	1,535	9,762
Cash, cash equivalents and restricted cash, at end of period	$ 11,730	$ 6,532
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position		
Cash and cash equivalents	$ 11,590	$ 6,392
Restricted cash	$ 140	$ 140
Cash, cash equivalents and restricted cash in statement of financial position	$ 11,730	$ 6,532
Supplemental cash flow information:		
Cash paid for interest	$ 14	$ 13
Supplemental disclosures of non-cash investing and financing information:		
Acquisition of equipment through capital lease	$ —	$ 73
Redeemable convertible preferred stock warrant issued in connection with convertible notes	$ —	$ 1,040
Issuance of derivative instrument related to convertible notes payable	$ 6,603	$ —
Unpaid deferred offering costs	$ 1,577	$ —
Deferred offering costs paid in restricted stock awards	$ 91	$ —

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

1. The Company

Kodiak Sciences Inc. (the "Company") is a clinical stage biopharmaceutical company specializing in novel therapeutics to treat high-prevalence ophthalmic diseases. The Company devotes substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturer and contract research organizations, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

The Company has incurred significant losses and negative cash flows from operations since inception and had an accumulated deficit of $96.1 million as of September 30, 2018. The Company believes that its cash and cash equivalents as of September 30, 2018 along with the net proceeds from its initial public offering ("IPO") will be sufficient for the Company to continue as a going concern for at least 12 months from the issuance date of these condensed consolidated financial statements for the period ended September 30, 2018.

Initial Public Offering

In October 2018, the Company sold and issued 9,000,000 shares of common stock at a price to the public of $10.00 per share for gross proceeds of $90.0 million. In November 2018, the Company sold and issued an additional 400,000 shares of common stock at $10.00 per share to the underwriters of the IPO following the partial exercise of their over-allotment option for gross proceeds of $4.0 million. The aggregate net proceeds to the Company from the IPO, inclusive of the partial over-allotment option exercise, were approximately $83.7 million after deducting underwriting discounts and commissions and other offering costs.

Upon the closing of the IPO, all convertible preferred shares then outstanding automatically converted into 12,385,154 shares of common stock, 500,000 redeemable convertible preferred stock warrants automatically converted into common stock warrants and 100,000 of such warrants were exercised immediately following the closing of the IPO. The 2017 convertible notes converted into 2,637,292 shares of common stock and the 2018 convertible notes converted into 4,295,677 shares of common stock upon closing of the IPO. In connection with the IPO, the Company amended and restated its certificate of incorporation and bylaws. The condensed consolidated financial statements as of September 30, 2018, including share and per share amounts, do not give effect to the IPO, as it closed subsequent to September 30, 2018.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2017 and notes thereto, included in the Company's final prospectus for the IPO filed with the SEC pursuant to Rule 424(b)(4) on October 5, 2018 ("final prospectus").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to present fairly the Company's financial position as of September 30, 2018, the results of its operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results for the year ending December 31, 2018, or for any future period.

The year-end condensed consolidated balance sheet data as of December 31, 2017 was derived from audited financial statements but does not include all disclosures required by U.S. GAAP.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and expenses during the reporting period. Such estimates include the valuation of redeemable convertible preferred stock warrant liability, derivative instruments, deferred tax assets, useful lives of property and equipment, and stock-based compensation. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

There were no changes to the Company's significant accounting policies, as described in the final prospectus, that have a material impact on these condensed consolidated financial statements.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB, under its ASC or other standard setting bodies, and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. The Company adopted this new guidance beginning January 1, 2018, on a prospective basis, which did not result in a material impact on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The amendments of this standard provide guidance on restricted cash disclosures and presentation in the statement of cash flows. This guidance is effective for interim and annual periods beginning after December 15, 2017. The Company adopted ASU 2016-18 effective January 1, 2018, which required the change in restricted cash to be included as part of the total change in cash and cash equivalents on the statement of cash flows. While restricted cash is still presented as a separate line item in the Company's balance sheet, it will no longer be presented as a separate item in the statements of cash flows. This did not result in a material impact on the Company's consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory*, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. ASU 2016-16 is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this new guidance beginning January 1, 2018, which did not result in a material impact on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which requires changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The amendments in this update are effective for interim and annual periods beginning after December 15, 2017. The Company adopted this new guidance beginning January 1, 2018, on a retrospective basis, which did not result in a material impact on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The updated guidance enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. The amendment to the standard is effective for financial statements issued for interim and annual periods beginning after December 15, 2017. The Company adopted this new guidance beginning January 1, 2018, on a retrospective basis, which did not result in a material impact on its consolidated financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurements*, which eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of the FASB's disclosure framework project. The standard is effective for interim and annual periods beginning after December 15, 2019. The standard specifies certain amendments which should be applied prospectively while all other amendments should be applied retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which the grantor acquires goods and services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. The transition method provided by ASU 2018-07 is a modified retrospective basis which recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The amendments in ASU 2018-07 are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This update simplifies the accounting for certain financial instruments with down round features, a provision in an equity-linked financial instrument (or embedded feature) that provides a downward adjustment of the current exercise price based on the price of future equity offerings. Down round features are common in warrants, preferred shares, and convertible debt instruments issued by private companies and early-stage public companies. This update requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The provisions of this update related to down rounds are effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The amendments in Part I should be applied (1) retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the statement of financial position as of the beginning of the first fiscal year and interim periods; (2) retrospectively to outstanding financial instruments with a down round feature for each prior reporting period presented. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. Topic 842 supersedes the previous leases standard, ASC 840 *Leases*. In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements*, and ASU 2018-11, *Leases (Topic 842), Targeted Improvements*. ASU 2018-10 clarifies certain provisions and correct unintended applications of the guidance such as the application of implicit rate, lessee reassessment of lease classification, and certain transition adjustments that

should be recognized to earnings rather than to stockholders' equity. ASU 2018-11 provides an alternative transition method and practical expedient for separating contract components for the adoption of Topic 842. ASU 2016-02, ASU 2018-10, and ASU 2018-11 (collectively, "the new lease standards") is effective for interim and annual periods beginning after December 15, 2018 and should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, and early adoption is permitted. The Company is currently evaluating the impact of the new lease standards on its consolidated financial statements and related disclosures; however, the Company anticipates recognizing assets and liabilities arising from any leases that meet the requirements under the new lease standards on the adoption date and including qualitative and quantitative disclosures in its consolidated financial statements.

3. Property and Equipment, net

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

	September 30, 2018	December 31, 2017
Leasehold improvement	$ 1,260	$ 1,260
Laboratory equipment	1,225	1,174
Computer equipment	52	52
Computer software	178	173
Furniture and fixtures	225	225
Office equipment	79	79
Total property and equipment	3,019	2,963
Less: Accumulated depreciation	(1,821)	(1,454)
Property and equipment, net	$ 1,198	$ 1,509

All long-lived assets are maintained in the United States. Depreciation expense, including depreciation of assets under capital leases, was $0.1 million and $0.1 million for the three months ended September 30, 2018 and 2017, respectively, and $0.4 million and $0.4 million for the nine months ended September 30, 2018 and 2017, respectively.

4. Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued salaries and benefits	$ 1,068	$ 1,129
Accrued legal fees	858	35
Accrued research and development	730	4,293
Accrued professional fees	704	19
Accrued other liabilities	299	326
Total accrued and other current liabilities	$ 3,659	$ 5,802

5. Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which 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.

The following tables present the Company's fair value hierarchy for assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2018			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 11,350	$ —	$ —	$ 11,350
Total	$ 11,350	$ —	$ —	$ 11,350
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ —	$ —	$ 5,000	$ 5,000
2018 derivative instrument	—	—	8,517	8,517
Total	$ —	$ —	$ 13,517	$ 13,517

	Fair Value Measurements at December 31, 2017			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 1,217	$ —	$ —	$ 1,217
Total	$ 1,217	$ —	$ —	$ 1,217
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ —	$ —	$ 2,300	$ 2,300
Total	$ —	$ —	$ 2,300	$ 2,300

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Redeemable Convertible Preferred Stock Warrant Liability	2018 Derivative Instrument Liability
Fair value as of December 31, 2017	$ 2,300	$ —
Issuance of financial instruments	—	6,603
Change in fair value included in other income (expense), net	2,700	1,914
Fair value as of September 30, 2018	$ 5,000	$ 8,517

The estimated fair value of the 2017 convertible notes (Level 3 instrument for disclosure purposes) was $26.4 million as of September 30, 2018 and $19.0 million as of December 31, 2017. The estimated fair value of the 2018 convertible notes (Level 3 instrument for disclosure purposes) was $43.0 million as of September 30, 2018.

The fair value of the redeemable convertible preferred stock warrants, 2017 and 2018 convertible notes and derivative instruments as of September 30, 2018 was inferred from the $10.00 per share of common stock from the IPO completed in October 2018. Upon the closing of the IPO, the redeemable convertible preferred stock warrants automatically converted into common stock warrants and the 2017 and 2018 convertible notes were converted into common stock. The estimated fair value of the 2017 derivative instrument was immaterial as of September 30, 2018, due to the probability of occurrence of the underlying events being remote. The estimated fair value of the 2018 derivative instrument considered the probability and timing of occurrence of the IPO and assumed a discount rate of 40%.

The Company used a hybrid method between the probability-weighted expected return method ("PWERM") and the Black-Scholes option pricing model ("OPM") to estimate the fair value of the warrants, 2017 and 2018 convertible notes and derivative instruments as of December 31, 2017. The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the Company, as well as the economic and control rights of each share class. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. The Company estimated the probability-weighted value across multiple scenarios, using the OPM to estimate the allocation of value within one of or more of those scenarios. In this valuation, the Company considered two possible outcomes under PWERM: (1) an IPO and (2) continued operations as a private company scenario, which is modeled using the OPM. For the IPO scenario, the fair value of the Company's common stock is consistent with the methods outlined in the Practice Aid. Estimates of fair value using valuation the OPM are affected by assumptions regarding a number of complex variables, including expected term, expected volatility, expected dividend, and risk-free interest rate. The Company considered as inputs to the PWERM the probability of occurrence of an IPO, the enterprise value and the discount rate, which is a blended rate that reflects the risk associated with the business during the forecasted period. At December 31, 2017, the fair values recognized for the warrants and the derivative instruments, and for disclosure purposes of the fair value of convertible notes, assumed a discount rate of 57.5%, volatility of 75%, a risk-free rate of 1.97%, no dividends expected to be paid, and an expected term based on the timing for the IPO scenario and the private scenario.

6. Convertible Notes

2017 Convertible Notes

In August 2017, the Company received $10.0 million in gross proceeds from the issuance of the 2017 convertible notes and warrants to purchase Series B redeemable convertible preferred stock (Note 11). Of this, $8.0 million aggregate principal amount of the 2017 convertible notes were issued to related parties. Interest on the unpaid principal balance of the 2017 convertible notes accrued and compounded monthly from October 1, 2017 at a rate of 2.5% per month and was payable at maturity. Unless converted or redeemed upon occurrence of certain events, the 2017 convertible notes were to mature on December 1, 2020. The 2017 convertible notes included embedded derivatives that were required to be bifurcated and accounted for separately as a single, compound derivative instrument (Note 12).

The discount on 2017 convertible notes was amortizable over the contractual period of 3.31 years, using the effective interest rate method. The 2017 convertible notes had an annual effective interest rate of 38.18% per year. The 2017 convertible notes interest expense for the three months ended September 30, 2018 was $1.0 million, consisting of $1.0 million of contractual interest expense and less than $0.1 million of debt discount and issuance costs amortization. The 2017 convertible notes interest expense for the nine months ended September 30, 2018 was $2.8 million, consisting of $2.7 million of contractual interest expense and $0.1 million of debt discount and issuance costs amortization.

The Company's obligations with respect to the 2017 convertible notes were secured by all of its tangible and intangible assets. The 2017 convertible notes included covenants that restricted the Company's ability to issue capital stock, repurchase or redeem capital stock, dispose of assets, incur debt, incur liens and make distributions to stockholders, including dividends. The 2017 convertible notes had customary events of default.

After January 31, 2018, each holder of 2017 convertible notes may have at any time, at its option, elected to convert the principal amount and accrued interest of such convertible notes into shares of Series B redeemable convertible preferred stock at a price of $5.00 per share. In September 2018, the purchase agreement for the 2017 convertible notes was amended and effective immediately prior to the closing of the Company's IPO. Following the amendment, the 2017 convertible notes were convertible into an equivalent number of shares of common stock in lieu of Series B redeemable convertible preferred stock and interest accrued from the initial public filing of a Registration Statement on Form S-1 on September 7, 2018 to immediately prior to the closing of the Company's IPO would be waived. The Company issued 2,637,292 shares of common stock to the holders of the 2017 convertible notes at the closing of the Company's IPO on October 9, 2018.

2018 Convertible Notes

In February 2018, the Company received $33.0 million in gross proceeds from the issuance of 2018 convertible notes, of which the Company issued $31.2 million aggregate principal amount on February 2, 2018 ("first tranche") and $1.8 million aggregate principal amount on February 23, 2018 ("second tranche"). Of this, $9.6 million were issued to related parties. Interest on the unpaid principal balance of the 2018 convertible notes accrued from the date of issuance and compounded monthly from February 28, 2018 at a rate of 6.0% per year and is payable at maturity. Unless converted, the 2018 convertible notes were to mature on the earlier of (1) December 1, 2020 and (2) the date of the consummation of a change of control. The 2018 convertible notes included embedded derivatives that are required to be bifurcated and accounted for separately as a single, compound derivative instrument (Note 12).

The discount on 2018 convertible notes for the first and second tranche was amortizable over the contractual period of 2.83 years and 2.77 years, respectively, using the effective interest rate method. The 2018 convertible notes had an annual effective interest rate of 15.10% per year for the first tranche and 15.45% per year for the second tranche. The 2018 convertible notes interest expense for the three months ended September 30, 2018 was $1.0 million, consisting of $0.5 million of contractual interest expense and $0.5 million of debt discount and issuance costs amortization. The 2018 convertible notes interest expense for the nine months ended September 30, 2018 was $2.5 million, consisting of $1.3 million of contractual interest expense and $1.2 million of debt discount and issuance costs amortization.

The Company's obligations with respect to the 2018 convertible notes were unsecured and subordinated to its obligations with respect to the 2017 convertible notes. The 2018 convertible notes included covenants that restricted the Company's ability to issue capital stock, repurchase or redeem capital stock, dispose of assets, incur debt, incur liens and make distributions to stockholders, including dividends. The 2018 convertible notes had customary events of default.

The 2017 and 2018 convertible notes contained a clause in which failure to communicate to the lender any material adverse change or effect on the business, condition, operations, or ability to perform obligations under the terms of the 2017 and 2018 notes was considered an event of default.

The 2018 convertible notes were automatically convertible into shares of the Company's common stock at a price equal to (1) 80% of the initial price to public in a qualified initial public offering if such offering was completed prior to February 2, 2019 and (2) 75% of the initial price to public in a qualified initial public offering if such offering was completed on or after February 2, 2019. A qualified initial public offering for the purposes of the 2018 convertible notes was one in which the Company generated aggregate gross proceeds of at least $75.0 million or all of the 2017 convertible notes converted into shares of the Company's common stock. The Company issued 4,295,677 shares of common stock to the holders of the 2018 convertible notes at the closing of the Company's IPO on October 9, 2018.

7. Commitments and Contingencies

Leases

In January 2013, the Company executed a non-cancellable lease agreement for office and laboratory space in Palo Alto, California. The lease began in October 2013 and would expire in October 2018. In March 2016, the Company executed a lease amendment agreement which was effective March 2016 and extended the lease term until October 2023.

The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense was $0.1 million and $0.1 million for the three months ended September 30, 2018 and 2017, respectively, and $0.4 million and $0.4 million for the nine months ended September 30, 2018 and 2017, respectively.

The following table summarizes the Company's future minimum commitments under non-cancelable contracts (in thousands):

As of September 30, 2018:	**Operating Lease**
Remaining Fiscal 2018	$ 138
2019	564
2020	581
2021	598
2022	616
Thereafter	526
Total payments	$ 3,023

Other Commitments; Contingencies

The Company has entered into service agreements with Lonza AG and its affiliates ("Lonza"), pursuant to which Lonza agreed to perform activities in connection with the manufacturing process of certain compounds. Such agreements, and related amendments, state that planned activities that are included in the signed work orders are, in some cases, binding and, hence, obligate the Company to pay the full price of the work order upon satisfactory delivery of products and services. Per the terms of the agreements, the Company has the option to cancel signed orders at any time upon written notice, which may or may not be subject to payment of a cancellation fee. The level of cancellation fees is sometimes dependent on the timing of the written notice in relation to the commencement date of the work, with the maximum cancellation fee equal to the full price of the work order. As of September 30, 2018, the total amount of unconditional purchase obligations, including accrued amounts, under these agreements was $2.9 million. Purchases under this agreement for the nine months ended September 30, 2018 and 2017 were $2.1 million and $8.5 million, respectively. As of September 30, 2018, the Company had not incurred any cancellation fees for the work performed by Lonza.

The Company is also party to a cancellable assignment and license agreement that would require the Company to make milestone payments of up to $33.2 million and royalty payments on net sales of products utilizing KSI-201 and related technology. Such milestones and royalties are dependent on future activity or product sales and are not estimable.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. Management is currently not aware of any matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows. The Company records a legal liability when it believes that it is both probable that a liability may be imputed, and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount.

Indemnification

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements; however, the Company has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

8. Redeemable Convertible Preferred Stock

As of September 30, 2018 and December 31, 2017, the Company's certificate of incorporation authorized the Company to issue up to 18,753,595 shares of redeemable convertible preferred stock.

As of September 30, 2018 and December 31, 2017, redeemable convertible preferred stock consisted of the following (in thousands, except per share and share amounts):

	Redeemable Convertible Preferred Stock		Liquidation Value	Carrying Value	Original Issuance Price (1)
	Authorized	Outstanding			
Series A redeemable convertible preferred stock	6,253,595	5,593,154	$ 16,364	$ 16,283	$ 3.17
Series B redeemable convertible preferred stock	12,500,000	6,792,000	33,960	33,734	$ 5.00
Total	18,753,595	12,385,154	$ 50,324	$ 50,017	

(1) In connection with the incorporation of the Company in the year ended December 31, 2015, all previously issued and outstanding Series A-1, Series B-1 and Series C-1 redeemable convertible preferred stock of Oligasis were converted into shares of the Company's Series A redeemable convertible preferred stock at a par value of $0.0001 per share. The original issuance price of Series A redeemable convertible preferred stock is calculated based on the original issuance price of the Oligasis' Series A-1, Series B-1 and Series C-1 redeemable convertible preferred stock of $1.34, $2.15, and $3.73, respectively, on a weighted-average basis.

On October 9, 2018, upon the closing of the Company's IPO, all outstanding redeemable convertible preferred stock automatically converted into shares of common stock. Prior to the closing of the Company's IPO, the holders of redeemable convertible preferred stock had the following various rights and preferences:

Liquidation Preference

In the event of any liquidation event, the holders of the Series B redeemable convertible preferred stock are entitled to receive in any distribution of any of the assets of the Company in preference to the holders of the Series A redeemable convertible preferred stock or common stock, an amount equal to the original issue price, adjusted for any stock splits, stock dividends, recapitalizations, reclassifications, combinations or similar transactions (collectively, "anti-dilution adjustments"), plus all declared and unpaid dividends on such shares. After full payment to holders of the Series B redeemable convertible preferred stock, payment should be made to the holders of Series A redeemable convertible preferred stock, in preference to the holders of the common stock, an amount equal to the original issue price, adjusted for any anti-dilution adjustments, plus all declared and unpaid dividends on such shares. After the payment of the liquidation preference, all remaining assets available for distribution will be distributed ratably among the holders of the common stock. If available assets are insufficient to pay the full liquidation preference of a given series of redeemable convertible preferred stock, the assets available for distribution to holders of such preferred stock will be distributed among such holders on a pro rata basis.

Notwithstanding the above, for purposes of determining the amount each holder of shares of redeemable convertible preferred stock is entitled to receive with respect to a liquidation event, each such holder of shares of a series of redeemable convertible preferred stock shall be deemed to have converted such holder's shares of such series into shares of common stock immediately prior to the liquidation event if, as a result of an actual conversion, such holder would receive, in the aggregate, an amount greater than the amount that would be distributed to such holder if such holder did not convert such series of redeemable convertible preferred stock into shares of common stock. If any such holder shall be deemed to have converted shares of redeemable convertible preferred stock into common stock pursuant to this paragraph, then such holder shall not be entitled to receive any distribution that would otherwise be made to holders of redeemable convertible preferred stock that have not converted into shares of common stock.

Conversion

Shares of any series of redeemable convertible preferred stock can be converted, at the option of the stockholder, into such number of fully paid and non-assessable shares of common stock. The conversion price is determined by dividing the original issuance price applicable to each series of redeemable convertible preferred stock, adjusted for any anti-dilution adjustments, by the applicable conversion price for such series. As of September 30, 2018, the Company's redeemable convertible preferred stock is convertible into the Company's shares of common stock on a one-for-one basis.

Shares of redeemable convertible preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate for such share, upon earlier to occur of: (1) the date, or the occurrence of event, specified by the vote of or written consent of the holders of at least a majority of the redeemable convertible preferred stock voting together as a single class on an as-converted basis; and (2) immediately prior to the consummation of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act, covering the offer and sale of the Company's common stock, provided that the per share price is at least $10.00 and gross proceeds to the Company are equal to or greater than $75.0 million.

Dividends

The redeemable convertible preferred stock dividends are not cumulative and are payable only when declared by the board of directors. No such dividends have been declared. Such dividends are in preference to any dividends to holders of common stock.

Voting Rights

Each holder of redeemable convertible preferred stock shall be entitled to the number of votes equal to the number of shares of common stock into which the shares of redeemable convertible preferred stock held by such holder could be converted as of the record date. Holders of redeemable convertible preferred stock and common stock generally vote as a single class.

Redemption and Balance Sheet Classification

The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the stockholders upon the occurrence of certain deemed Liquidation Events that are considered not solely within the Company's control.

9. Common Stock

As of September 30, 2018 and December 31, 2017, the Company's certificate of incorporation authorized the Company to issue 28,500,000, shares of common stock at the par value of $0.0001 per share. The holder of each share of common stock is entitled to one vote per share. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding or reserved for issuance) by the affirmative vote of the holders of a majority (assuming the conversion of all redeemable convertible preferred stock into shares of the Company's common stock) of the capital stock of the Company entitled to vote and without a separate class vote of the common stock.

10. Stock-based Compensation

2015 Equity Incentive Plan

In September 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan") under which 2,810,513 shares of common stock were reserved for issuance through grants of incentive stock options ("ISOs"), nonqualified stock options ("NSOs") and restricted stock awards to employees, directors and consultants of the Company. The awards outstanding under the previously terminated 2009 Share Incentive Plan continued to be governed by their existing terms. Options under the Plans may be granted for periods of up to ten years and at prices based upon the estimated fair value of the shares on the date of grant as determined by the board of directors; provided, however, that (1) the exercise price of an option shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (2) the exercise price of an ISO granted to a greater than 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, and (3) the term of an ISO granted to a greater than 10% stockholder should not exceed five years. Options granted generally vest over four years. Shares issued under the 2015 Plan may, but need not, be exercisable immediately, but subject to a right of repurchase by the Company of any unvested shares.

Stock Options

Stock option activity under the 2015 Plan is summarized as follows (in thousands, except share and per share data).

		Outstanding Awards			
	Number of Shares Available for Grant	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2017	605,557	1,204,414	$ 0.98	8.49	$ 41
Shares authorized	2,125,000	—			
RSAs granted	(27,500)	—			
Options granted	(2,824,698)	2,824,698	$ 6.29		
Options exercised	—	(47,800)	$ 1.03		2
Options forfeited or canceled	185,000	(185,000)	$ 5.19		
Balance, September 30, 2018	63,359	3,796,312	$ 4.73	9.07	$ 21,117
Shares exercisable, September 30, 2018		1,632,095	$ 2.88	8.47	$ 12,094
Vested and expected to vest, September 30, 2018		3,796,312	$ 4.73	9.07	$ 21,117

During the nine months ended September 30, 2018 and 2017, the Company granted 2,429,698 and 107,500 stock options, respectively, to employees with a weighted-average grant date fair value of $3.46 and $0.62 per share, respectively.

The total fair value of employee options vested during the nine months ended September 30, 2018 and 2017 was $0.6 million and $0.2 million, respectively.

Fair Value of Options Granted

The fair value of the shares of common stock underlying the stock options was determined by the board of directors as there has been no historical public market for the Company's common stock prior to the IPO.

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected volatility	54%	N/A	55%	63%
Risk-free interest rate	2.76%	N/A	2.71%	1.89%
Dividend yield	0%	N/A	0%	0%
Expected term	6.07	N/A	5.99	6.00

Non-Employee Stock-Based Compensation

The Company granted 395,000 and 30,000 stock options to non-employees during the nine months ended September 30, 2018 and 2017, respectively.

The fair value of stock options granted to non-employees is calculated at each grant date and remeasured at each reporting date using the Black-Scholes option pricing model. The fair value of non-employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected volatility	58%	63%	56%	63%
Risk-free interest rate	3.01%	2.29%	2.68%	2.28%
Dividend yield	0%	0%	0%	0%
Expected term	9.39	9.64	9.11	9.63

Restricted Stock Awards

Restricted stock award (“RSAs”) activity is summarized as follows:

	Number of Shares Underlying Outstanding RSAs	Weighted Average Grant Date Fair Value
Unvested, December 31, 2017	291,633	$ 0.45
Granted	27,500	$ 5.38
Vested	210,959	$ 1.03
Unvested, September 30, 2018	108,174	$ 0.57

Stock-based compensation is classified in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 528	$ 43	$ 892	$ 129
General and administrative	272	26	600	78
Total stock-based compensation	$ 800	$ 69	$ 1,492	$ 207

As of September 30, 2018, the unrecognized stock-based compensation of unvested employee options and unvested RSAs was $8.2 million and it is expected to be recognized over a weighted-average period of 1.59 years.

11. Redeemable Convertible Preferred Stock Warrants

On August 11, 2017 with the issuance of the 2017 convertible notes (Note 6), the Company issued warrants to purchase 500,000 shares of Series B redeemable convertible preferred stock at an exercise price of $0.01 per share, including warrants issued to related parties to purchase an aggregate of 400,000 shares of Series B redeemable convertible preferred stock.

Upon the conversion of the Series B redeemable convertible preferred stock into shares of common stock, the outstanding warrants would convert into warrants to purchase 500,000 shares of common stock at an exercise price of $0.01 per share. The outstanding warrants terminate at the earlier of August 11, 2022 and a change of control unless exercised. These warrants have a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net number of shares based on the fair market value of the Company's stock at the time of exercise of the warrants after deduction of the aggregate exercise price. These warrants contain provisions for adjustment of the exercise price and number of shares issuable upon the exercise of warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.

The estimated fair value of the redeemable convertible preferred stock warrants on the date of issuance of $1.0 million was recorded as a debt discount. The redeemable convertible preferred stock warrant liability had a fair value of $5.0 million as of September 30, 2018 and $2.3 million as of December 31, 2017. The change in fair value was recorded in the condensed consolidated statements of operations and comprehensive loss.

As of September 30, 2018, all redeemable convertible preferred stock warrants remained outstanding. Upon the closing of the IPO, 500,000 redeemable convertible preferred stock warrants automatically converted into common stock warrants and 100,000 of such warrants were exercised immediately following the closing of the IPO.

12. Derivative Instruments

The redemption features of the 2017 convertible notes met the requirements for separate accounting and were accounted for as a single, compound derivative instrument. The 2017 derivative instrument is recorded at fair value, which was immaterial as of the issuance date, December 31, 2017 and September 30, 2018, due to the probability of occurrence of the underlying events being remote.

The redemption features of the 2018 convertible notes met the requirements for separate accounting and are accounted for as a single, compound derivative instrument. The 2018 derivative instrument was recorded at fair value, which was $6.6 million as of the issuance date and $8.5 million as of September 30, 2018.

13. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss attributable to common stockholders	$ (10,452)	$ (4,583)	$ (26,781)	$ (16,366)
Denominator:				
Weighted-average shares outstanding	7,980,457	7,933,130	7,954,583	7,931,606
Less: weighted-average unvested restricted shares and shares subject to repurchase	(128,897)	(383,419)	(189,695)	(452,083)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,851,560	7,549,711	7,764,888	7,479,523
Net loss per share attributable to common stockholders, basic and diluted	$ (1.33)	$ (0.61)	$ (3.45)	$ (2.19)

The following potentially dilutive securities, presented on an as-converted to common stock basis, were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive:

	As of September 30,	
	2018	**2017**
Redeemable convertible preferred stock	12,385,154	12,385,154
2017 convertible notes (1)	2,689,744	2,000,000
2018 convertible notes (2)	4,289,955	—
Series B redeemable convertible preferred stock warrants	500,000	500,000
Options to purchase common stock	3,796,312	1,229,212
Unvested restricted stock awards	108,174	356,062
Unvested early exercised common stock options	—	4,043
Total	23,769,339	16,474,471

(1) Calculated as $10.0 million in principal and $3.5 million in accrued but unpaid interest as of September 30, 2018 and $10.0 million in principal and no accrued but unpaid interest as of September 30, 2017, convertible at $5.00 per share of common stock.

(2) Calculated as $33.0 million in principal and $1.3 million in accrued but unpaid interest as of September 30, 2018, convertible at 80% of the $10.00 per share of common stock from the Company's IPO.

14. Related Party Transactions

Baker Bros. Advisors LP, which holds more than 5% of the Company's stock, purchased $6.6 million aggregate principal amount of 2018 convertible notes and $3.0 million aggregate principal amount of 2017 convertible notes and warrants to purchase an aggregate of 150,000 shares of the Company's Series B redeemable convertible preferred stock (see Note 6 and 11).

The Dustin Moskovitz Trust DTD 12/27/05, which holds more than 5% of the Company's stock, purchased $3.0 million aggregate principal amount of 2018 convertible notes and $5.0 million aggregate principal amount of 2017 convertible notes and warrants to purchase an aggregate of 250,000 shares of the Company's Series B redeemable convertible preferred stock (see Note 6 and 11).

15. Subsequent Events

The Company evaluated subsequent events that occurred after the balance sheet date up to the date on which the condensed consolidated financial statements were available for issuance.

2018 Equity Incentive Plan

The Company's board of directors approved the 2018 Equity Incentive Plan ("2018 Plan") in August 2018, which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. The 2018 Plan permits the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares. A total of 4,300,000 shares of common stock were initially reserved for issuance under the 2018 Plan. The 2018 Plan was approved by the Company stockholders after its adoption by the board of directors.

2018 Employee Share Purchase Plan

The Company's board of directors approved the 2018 Employee Share Purchase Plan ("ESPP") in August 2018, which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. A total of 460,000 shares of common stock were initially reserved for issuance under the ESPP. The ESPP was approved by the Company stockholders after its adoption by the board of directors.

Corporate Housing

In November 2018, the Company entered into an agreement with our CEO to lease his personal property, located 0.5 miles from Kodiak's Palo Alto facility, to the Company at fair market value to provide flexible corporate housing for relocating employees. Total expected lease payments under the agreement are $0.1 million.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our audited consolidated financial statements and related notes for the year ended December 31, 2017 included in our final prospectus for our initial public offering, or IPO, filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) on October 5, 2018. This discussion and other parts of this Quarterly Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risk, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth under the section of this Quarterly Report titled "Part II, Item 1A — Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Part II, Item 1A — Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases. Our most advanced product candidate is KSI-301, a biologic therapy built with our antibody biopolymer conjugate platform, or ABC platform, which is designed to maintain potent and effective drug levels in ocular tissues. We believe that KSI-301, if approved, has the potential to become an important anti-vascular endothelial growth factor, or anti-VEGF, therapy in wet age-related macular degeneration, or wet AMD, diabetic retinopathy, or DR, including diabetic macular edema, or DME, and other retinal vascular diseases. KSI-301 and our ABC Platform were developed at Kodiak, and we own worldwide rights to those assets, including composition of matter patent protection with respect to KSI-301. We have applied our ABC Platform to develop additional product candidates beyond KSI-301, including KSI-501, our bispecific anti-IL-6/VEGF bioconjugate. We intend to progress these and other product candidates to address high-prevalence ophthalmic diseases.

In July 2018, we commenced a Phase 1 dose escalation study in patients with diabetic macular edema. Dosing has been successfully completed in all patients in all pre-planned dose cohorts. KSI-301 was well tolerated with no drug-related adverse events and, notably, no intraocular inflammation observed in any patient to date. In addition, bioactivity of KSI-301 was demonstrated at all three dose levels tested.

We also expect to initiate an open-label, multiple-dose Phase 1b study of KSI-301 in the United States in patients with wet AMD, DME/DR, and retinal vein occlusion in the fourth quarter of 2018 and complete enrollment in 2019. We intend to present on-going data from the Phase 1b study at medical meetings in 2019.

Having successfully demonstrated early safety and tolerability in the Phase 1 study, with the additional observations around bioactivity, we plan to further evaluate the highest dose tested of KSI-301, 5 mg, in a series of Phase 2 studies in wet AMD and DME/DR.

We expect to be dosing patients in a global Phase 2 study of KSI-301 in wet AMD in early 2019. This study is intended to evaluate the non-inferiority of intravitreal KSI-301 dosed on an every 12-, 16- or even 20-week regimen compared to standard of care aflibercept dosed every 8 weeks. The FDA indicated that this study, if successful, can be supportive of a marketing application for KSI-301, and we are designing and intend to execute this Phase 2 study as a pivotal study, with an option for an administrative interim analysis in 2020. A primary data readout is anticipated in 2021.

We additionally plan to initiate two Phase 2 studies in China, one in wet AMD and one in DME/DR, and we are planning for these studies to have the same clinical design frameworks as our United States and European Union studies. We expect to hold our China pre-IND meeting for KSI-301 in 2019.

We plan to continue to use third-party contract research organizations, or CROs, to carry out our preclinical and clinical development. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We currently do not need commercial manufacturing capacity. We do not have any products approved for sale and have not generated any product revenue since inception.

Prior to the completion of our IPO in October 2018, we had funded our operations primarily with an aggregate of $94.4 million in gross cash proceeds from the sale and issuance of redeemable convertible preferred stock, convertible notes and warrants to purchase Series B redeemable convertible preferred stock.

In October 2018, we sold and issued 9,000,000 shares of common stock at a price to the public of $10.00 per share for gross proceeds of $90.0 million. In November 2018, we sold and issued an additional 400,000 shares of common stock at $10.00 per share to the underwriters of our IPO following the partial exercise of their over-allotment option for gross proceeds of $4.0 million. The aggregate net proceeds from our IPO, inclusive of the partial over-allotment option exercise, were approximately $83.7 million after deducting underwriting discounts and commissions and other offering costs.

Upon the closing of our IPO, all convertible preferred shares then outstanding automatically converted into 12,385,154 shares of common stock, 500,000 redeemable convertible preferred stock warrants automatically converted into common stock warrants and 100,000 of such warrants were exercised immediately following the closing of our IPO. The 2017 convertible notes converted into 2,637,292 shares of common stock and the 2018 convertible notes converted into 4,295,677 shares of common stock upon closing of our IPO.

Since inception in June 2009, we have devoted substantially all of our resources to discovering and developing product candidates and manufacturing processes, building our ABC Platform and assembling our core capabilities in drug development for ophthalmic disease.

We have incurred significant operating losses to date and expect that our operating losses will increase significantly as we advance our product candidates, particularly KSI-301, through preclinical and clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization; broaden and improve our platform; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. In addition, we expect to incur additional costs associated with operating as a public company. Our net losses were $26.8 million and $16.4 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $96.1 million.

Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of KSI-301 for wet AMD or DME/DR or delay our efforts to advance and expand our product pipeline.

As of September 30, 2018, we had cash and cash equivalents of $11.6 million. We believe that those cash and cash equivalents along with the net proceeds of $83.7 million from our IPO will be sufficient to fund our projected operations for at least the next 12 months.

Components of Operating Results

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our ABC Platform and product candidates. These expenses include certain payroll and personnel expenses, including stock-based compensation, for our research and product development employees; laboratory supplies and facility costs; consulting costs; contract manufacturing and fees paid to CROs to conduct certain research and development activities on our behalf; and allocated overhead, including rent, equipment, depreciation and utilities. We expense both internal and external research and development expenses as they are incurred. Costs of certain activities, such as manufacturing and preclinical and clinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We are focusing substantially all of our resources and development efforts on the development of our product candidates, in particular KSI-301. We expect our research and development expenses to increase substantially during the next few years, as we seek to initiate our Phase 2 studies, complete our clinical program, pursue regulatory approval of our drug candidates and prepare for a possible commercial launch. Predicting the timing or the final cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our drug candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including stock-based compensation; professional fees for legal, consulting, accounting and tax services; allocated overhead, including rent, equipment, depreciation and utilities; and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining

compliance with stock exchange listing and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Expense

Interest expense consists primarily of interest expense related to our convertible notes, including accretion of debt discount and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of warrants for Series B redeemable convertible preferred stock, changes in fair value of the derivative instruments and interest income.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		Change	
	2018	2017	Dollar	Percent
	(in thousands)			
Operating expenses:				
Research and development	$ 4,709	$ 3,148	$ 1,561	50%
General and administrative	1,671	831	840	101%
Loss from operations	6,380	3,979	2,401	60%
Interest expense (includes $1,076 and $311 attributable to related parties for the three months ended September 30, 2018 and 2017)	(1,982)	(395)	(1,587)	NM
Other income (expense), net (includes $1,129 and $176 other expense attributable to related parties for the three months ended September 30, 2018 and 2017)	(2,090)	(209)	(1,881)	NM
Net loss	$ 10,452	$ 4,583	$ 5,869	128%

* NM—not meaningful

Research and Development Expenses

Research and development expenses increased $1.6 million, or 50%, from the three months ended September 30, 2017 to the three months ended September 30, 2018.

The following table summarizes our research and development expenses:

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
ABC Platform external expenses (1)	$ 364	$ —	$ 364
KSI-301 program external expenses (2)	1,684	1,527	157
Payroll and personnel expenses (3)	1,590	689	901
Other research and development expenses (4)	1,071	932	139
Total research and development expenses	$ 4,709	$ 3,148	$ 1,561

(1) ABC Platform external expenses primarily represent fees incurred for services of CMOs and CROs related to our ABC Platform.
(2) KSI-301 program external expenses primarily represent fees incurred for services of CMOs and CROs related to development of KSI-301.

(3) Payroll and personnel expenses include compensation of our personnel involved in research and development activities, including salaries, benefits and stock-based compensation. We do not allocate payroll and personnel expenses to specific programs, because these expenses relate to multiple programs and, as such, are separately classified.

(4) Other research and development expenses represent direct expenses related to research and development activities other than those listed above.

ABC Platform external expenses increased from zero to $0.4 million, from the three months ended September 30, 2017 to the three months ended September 30, 2018. The increase was primarily due to focus on ABC Platform development.

KSI-301 program external expenses increased by $0.2 million from the three months ended September 30, 2017 to the three months ended September 30, 2018 due to the Phase 1 and Phase 2 clinical trial costs incurred.

Payroll and personnel expenses increased by $0.9 million from the three months ended September 30, 2017 to the three months ended September 30, 2018. The increase was a result of increased headcount.

Other research and development expenses remained relatively constant from the three months ended September 30, 2017 to the three months ended September 30, 2018. Our other research and development expenses may fluctuate in future periods as we elect to develop KSI-501 or other product candidates.

General and Administrative Expenses

General and administrative expenses increased $0.8 million, or 101%, from the three months ended September 30, 2017 to the three months ended September 30, 2018. The increase in general and administrative expenses was primarily attributable to an increase of $0.3 million in professional services related to accounting, audit, legal and consulting services in connection with our IPO, an increase of $0.3 million in salaries, including stock-based compensation, and an increase of $0.2 million in additional allocated overhead expenses due to increased headcount.

Interest Expense

Interest expense increased $1.6 million from the three months ended September 30, 2017 to the three months ended September 30, 2018, which was mainly attributable to interest expense on convertible notes issued in August 2017 and February 2018, including accretion of discount and issuance costs.

Other Income (Expense), Net

Other income (expense), net increased $1.9 million from the three months ended September 30, 2017 to the three months ended September 30, 2018, which was mainly attributable to the movement in fair value of the redeemable convertible preferred stock warrant liability and derivative instrument related to the convertible notes issued in February 2018, offset by interest income of $0.1 million.

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,		Change	
	2018	2017	Dollar	Percent
	(in thousands)			
Operating expenses:				
Research and development	$ 11,942	$ 13,246	$ (1,304)	-10%
General and administrative	5,075	2,517	2,558	102%
Loss from operations	17,017	15,763	1,254	8%
Interest expense (includes $2,944 and $311 attributable to related parties for the nine months ended September 30, 2018 and 2017)	(5,329)	(407)	(4,922)	NM
Other income (expense), net (includes $2,714 and $176 other expense attributable to related parties for the nine months ended September 30, 2018 and 2017)	(4,435)	(196)	(4,239)	NM
Net loss	$ 26,781	$ 16,366	$ 10,415	64%

* NM—not meaningful

Research and Development Expenses

Research and development expenses decreased $1.3 million, or 10%, from the nine months ended September 30, 2017 to the nine months ended September 30, 2018, as we incurred expenses relating to KSI-301 drug substance manufacturing runs for use in our Phase 1 and Phase 2 clinical trials primarily in fiscal 2017.

The following table summarizes our research and development expenses:

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
ABC Platform external expenses (1)	$ 912	$ 933	$ (21)
KSI-301 program external expenses (2)	5,173	6,954	(1,781)
Payroll and personnel expenses (3)	3,456	2,382	1,074
Other research and development expenses (4)	2,401	2,976	(575)
Total research and development expenses	$ 11,942	$ 13,245	$ (1,303)

(1) ABC Platform external expenses primarily represent fees incurred for services of CMOs and CROs related to our ABC Platform.
(2) KSI-301 program external expenses primarily represent fees incurred for services of CMOs and CROs related to development of KSI-301.
(3) Payroll and personnel expenses include compensation of our personnel involved in research and development activities, including salaries, benefits and stock-based compensation. We do not allocate payroll and personnel expenses to specific programs, because these expenses relate to multiple programs and, as such, are separately classified.
(4) Other research and development expenses represent direct expenses related to research and development activities other than those listed above.

ABC Platform external expenses remained relatively constant from the nine months ended September 30, 2017 to the nine months ended September 30, 2018.

KSI-301 program external expenses decreased by $1.8 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018 due to completion of drug substance manufacturing runs for use in Phase 1 and Phase 2 clinical trials primarily in fiscal 2017.

Payroll and personnel expenses increased by $1.1 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The increase was a result of increased headcount.

Other research and development expenses decreased by $0.6 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The decrease was primarily due to increased focus on KSI-301. Our other research and development expenses may fluctuate in future periods as we elect to develop KSI-501 or other product candidates

General and Administrative Expenses

General and administrative expenses increased $2.6 million, or 102%, from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The increase in general and administrative expenses was primarily attributable to an increase of $1.4 million in professional services related to accounting, audit, legal and consulting services in connection with our IPO, an increase of $0.8 million in salaries, including stock-based compensation, and an increase of $0.4 million in additional allocated overhead expenses due to increased headcount.

Interest Expense

Interest expense increased $4.9 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018, which was mainly attributable to interest expense on convertible notes issued in August 2017 and February 2018, including accretion of discount and issuance costs.

Other Income (Expense), Net

Other income (expense), net increased $4.2 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018, which was mainly attributable to the movement in fair value of the redeemable convertible preferred stock warrant liability and derivative instrument related to the convertible notes issued in February 2018, offset by interest income of $0.2 million.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

Prior to the completion of our IPO in October 2018, we had funded our operations primarily with an aggregate of $94.4 million in gross cash proceeds from the sale and issuance of redeemable convertible preferred stock, convertible notes and warrants to purchase Series B redeemable convertible preferred stock. As of September 30, 2018, we had cash and cash equivalents of $11.6 million.

In October 2018, we sold and issued 9,000,000 shares of common stock at a price to the public of $10.00 per share for gross proceeds of $90.0 million. In November 2018, we sold and issued an additional 400,000 shares of common stock at $10.00 per share to the underwriters of our IPO following the partial exercise of their over-allotment option for gross proceeds of $4.0 million. The aggregate net proceeds from our IPO, inclusive of the partial over-allotment option exercise, were approximately $83.7 million after deducting underwriting discounts and commissions and other offering costs.

Future Funding Requirements

We have incurred net losses since our inception. For the nine months ended September 30, 2018 and 2017, we had net losses of $26.8 million and $16.4 million, respectively, and we expect to continue to incur additional losses in future periods. As of September 30, 2018, we had an accumulated deficit of $96.1 million. Based on our current business plan, we believe that those cash and cash equivalents along with the net proceeds from our IPO will be sufficient to fund our projected operations for at least the next 12 months.

We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents, will enable us (i) to advance KSI-301 through completion of enrollment of the global Phase 2 clinical trial in the U.S., the European Union, or EU, and rest of the world in patients with wet AMD as well as through completion of a Phase 1b clinical trial; (ii) to advance KSI-301 into Phase 2 clinical trials in China for wet AMD and DME/DR and through an administrative interim analysis in each of the studies (anticipated to occur when approximately 200 patients have completed approximately six months of treatment duration, per study); (iii) to advance KSI-301 into the global Phase 2 clinical trial in the U.S., EU and rest of the world in patients with DME/DR; (iv) towards research and development of our pipeline including KSI-501 and to initiate additional clinical studies in ophthalmology; and (v) to satisfy our working capital needs and other general corporate purposes. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we expect. Because of the risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including those listed above.

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates or enter into collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect our losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional costs associated with operating as a public company.

The expected use of the net proceeds from our IPO represents our intentions based upon our current plans and business conditions. However, we have based these estimates on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. The timing and amount of our operating expenditures and capital requirements will depend on many factors, including:

- the scope, timing, 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 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 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 and timing associated with commercializing our product candidates, if they receive marketing approval.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. 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 rights to our product candidates in certain territories or indications to others that we would prefer to develop and commercialize ourselves.

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. See the section of this Quarterly Report titled “Part II, Item 1A — Risk Factors” for additional risks associated with our substantial capital requirements.

2017 Convertible Notes

In August 2017, we received $10.0 million in gross proceeds from the issuance of the 2017 convertible notes and warrants to purchase Series B redeemable convertible preferred stock. Upon the closing of our IPO, 500,000 redeemable convertible preferred stock warrants automatically converted into common stock warrants and 100,000 of such warrants were exercised immediately following the closing of our IPO. The 2017 convertible notes converted into 2,637,292 shares of common stock at the closing of our IPO.

2018 Convertible Notes

In February 2018, we received $33.0 million in gross proceeds from the issuance of the 2018 convertible notes. The 2018 convertible notes converted into 4,295,677 shares of common stock at the closing of our IPO.

Summary 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:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (20,691)	$ (12,758)
Investing activities	(56)	(159)
Financing activities	30,942	9,687
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 10,195	$ (3,230)

Cash Flows from Operating Activities

Net cash used in operating activities was $20.7 million for the nine months ended September 30, 2018. Cash used in operating activities was primarily due to the use of funds in our operations to develop KSI-301, resulting in a net loss of $26.8 million, adjusted by non-cash charges of $11.8 million offset by a change in operating assets and liabilities of $5.7 million. The non-cash charges consisted of $2.7 million in loss due to change in fair value of redeemable convertible preferred stock warrant liability, $1.9 million in loss due to change in fair value of derivative instrument related to the convertible notes issued in February 2018, $5.3 million in non-cash interest expense and amortization of debt discount and issuance costs, $0.4 million of depreciation expense, and $1.5 million of stock-based compensation. The change in net operating assets and liabilities was primarily due to a decrease in accrued liabilities of $3.5 million mainly related to a decrease in accrued research and development and accrued compensation expenses, a decrease in accounts payable of $1.8 million due to the timing of vendor payments and an increase in prepaid and other assets of $0.5 million mainly due to an increase in advance payments.

Net cash used in operating activities was $12.8 million for the nine months ended September 30, 2017. Cash used in operating activities was primarily due to the use of funds in our operations to develop KSI-301, resulting in a net loss of $16.4 million, adjusted by non-cash charges of $1.2 million and change in operating assets and liabilities of $2.4 million. The non-cash charges consisted of $0.2 million in loss due to change in fair value of redeemable convertible preferred stock warrant liability, $0.4 million in non-cash interest expense and amortization of debt discount and issuance costs, $0.4 million of depreciation expense and $0.2 million of stock-based compensation. The change in net operating assets and liabilities was primarily due to an increase in accounts payable of $2.0

million due to the timing of vendor payments and an increase in prepaid and other assets of $0.4 million mainly due to an increase in advance payments.

Cash Flows from Investing Activities

Net cash used in investing activities was less than $0.1 million for the nine months ended September 30, 2018 and related to the purchase of property and equipment.

Net cash used in investing activities was $0.2 million for the nine months ended September 30, 2017 and related to purchase of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $30.9 million for the nine months ended September 30, 2018, which consisted of $33.0 million of gross proceeds from issuance of convertible notes and less than $0.1 million proceeds from option exercises, offset by $1.8 million of deferred offering costs, $0.1 million of debt issuance costs, $0.1 million of principal payments under a capital lease agreement and $0.1 million payments related to tenant improvement allowance payable.

Net cash provided by financing activities was $9.7 million for the nine months ended September 30, 2017, which consisted of $10.0 million of gross proceeds from issuance of convertible notes offset by $0.2 million of debt issuance costs, $0.1 million of principal payments under a capital lease agreement and $0.1 million payments related to tenant improvement allowance payable.

Contractual Obligations and Commitments

As of September 30, 2018, there have been no material changes from the contractual obligations and commitments previously disclosed in our final prospectus filed with the SEC on October 5, 2018.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or 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, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported 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 discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

During the nine months ended September 30, 2018, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates" in our final prospectus filed with the SEC on October 5, 2018 and Note 2 to our unaudited condensed consolidated financial statements included in "Part I, Item 1 — Financial Statements" of this Quarterly Report. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development expenses;
- valuation of convertible debt, derivatives, and warrants;
- share-based compensation; and
- determination of the fair value of common shares prior to our IPO.

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.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or 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 until such pronouncements are made applicable to private companies, unless we otherwise irrevocably elect not to avail ourselves of this exemption. However, we have chosen to irrevocably "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth

companies. Section 107 of the JOBS Act provides that our decision to not take advantage of the extended transition period for complying with new or revised accounting standards is irrevocable.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is discussed under Note 2 to our unaudited condensed consolidated financial statements included in "Part I, Item 1 — Financial Statements" of this Quarterly Report.

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. As of September 30, 2018, we had cash and cash equivalents of $11.6 million, consisting of cash held in bank accounts and money market funds denominated in U.S. dollars. Due to the nature of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

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.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures at the end of the period covered by this Quarterly Report. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. As of the date of this report, there are no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, or Quarterly Report, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and our unaudited condensed consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report

Risks Related to Our Business, Financial Condition and Capital Requirements

We are in the early clinical stage of drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases. We commenced operations in June 2009, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We met the primary endpoint for our ongoing Phase 1 clinical trial for our most advanced product candidate, KSI-301, in September 2018, but have not initiated clinical trials for any of our other product candidates. To date, we have not completed a clinical trial (including a pivotal clinical trial), obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company and early stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net losses of $26.8 million and $16.4 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $96.1 million.

We have invested significant financial resources in research and development activities, including for our product candidates and our ABC Platform. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
- continue our research and discovery activities;
- continue the development of our ABC Platform;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;

- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

As of September 30, 2018, we had cash and cash equivalents of $11.6 million. We believe that our existing cash and cash equivalents along with the net proceeds from our initial public offering, or IPO, will be sufficient to fund our projected operations for at least the next 12 months.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, if ever.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates from payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more debt or equity financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable could decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may adversely affect our viability.

If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the sale of equity securities, including our IPO, convertible notes and warrants. Developing our product candidates is expensive, and we expect to substantially increase our spending as we advance KSI-301 into Phase 2 clinical trials. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding beyond the net proceeds from our IPO.

As of September 30, 2018, we had $11.6 million in cash and cash equivalents. We believe that our existing cash and cash equivalents along with the net proceeds from our IPO will be sufficient to fund our projected operations for at least the next 12 months, our estimate as to how long we expect our existing cash and cash equivalents to be available to fund our operations is based on assumptions that may prove inaccurate, and we could deplete our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product candidates may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biopharmaceutical industry, in particular for retinal diseases, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our prospects are heavily dependent on KSI-301, which is in the early stages of clinical development and is the only product candidate that we expect to be in clinical development in the near term.

KSI-301 is our only product candidate that we expect to be in clinical studies in the near term. We initiated an ongoing Phase 1 clinical trial of KSI-301 in July 2018 and reached the primary endpoint in September 2018. Neither KSI-301 nor any of our other product candidates has been dosed in a pivotal clinical trial, and it may be years before any such trial is completed, if at all. Further, we cannot be certain that either KSI-301 or any of our product candidates will be successful in clinical trials.

Our early encouraging preclinical and Phase 1 clinical trial results for KSI-301 are not necessarily predictive of the results of our ongoing or future discovery programs or clinical studies. Our Phase 1 clinical trial was designed to evaluate safety and tolerability of KSI-301. Although it has yielded early evidence of bioactivity, it consisted of only nine subjects, and we expect that our Phase 2 trials will have materially different design parameters. For example, our Phase 1 trial did not evaluate durability of KSI-301 across the planned 12-, 16- or 20-week dosing intervals that we intend to evaluate in our Phase 2 trials. Promising results in preclinical studies and Phase 1 clinical trials of a drug candidate may not be predictive of similar results in later-stage preclinical studies or in humans during clinical studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in early-stage development, including early-stage clinical studies, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway, or safety or efficacy observations made in preclinical studies and clinical studies, including previously unreported adverse events.

There can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical study protocols and the rate of dropout among clinical study participants. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical studies nonetheless failed to obtain FDA approval.

We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion. While we have certain preclinical programs in development and intend to develop other product candidates, it will take additional investment and time for such programs to reach the same stage of development as KSI-301.

A failure of KSI-301 in clinical development may require us to discontinue development of other product candidates based on our ABC Platform.

If KSI-301 fails in development as a result of any underlying problem with our platform, then we may discontinue development of some or all of our product candidates that are based our ABC Platform. If we discontinue development of KSI-301, or if KSI-301 were to fail to receive regulatory approval or were to fail to achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.

We are at an early stage of development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive;
- the product candidates and ABC Platform that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights or may be covered by third party patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and, because our product candidates and our ABC Platform are in an early stage of development, there is a relatively higher risk of failure and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our ABC Platform and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates is in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

If any of our product candidates successfully completes clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the European Union, or EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on our collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. That approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical studies to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an investigational new drug application, or IND, or a clinical trial application, or CTA, will result in the FDA, European Medicines Agency, or EMA, the China Drug Authority, or CDA, or any other regulatory authority as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design or, in the case of China, the registration category for the drug candidate to be studied in the clinical trial;

- the determination by the reviewing regulatory authority to require more costly or lengthy clinical trials than we currently anticipate;
- delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments on trials conducted by competitors for related technology that raises FDA, EMA, CDA or any other regulatory authority concerns about risk to patients of the technology broadly; or if the FDA, EMA, CDA or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, or cGCPs, requirements, or applicable EMA, CDA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA, CDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, CDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the commencement or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA, CDA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results and financial condition.

Our most advanced product candidate, KSI-301, is an anti-VEGF biologic that we intend to study in wet AMD and DME/DR. There are some potential side effects associated with intravitreal anti-VEGF therapies such as intraocular hemorrhage, intraocular pressure elevation, retinal detachment, inflammation or infection inside the eye and over-inhibition of VEGF, as well as the potential for potential systemic side effects such as heart attack, stroke, wound healing problems, and high blood pressure. Recent trends in the development of anti-VEGF therapies have favored increased molar dosages, as compared to currently marketed treatments. To date these heightened dosages have not exhibited a safety profile significantly worse than that of current treatments. However, anti-VEGF product candidates featuring higher molar dosages, including KSI-301, may heighten the risk of adverse effects associated with anti-VEGF treatments generally, both in the eye and in the rest of the body. There are risks inherent in the intravitreal injection procedure of drugs like KSI-301 which can cause injury to the eye and other complications including conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, intra-ocular inflammation, and endophthalmitis.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study and/or result in potential product liability claims. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management’s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;

- we may be required to create a Risk Evaluation and Mitigation Strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- 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.

We may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol, including certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have such patient eligibility criteria;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to a trial site;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

For example, because patients with early stages of DR often lack symptoms, it may be challenging to identify and enroll patients at early stages of disease that may be required for a clinical trial. Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to commence sales of and generate revenues from our product candidates, which may harm our business and results of operation.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy or durability of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. For those product candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. This is especially true for anti-VEGF biologic agents where Lucentis and EYLEA are established products with accepted safety profiles.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety, efficacy or durability results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety, efficacy and durability profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We may be unable to design and execute clinical trials that support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates through our ABC Platform. Our ABC Platform may not produce a pipeline of viable product candidates, or our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive. Our research methodology may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates for the treatment of retinal diseases will require substantial additional funding beyond the net proceeds from our IPO and is prone to the risks of failure inherent in drug development. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may retain their market share with existing drugs, or achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the retinal disease indications for which we have product candidates, including wet AMD and DME/DR. Certain of our competitors have commercially approved products for the treatment of retinal diseases that we are pursuing or may pursue in the future, including Roche and Regeneron for the treatment of wet AMD and DME/DR. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to KSI-301. Companies that we are aware are developing therapeutics in the retinal disease area include large companies with significant financial resources, such as Roche, Novartis, Bayer and Regeneron, Allergan, Mylan and Momenta. In addition to competition from other companies targeting retinal indications, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. 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. Furthermore, currently approved products could be discovered to have application for treatment of retinal disease indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA, CDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. For more information regarding potential disputes concerning intellectual property, see the subsection titled "Risks Related to Our Intellectual Property."

The manufacture of our product candidates is highly complex and requires substantial lead time to produce.

Manufacturing our product candidates involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells, and harvesting and purifying the biologic produced by them. These processes require specialized facilities, highly specific raw materials and other production constraints. As a result, the cost to manufacture a biologic is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Because of the complex nature of our products, we need to oversee manufacture of multiple components that require a diverse knowledge base and specialized personnel.

Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as our product candidates generally cannot be adequately characterized prior to manufacturing the final product. As a result, an assay of the finished product is not sufficient to ensure that the product will perform in the intended manner. Accordingly, we expect to employ multiple steps to attempt to control our manufacturing process to assure that the process works, and the product or product candidate is made strictly and consistently in compliance with the process

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, improper storage or transfer, inconsistency in yields and variability in product characteristics. Even minor deviations from normal manufacturing, distribution or storage processes could result in reduced production yields, product defects and other supply disruptions. Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt commercialization. Production of additional drug substance and drug product for any of our product candidates may require substantial lead time. For example, currently any new large-scale batches of KSI-301 would require at least 12 months to manufacture. In the event of significant product loss and materials shortages, we may be unable to produce adequate amounts of our product candidates or products for our operational needs.

Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and 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.

These challenges are magnified by the international nature of our supply chain, which, for KSI-301, requires drug substance and drug product sourced from single source suppliers from China, Japan, the United Kingdom, and Switzerland.

We have no experience manufacturing any of our product candidates at a commercial scale. If we or any of our third-party manufacturers encounter difficulties in production, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to establish a commercially viable cost structure.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them in small and large quantities. Our third-party manufacturer has made only a limited number of lots of KSI-301 to date and has not made any commercial lots. The manufacturing processes for KSI-301 have never been tested at commercial scale and the process validation requirement (the requirement to consistently produce the active pharmaceutical ingredient used in KSI-301 in commercial quantities and of specified quality on a repeated basis and document its ability to do so) has not yet been satisfied. 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 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 our product candidates may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA, CDA and foreign regulatory authority approval processes and continuous oversight. We will need to contract with manufacturers who can meet all applicable FDA, EMA, CDA and foreign regulatory authority requirements, including complying with current good manufacturing practices, or cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA, CDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, CDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. 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 or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support 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 commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists 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 and other commercialization 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 commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products 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 commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products, we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

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

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA, CDA or other regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA, CDA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product 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 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 any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA, CDA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, 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 drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Our product candidates for which we intend to seek approval as biologic products may face competition from biological products that are biosimilar to or interchangeable with our product candidates sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, 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 12 years from the date on which the reference product was first licensed. During this 12-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 their 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.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-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, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA, CDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA, CDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA, EMA, CDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA, CDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA, EMA, CDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication, when compared to the standard of care, is acceptable;
- the FDA, EMA, CDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA, CDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, CDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

We plan to conduct clinical trials for our product candidates outside the United States, and the FDA, EMA, CDA and applicable foreign regulatory authorities may not accept data from such trials.

We plan to conduct one or more of our clinical trials outside the United States, including in Europe and in China. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, CDA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice and (2) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, CDA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction, including any trials that we may conduct in China. If the FDA, EMA, CDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming, would delay aspects of our business plan and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA, EMA or CDA grants marketing approval of a product candidate, we would not be permitted to manufacture, market or promote the product candidate in other countries unless and until comparable regulatory authorities in foreign jurisdictions had approved the candidate for use in their countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials. There can be no assurance that any clinical trials conducted in one jurisdiction will be accepted by regulatory authorities in other jurisdictions.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any collaborator we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, CDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application, or MAA. 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.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, CDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to

a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency 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, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Affordable Care Act, or ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Recent changes in the U.S. administration could lead to repeal of or changes in some or all of the ACA and complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. Until the ACA is fully implemented or there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA, CDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA, CDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. In connection with our IPO, we adopted a code of business conduct and ethics that applies to all our employees, including management, and our directors. However, it is not always possible to identify and deter misconduct by employees and third parties, 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 be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws. The laws that may impact our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that 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 False Claims Act;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage 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 any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate or may operate in the future, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There can be no assurance that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of our research, preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our product candidates and preclinical studies and expect to continue to do so for clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely exclusively on a third-party manufacturer, Lonza AG, for the manufacture of our materials for preclinical studies and clinical trials and expect to continue to do so for preclinical studies, clinical trials and for commercial supply of any product candidates that we may develop.

We may be unable to establish any further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party or us;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible early termination of the agreement by us at a time that requires us to pay a cancellation fee;
- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting; and
- the inability to produce required volume in a timely manner and to quality standards.

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

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

Our current and anticipated future reliance upon others for the manufacture of any product candidates we may develop, or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

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.

Reliance on third parties to conduct clinical trials, assist in research and development and to manufacture our product candidates, will at times require us to share trade secrets with them. We seek to protect our proprietary technology by in part 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.

We rely on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our reliance on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We may depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or our ABC Platform; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and 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 the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development 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 product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Part II, Item 1A — Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our ABC Platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology 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 ABC Platform and any proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our ABC Platform, product candidates and other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio directed to certain aspects of our technology and product candidates is also at an early stage. We have filed or intend to file patent applications on core aspects of our technology and product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we only have filed provisional patent applications on certain aspects of our technology and product candidates, and none of these provisional patent applications is eligible to become an issued patent until, among other things, we file a

non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our ABC Platform and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such ABC Platform, product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our ABC Platform and product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our patent applications does not issue as a patent in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, and obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable 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 output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. In addition, our own fixed applications may become prior art against our current or future patent applications. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our ABC Platform, product candidates or other technologies or that effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents may be challenged, narrowed, circumvented, rendered unenforceable or invalidated by third parties. Consequently, we do not know whether our ABC Platform, product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our ABC Platform, product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions and other challenges in a foreign patent office or administrative tribunal, that challenge our or our licensor’s priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, 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 ABC Platform, product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Filing, prosecuting and defending patents relating to our ABC Platform, product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as U.S. laws. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. Payment within these late fee windows may be employed in order to simplify the payment of these fees generally. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while not relevant for KSI-301, if we rely on a different product, its development could involve the use of government funds, which can require additional compliance aspects to make certain all rights are transferred to or remain with us.

Issued patents may be challenged or invalidated, and recent changes in U.S. patent law have diminished and may further diminish the value of patents in general. We rely on patents to protect our products, and any diminishment in the scope or value of our patents would adversely affect our business.

If we initiated legal proceedings against a third party to enforce a patent directed to our ABC Platform, product candidates or other technologies, the defendant could allege that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including obviousness, lack of novelty, lack of written description, or non-enablement. Grounds for an unenforceability challenge include an allegation that someone connected with prosecution of the patent withheld material information from the USPTO with an intent to deceive the USPTO, or made a misleading statement, during prosecution. The filing of a legal proceeding could also result in the third party challenging the patent at the USPTO, such as in post-grant and inter partes review.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For patent filings beginning in March 2013, the United States employs a first inventor to file system in which, assuming that other requirements for patentability 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. Under the current patent laws, a third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our ABC Platform, product candidates or other technologies or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications.

Changes to U.S. patent laws since 2011 also include allowing third party submissions of prior art to the USPTO during patent prosecution and additional procedures for attacking the validity of a patent through USPTO administered post-grant proceedings, including re-examination, post-grant review, inter partes review, interference proceedings and derivation proceedings. Some of these changes apply to patents issued prior to 2011. These and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings) could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our ABC Platform, product candidates or other technologies. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standards applied in United States federal courts that apply to actions seeking to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if challenged in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not otherwise have been invalidated if first challenged by the third party as a defendant in a district court action.

As compared to intellectual property-reliant companies generally, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Any future changes to patent laws could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our ABC Platform, product candidates or other technologies. Increased uncertainty with respect to, or loss of, patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. Patent term extension in the United States and/or foreign countries and territories may not be available if, among other things, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension received is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship 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 owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor or owner or co-owner. For example, we may have inventorship disputes arise from conflicting obligations of employees, collaborators, consultants or others who are involved in developing our ABC Platform, product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned or in-licensed patents, trade secrets or other 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, intellectual property that is important to our ABC Platform, product candidates and other technologies. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 our ABC Platform, product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Over time, we expect our trade secrets and know-how to be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, train our employees not to bring or use proprietary information or technology from former employers to us or in their work and remind former employees when they leave their employment of their confidentiality obligations to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our 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 contain such breaches or disclosures or 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 without the protection of a confidentiality agreement found unenforceable by relevant courts or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have improperly used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. Where post-filing date patent assignments are not executed by an inventor, it is our practice to employ and record the assignment provision that can be found in the employee's employment agreement. This is done when possible, and when the intellectual property is of interest to us.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our ABC Platform, product candidates and other technologies.

The field of discovering treatments for retinal diseases is highly competitive and dynamic. Due to the focused research and development that is taking place in this field by several companies, including us and our competitors, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to ABC technology and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our ABC Platform, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our ABC Platform, product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued or that a third party, including a competitor in the fields in which we are developing our ABC Platform, product candidates and other technologies, might assert are infringed by our current or future ABC Platform, product candidates or other technologies. Such a dispute may concern claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our ABC Platform, product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our ABC Platform, product candidates or other technologies, could be found to be infringed by our ABC Platform, product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that later result in issued patents that our ABC Platform, product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our ABC Platform, product candidates or other technologies infringes these patents. If a third party alleges that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our ABC Platform, product candidates or other technologies, even if we believe such claims are without merit. In that event, the successful plaintiff may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees, royalties or both. Any license granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our ABC Platform, product candidates or other technologies, or our commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We are aware of a number of patents and applications that are directed to one or more aspects of KSI-301. Our intent is to maintain our development efforts under 35 U.S.C. Section 271(e)(1) (which provides a safe harbor from patent infringement claims related to certain drug development activities) through to at least the launch of any KSI-301 product. As such, we do not intend to launch KSI-301 when any valid patent is still in force. We are aware of at least one pending application with claims that are directed to some aspect of KSI-301, and that could, if issued, result in a patent term beyond our intended launch date of KSI-301. If this were to occur, we may challenge the validity of the claims, obtain a license, modify KSI-301, or delay launch.

If we choose to further the pipeline and develop a different product, such a product would be delayed until the expiration of any valid patent that is still in force on such product. Alternatively, our options for addressing any such patents relating to these non-KSI-301 products would include the following: challenge the validity of the claims, obtain a license, or modify the non-KSI-301 product.

Defending against infringement claims, regardless of their merit, would involve substantial litigation expense, would be a substantial diversion of management and other employee resources from our business and may adversely impact our reputation. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform technology, product candidates or other technologies during ongoing litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform, product candidates or other technologies during ongoing litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing ABC Platform, product candidates or other technologies. In addition, we may have to pay substantial damages (including treble damages and attorneys' fees for willful infringement) obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. If we were unable to further develop and commercialize our ABC Platform, product candidates or other technologies, it would harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. If we assert our intellectual property against others, it could increase the likelihood that our patents or the patents of our licensing partners become involved in inventorship, priority or validity disputes. As discussed above, countering or defending against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if we prevail in asserting our intellectual property, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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 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 conduct such litigation or proceedings adequately or to assert all claims we believe to be viable. 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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on trademarks, service marks, tradenames and brand names. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, any registered or unregistered trademarks or trade names that we currently have or may in the future acquire may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we do not own any registered trademarks for the marks "KODIAK" or "KODIAK SCIENCES" in the United States. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We engage a third-party watching service to monitor use by third parties of names that are identical or similar to our name. We have identified at least two companies that are using names that we continue to monitor. If we deem it appropriate, we may decide to take action with respect to those companies. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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 products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may license or own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;

- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties 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;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our Chief Executive Officer, Dr. Victor Perlroth, and our scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our operations at our facility in Palo Alto, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants, including early exercise stock options exercisable for restricted stock that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of all of these individuals or the lives of any of our other employees. If we are unable to attract, incentivize and retain quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of November 1, 2018, we had 28 employees, all of whom were full-time. As our development plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional managerial, operational, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems and procedures; and
- managing increasing operational and managerial complexity.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent 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 consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if 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 our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

A failure to maintain an effective system of internal control over financial reporting could result in material misstatements of our financial statements in future periods and may impair our ability to comply with the accounting and reporting requirements applicable to public companies.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

If we engage in acquisitions, in-licensing or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

All of our operations including our corporate headquarters are located in a single facility in Palo Alto, California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We recently implemented a new enterprise resource planning, or ERP, system as well as other systems as part of our ongoing technology and process improvements. Our ERP system is critical to our ability to accurately maintain books and records and prepare our financial statements. If we encounter unforeseen problems with our ERP system or other systems and infrastructure, our business, operations, and financial results could be adversely affected.

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

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the FCPA or comparable foreign laws; and
- business interruptions resulting from geo-political actions, including war and terrorism or natural disasters.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

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

As of December 31, 2017, we had federal net operating loss carryforwards, or NOLs, of $18.1 million, which will begin to expire in 2035. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of our IPO and our most recent private placements and other transactions that have occurred since our incorporation, we may have experienced, such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation. We will be unable to use our NOLs if we do not attain profitability sufficient to offset our available NOLs prior to their expiration.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, the Tax Cuts and Jobs Act, or Tax Act, was enacted into law with many significant changes to the U.S. tax laws, the consequences of which have not yet been determined. Under the Tax Act, the corporate tax rate will be reduced to 21% from 35% for tax years beginning after December 31, 2017. This will affect the gross amount of our deferred tax assets with a corresponding offset to valuation allowance. The Tax Act also limits the utilization of NOLs arising in tax years beginning after December 31, 2017 to 80% of taxable income per year. However, existing NOLs that arose in years prior to December 31, 2017 are not affected by these provisions. We are currently evaluating the Tax Act and its potential effects on our financial statements. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations.

Risks Related to Ownership of Our Common Stock

We do not know whether an active market will develop for our common stock or be sustained, and, as a result, it may be difficult for you to sell your shares of our common stock.

If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares.

The market price of our common stock may be volatile. As a result, you may not be able to sell your common stock at or above the price that you paid for such shares. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- failure to develop our ABC Platform;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- the level of expenses related to any of our research programs, product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of market standoff or lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this "Part II, Item 1A — Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, upon the expiration of the market standoff and lock-up agreements, the early release of these agreements or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. The 9,400,000 shares we sold in connection with our IPO and the partial exercise of the underwriters' overallotment option may be resold in the public market immediately. The remaining 27,429,857 shares, or 74.5% of our outstanding shares after our IPO as of November 6, 2018, are currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning 180 days after the date of the final prospectus related to our IPO. The representatives may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act.

Moreover, holders of an aggregate of 19,818,123 shares of our common stock have rights, subject to 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 other stockholders. We also register shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section of our final prospectus titled "Underwriting." If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

We will seek additional capital through one or a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Our directors, executive officers and 5% stockholders own a significant percentage of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, holders of more than 5% of our outstanding common stock and their respective affiliates beneficially own shares representing approximately 59.7% of our outstanding common stock as of November 14, 2018. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may 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, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, 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 exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we 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 will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds received from our IPO. Our management may spend a portion or all of the net proceeds from our IPO in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from our IPO in a manner that does not produce income or that loses value.

Delaware law and provisions in our certificate of incorporation and bylaws that became effective immediately prior to the closing of our IPO might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our certificate of incorporation and bylaws that became effective immediately prior to the closing of our IPO may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents will:

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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 bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our certificate of incorporation, or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our bylaws further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions 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, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

Recent Sales of Unregistered Equity Securities

On October 9, 2018, upon the closing of the IPO, all convertible preferred shares then outstanding automatically converted into 12,385,154 shares of common stock, 500,000 redeemable convertible preferred stock warrants automatically converted into common stock warrants and 100,000 of such warrants were exercised immediately following the closing of the IPO. The 2017 convertible notes converted into 2,637,292 shares of common stock and the 2018 convertible notes converted into 4,295,677 shares of common stock at the closing of the IPO. The issuance of such common stock upon conversion of the redeemable convertible preferred stock and convertible notes and the issuance of such common stock warrants upon conversion of the redeemable convertible preferred stock warrants were exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 3(a)(9) thereof, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. The issuance of the common stock upon the cash exercise of 100,000 common stock warrants was exempt from the registration under the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof as a transaction by an issuer not involving a public offering. No underwriters were involved in the issuance of the shares of common stock or common stock warrants.

During the period between July 1, 2018 and September 30, 2018, we issued to certain of our employees, consultants and directors, options to purchase an aggregate of 525,000 shares of our common stock at a weighted average exercise price of $10.29 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities. We filed a registration statement on Form S-8 under the Securities Act on October 9, 2018 to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plan.

Use of Proceeds from Initial Public Offering

On October 9, 2018, we closed our IPO, in which we sold and issued 9,000,000 shares of common stock at a price to the public of $10.00 per share. On November 6, 2018, we sold and issued an additional 400,000 shares of common stock at $10.00 per share to the underwriters of our IPO following the partial exercise of their over-allotment option.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-227237), which was declared effective by the SEC on October 3, 2018. Following the sale of the above shares, the offering terminated. Morgan Stanley, BofA Merrill Lynch and Barclays acted as joint book-running managers and Chardan acted as lead manager.

We received aggregate gross proceeds from our IPO of $94.0 million, or aggregate net proceeds of $87.6 million, inclusive of the partial over-allotment option exercise, after deducting underwriting discounts and commissions but before deducting offering costs payable by us, which are estimated to be $3.8 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock or (iii) any of our affiliates.

We had not used any of the net proceeds from our IPO as of September 30, 2018 because our IPO closed on October 9, 2018. There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 5, 2018.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Company				
3.2	Amended and Restated Bylaws of the Company				
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 Accounting and 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 Accounting and 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				

* The certifications filed as Exhibits 32.1 and 32.2 are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

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.

KODIAK SCIENCES INC.

Date: November 16, 2018 By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 16, 2018 By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 3.1

KODIAK SCIENCES INC.

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

Kodiak Sciences Inc., a corporation organized and existing under the laws of the State of Delaware (the "***Corporation***"), hereby certifies as follows:

A. The name of the Corporation is Kodiak Sciences Inc. The Corporation was originally formed as a Delaware limited liability company on June 22, 2009 under the name "Oligasis, LLC" and was converted into the Corporation under the name "Kodiak Sciences Inc." on September 8, 2015.

B. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware (the "***DGCL***"), and has been duly approved by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

C. The Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as set forth in Exhibit A attached hereto, effective as of 9:00 A.M Eastern Time on October 9, 2018.

IN WITNESS WHEREOF, Kodiak Sciences Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer on October 8, 2018.

By: /s/ Victor Perlroth
Victor Perlroth
President and Chief Executive Officer

Exhibit A

ARTICLE I

The name of the corporation is Kodiak Sciences Inc.

ARTICLE II

The address of the corporation's registered office in the State of Delaware is 251 Little Falls Drive, Wilmington, County of New Castle, Delaware 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE III

The purpose of the corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

The total number of shares of stock that the corporation shall have authority to issue is 500,000,000, consisting of the following:

490,000,000 shares of Common Stock, par value $0.0001 per share. Each share of Common Stock shall entitle the holder thereof as of the applicable record date to one (1) vote on each matter submitted to a vote at a meeting of stockholders on which the holders of shares of Common Stock are entitled to vote.

10,000,000 shares of Preferred Stock, par value $0.0001 per share, which may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of Preferred Stock, including without limitation authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing.

The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in the Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

ARTICLE V

Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, the number of directors that constitutes the entire Board of Directors of the corporation shall be fixed solely by resolution of the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board. For purposes of this Certificate of Incorporation, the term "***Whole Board***" shall mean the total number of authorized directorships whether or not there exist any vacancies or unfilled seats in previously authorized directorships. At each annual meeting of stockholders, directors of the corporation whose terms are expiring at such meeting shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been duly elected and qualified or until their earlier resignation or removal.

Effective upon the effective date of the corporation's initial public offering (the "***Effective Date***"), the directors of the corporation shall be divided into three classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. The Board of Directors may assign members of the Board of Directors already in office to such classes at the time such classification becomes effective. The term of office of the initial Class I directors shall expire at the first regularly-scheduled annual meeting of the stockholders following the Effective Date, the term of office of the initial Class II directors shall expire at the second annual meeting of the stockholders following the Effective Date and the term of office of the initial Class III directors shall expire at the third annual meeting of the stockholders following the Effective Date. At each annual meeting of stockholders, commencing with the first regularly-scheduled annual meeting of stockholders following the Effective Date, each of the successors elected to replace the directors of a Class whose term shall have expired at such annual meeting shall be elected to hold office until the third annual meeting next succeeding his or her election and until his or her respective successor shall have been duly elected and qualified.

Notwithstanding the foregoing provisions of this Article, each director shall serve until his or her successor is duly elected and qualified or until his or her death, resignation, or removal. If the number of directors is hereafter changed, any newly created directorships or decrease in directorships shall be so apportioned by the Board of Directors among the classes as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

From and after the Effective Date, and subject to the rights of holders of Preferred Stock with respect to the election of directors, for so long as directors of the corporation shall be divided into classes, any director may be removed from office by the stockholders of the corporation only for cause. Subject to the rights of holders of any series of Preferred Stock with respect to the election of directors, and except as otherwise provided in the DGCL or as permitted in the specific case by resolution of the Board of Directors, vacancies occurring on the Board of Directors for any reason and newly created directorships resulting from an increase in the authorized number of directors may be filled only by vote of a majority of the remaining members of the Board of Directors, although less than a quorum, or by a sole remaining director, and not by stockholders. A person so chosen to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall be duly elected and qualified.

ARTICLE VI

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors of the corporation is expressly authorized to adopt, amend or repeal the Bylaws of the corporation.

ARTICLE VII

Elections of directors need not be by written ballot unless the Bylaws of the corporation shall so provide. No stockholder will be permitted to cumulate votes at any election of directors.

ARTICLE VIII

8.1 Written Consent. From and after the Effective Date and subject to the rights of holders of any series of Preferred Stock, no action shall be taken by the stockholders of the corporation except at an annual or special meeting of the stockholders called in accordance with the Bylaws, and no action shall be taken by the stockholders by written consent.

8.2 Meetings of Stockholders. Except as otherwise expressly provided by the terms of any series of Preferred Stock permitting the holders of such series of Preferred Stock to call a special meeting of the holders of such series, special meetings of stockholders of the Corporation may be called only by the Board of Directors, the chairperson of the Board of Directors, the chief executive officer of the corporation or the president of the corporation (in the absence of a chief executive officer of the corporation), but a special meeting of stockholders may not be called by any other person or persons and the ability of the stockholders to call a special meeting is hereby specifically denied. The Board of Directors, acting pursuant to a resolution adopted by a majority of the Whole Board, or the chairperson of a meeting of stockholders may cancel, postpone or reschedule any previously scheduled meeting of stockholders at any time, before or after the notice for such meeting has been sent to the stockholders.

8.3 Advance Notice. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the corporation shall be given in the manner provided in the Bylaws.

ARTICLE IX

To the fullest extent permitted by the DGCL, as it presently exists or may hereafter be amended from time to time, a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Neither any amendment nor repeal of this Article, nor the adoption of any provision of this corporation's Certificate of Incorporation inconsistent with this Article, shall eliminate or reduce the effect of this Article in respect of any matter occurring, or any cause of action, suit or proceeding accruing or arising or that, but for this Article, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE X

Subject to any provisions in the Bylaws of the corporation related to indemnification of directors or officers of the corporation, the corporation may indemnify, to the fullest extent permitted by applicable law, any director or officer of the corporation who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "***Proceeding***") by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

The corporation shall have the power to indemnify, to the extent permitted by the DGCL, as it presently exists or may hereafter be amended from time to time, any employee or agent of the corporation who was or is a party or is threatened to be made a party to any Proceeding by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

A right to indemnification or to advancement of expenses arising under a provision of this Certificate of Incorporation or a bylaw of the corporation shall not be eliminated or impaired by an amendment to this Certificate of Incorporation or the Bylaws of the corporation after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

ARTICLE XI

Except as provided in ARTICLE IX and ARTICLE X above, the corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

The affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the corporation to alter, amend or repeal Article V, VI, VII, VIII, IX, X or this Article XI of this Certificate of Incorporation.

ARTICLE XII

The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "***Excluded Opportunity***" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, "***Covered Persons***"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation.

AMENDED AND RESTATED BYLAWS OF

KODIAK SCIENCES INC.

(as amended and restated on September 7, 2018 effective as of the closing of the corporation's initial public offering)

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

BYLAWS OF KODIAK SCIENCES INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of Kodiak Sciences Inc. shall be fixed in the corporation's certificate of incorporation. References in these bylaws to the certificate of incorporation shall mean the certificate of incorporation of the corporation, as may be amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock.

1.2 OTHER OFFICES

The corporation may at any time establish other offices at any place or places.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, determined by the board of directors. The board of directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the Delaware General Corporation Law (the "**DGCL**"). In the absence of any such designation or determination, stockholders' meetings shall be held at the corporation's principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held on such date, at such time, and at such place (if any) within or without the State of Delaware as shall be designated from time to time by the board of directors and stated in the corporation's notice of the meeting. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted. The board of directors, acting pursuant to a resolution adopted by a majority of the Whole Board (as such term is defined in the certificate of incorporation), or the chairperson of the meeting may cancel, postpone or reschedule any previously scheduled annual meeting at any time, before or after notice for such meeting has been sent to the stockholders.

2.3 SPECIAL MEETING

(i) A special meeting of the stockholders, other than those required by statute, may be called at any time only by (A) the board of directors, (B) the chairperson of the board of directors, (C) the chief executive officer or (D) the president (in the absence of a chief executive officer). A special meeting of the stockholders may not be called by any other person or persons. The board of directors or the chairperson of the meeting may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders.

(ii) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the board of directors, the chairperson of the board of directors, the chief executive officer or the president (in the absence of a chief executive officer). Nothing contained in this Section 2.3(ii) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(i) *Advance Notice of Stockholder Business.* At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be brought: (A) pursuant to the corporation's proxy materials with respect to such meeting, (B) by or at the direction of the board of directors, or (C) by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(i) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this Section 2.4(i). In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations) (the "**1934 Act**"), and subsequently included in the notice of meeting given by or at the direction of the board of directors, for the avoidance of doubt, clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of Section 2.4(i) above, a stockholder's notice must set forth all information required under this Section 2.4(i) and must be timely received by the secretary of the corporation. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the corporation not later than the 45th day nor earlier than the 75th day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; *provided*, *however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the tenth day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment, rescheduling or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this Section 2.4(i)(a). "**Public Announcement**" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

(b) To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the corporation's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class and number of shares of the corporation that are held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person, (4) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, (5) any material interest of the stockholder or a Stockholder Associated Person in such business, and (6) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the corporation's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (1) through (6), a "**Business Solicitation Statement**"). In addition, to be in proper written form, a stockholder's notice to the secretary must be supplemented not later than ten days following the record date for the determination of stockholders entitled to notice of the meeting to disclose the information contained in clauses (3) and (4) above as of the record date for notice of the meeting. For purposes of this Section 2.4, a "**Stockholder Associated Person**" of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made, or (iii) any person controlling, controlled by or under common control with such person referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this Section 2.4(i) and, if applicable, Section 2.4(ii). In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this Section 2.4(i), and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted.

(ii) *Advance Notice of Director Nominations at Annual Meetings.* Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this Section 2.4(ii) shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the board of directors of the corporation shall be made at an annual meeting of stockholders only (A) by or at the direction of the board of directors or (B) by a stockholder of the corporation who (1) was a stockholder of record at the time of the giving of the notice required by this Section 2.4(ii) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this Section 2.4(ii). In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the corporation.

(a) To comply with clause (B) of Section 2.4(ii) above, a nomination to be made by a stockholder must set forth all information required under this Section 2.4(ii) and must be received by the secretary of the corporation at the principal executive offices of the corporation at the time set forth in, and in accordance with, the final three sentences of Section 2.4(i)(a) above; provided, however, that in the event the number of directors to be elected to the board of directors is increased and there is no Public Announcement naming all of the nominees for director or specifying the size of the increased board made by the corporation at least ten (10) days before the last day a stockholder may deliver a notice of nomination pursuant to the foregoing provisions, a stockholder's notice required by this Section 2.4(ii) shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the secretary at the principal executive offices of the corporation not later than the close of business on the tenth day following the day on which such Public Announcement is first made by the corporation.

(b) To be in proper written form, such stockholder's notice to the secretary must set forth:

(1) as to each person (a "**nominee**") whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class and number of shares of the corporation that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (D) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (E) a description of all arrangements or understandings between or among the stockholder, any nominee or any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder or otherwise concerning such nomination or nominee's board service, (F) a written statement executed by the nominee acknowledging and representing that the nominee intends to serve a full term on the board of directors, and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Regulation 14A under the 1934 Act (including without limitation the nominee's written consent to being named in the proxy statement, if any, as a nominee and to serving as a director if elected or re-elected, as the case may be); and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (5) of Section 2.4(i)(b) above, and the supplement referenced in the second sentence of Section 2.4(i)(b) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (B) a statement whether either such stockholder or Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of a number of the corporation's voting shares reasonably believed by such stockholder or Stockholder Associated Person to be necessary to elect or re-elect such nominee(s) (such information provided and statements made as required by clauses (A) and (B) above, a "**Nominee Solicitation Statement**").

(c) At the request of the board of directors, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the corporation (1) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given and (2) such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the corporation under applicable law, securities

exchange rule or regulation, or any publicly-disclosed corporate governance guideline or committee charter of the corporation and (3) such other information that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee; in the absence of the furnishing of such information if requested, such stockholder's nomination shall not be considered in proper form pursuant to this Section 2.4(ii).

(d) Without exception, no person shall be eligible for election or re-election as a director of the corporation at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this Section 2.4(ii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or in any other notice to the corporation or if the Nominee Solicitation Statement applicable to such nominee or any other relevant notice contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded.

(iii) *Advance Notice of Director Nominations for Special Meetings.*

(a) For a special meeting of stockholders at which directors are to be elected or re-elected pursuant to Section 2.3, nominations of persons for election or re-election to the board of directors shall be made only (1) by or at the direction of the board of directors or (2) by any stockholder of the corporation who (A) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(iii) and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the corporation that includes the information set forth in Sections 2.4(ii)(b) and (ii)(c) above. To be timely, such notice must be received by the secretary at the principal executive offices of the corporation not later than the close of business on the later of the 90th day prior to such special meeting or the tenth day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors to be elected or re-elected at such meeting. In no event shall any adjournment, rescheduling or postponement of a special meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice. A person shall not be eligible for election or re-election as a director at a special meeting unless the person is nominated (i) by or at the direction of the board of directors or (ii) by a stockholder in accordance with the notice procedures set forth in this Section 2.4(iii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or in any other notice to the corporation or if the Nominee Solicitation Statement applicable to such nominee or any other relevant notice contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading.

(b) The chairperson of the special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

(iv) *Other Requirements and Rights.* In addition to the foregoing provisions of this Section 2.4, a stockholder must also comply with all applicable requirements of state law and of the 1934 Act and the rules and regulations thereunder with respect to the matters set forth in this Section 2.4, including, with respect to business such stockholder intends to bring before the annual meeting that involves a proposal that such stockholder requests to be included in the corporation's proxy statement, the requirements of Rule 14a-8 (or any successor provision) under the 1934 Act. Nothing in this Section 2.4 shall be deemed to affect any right of the corporation to omit a proposal from the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act.

2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 QUORUM

The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. Where a separate vote by a class or series or classes or series is required, a majority of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the board of directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business and discussion as seem to the chairperson to be in order. The chairperson of any meeting of stockholders shall have the power to adjourn the meeting to another place, if any, date or time, whether or not a quorum is present. The chairperson of any meeting of stockholders shall be designated by the board of directors; in the absence of such designation, the chairperson of the board, if any, the chief executive officer (in the absence of the chairperson of the board) or the president (in the absence of the chairperson of the board and the chief executive officer), or in their absence any other executive officer of the corporation, shall serve as chairperson of the stockholder meeting.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the shares of such class or series or classes or series present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Subject to the rights of the holders of the shares of any series of Preferred Stock or any other class of stock or series thereof that have been expressly granted the right to take action by written consent, any action required or permitted to be taken by the stockholders of the corporation must be effected at a duly called annual or special meeting of stockholders of the corporation and may not be effected by any consent in writing by such stockholders.

2.11 RECORD DATES

In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the board of directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the board of directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the board of directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A written proxy may be in the form of a telegram, cablegram, or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram, or other means of electronic transmission was authorized by the person.

2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided, however,* if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least 10 days prior to the meeting: (i) on a reasonably accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the corporation's principal place of business. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then such list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the corporation shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The corporation may designate one (1) or more persons as alternate inspectors to replace any inspector who fails to appear or fails or refuses to act.

Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors so appointed and designated shall (i) ascertain the number of shares of capital stock of the corporation outstanding and the voting power of each share, (ii) determine the shares of capital stock of the corporation represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of capital stock of the corporation represented at the meeting and such inspector or inspectors' count of all votes and ballots.

In determining the validity and counting of proxies and ballots cast at any meeting of stockholders of the corporation, the inspector or inspectors may consider such information as is permitted by applicable law. If there are multiple inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is *prima facie* evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS

The business and affairs of the corporation shall be managed by or under the direction of the board of directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution adopted by a majority of the Whole Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

If so provided in the certificate of incorporation, the directors of the corporation shall be divided into three classes.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the corporation. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. Unless otherwise provided in connection with a given resignation, acceptance of such resignation shall not be necessary to make it effective. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the board of directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws or permitted in the specific case by resolution of the board of directors, and subject to the rights of any holders of preferred stock of the corporation, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and not by stockholders. If the directors are divided into classes, a person so chosen to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The board of directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors, or any committee designated by the board of directors or any subcommittee, may participate in a meeting of the board of directors, or any such committee or subcommittee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairperson of the board of directors, the chief executive officer, the president, the secretary or a majority of the Whole Board, at such times and places as he or she or they shall designate.

Notice of the time and place of special meetings shall be:

(i) delivered personally by hand, by courier or by telephone;

(ii) sent by United States first-class mail, postage prepaid;

(iii) sent by facsimile;

(iv) sent by electronic mail; or

(v) otherwise given by electronic transmission (as defined in Section 7.2),

directed to each director at that director’s address, telephone number, facsimile number, electronic mail address or other contact for notice by electronic transmission, as the case may be, as shown on the corporation’s records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile, (iii) sent by electronic mail or (iv) otherwise given by electronic transmission, it shall be delivered, sent or otherwise directed to each director, as applicable, at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the corporation’s principal executive office) nor the purpose of the meeting, unless required by statute.

3.8 QUORUM; VOTING

At all meetings of the board of directors, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

The affirmative vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the board of directors, or of any committee or subcommittee thereof, may be taken without a meeting if all members of the board of directors or committee or subcommittee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board of directors or committee or subcommittee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this Section 3.9 at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the board of directors shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS

For so long as the directors of the corporation may be divided into classes, unless otherwise provided in the certificate of incorporation, any director may be removed from office by the stockholders of the corporation only for cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director’s term of office.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The board of directors may, by resolution passed by a majority of the Whole Board, designate one or more committees, each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors or in these bylaws, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the corporation.

4.2 COMMITTEE MINUTES

Each committee and subcommittee shall keep regular minutes of its meetings and report the same to the board of directors, or the committee, when required.

4.3 MEETINGS AND ACTION OF COMMITTEES

A majority of the directors then serving on a committee or subcommittee shall constitute a quorum for the transaction of business by the committee or subcommittee, unless the certificate of incorporation, these bylaws, a resolution of the board of directors or a resolution of a committee that created the subcommittee requires a greater or lesser number, *provided* that in no case shall a quorum be less than 1/3 of the directors then serving on the committee or subcommittee. The vote of the majority of the members of a committee or subcommittee present at a meeting at which a quorum is present shall be the act of the committee or subcommittee, unless the certificate of incorporation, these bylaws, a resolution of the board of directors or a resolution of a committee that created the subcommittee requires a greater number. Meetings and actions of committees and subcommittees shall otherwise be governed by, and held and taken in accordance with, the provisions of:

(i) Section 3.5 (place of meetings and meetings by telephone);

(ii) Section 3.6 (regular meetings);

(iii) Section 3.7 (special meetings and notice);

(iv) Section 3.8 (quorum; voting);

(v) Section 3.9 (action without a meeting); and

(vi) Section 7.5 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee or subcommittee and its members for the board of directors and its members. *However*:

(i) the time and place of regular meetings of committees and subcommittees may be determined either by resolution of the board of directors or by resolution of the committee or subcommittee;

(ii) special meetings of committees and subcommittees may also be called by resolution of the board of directors or the committee or subcommittee; and

(iii) notice of special meetings of committees and subcommittees shall also be given to all alternate members, as applicable, who shall have the right to attend all meetings of the committee or subcommittee. The board of directors, or, in the absence of any such action by the board of directors, the committee or subcommittee, may adopt rules for the government of any committee or subcommittee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the board of directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V - OFFICERS

5.1 OFFICERS

The officers of the corporation shall be a president and a secretary. The corporation may also have, at the discretion of the board of directors, a chairperson of the board of directors, a vice chairperson of the board of directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The board of directors shall appoint the officers of the corporation, except such officers as may be appointed in accordance with the provisions of Sections 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers as the business of the corporation may require. Each of such officers shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the board of directors or, except in the case of an officer chosen by the board of directors unless as otherwise provided by resolution of the board of directors, by any officer upon whom such power of removal may be conferred by the board of directors.

Any officer may resign at any time by giving written notice to the corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the corporation shall be filled by the board of directors or as provided in Section 5.3.

5.6 REPRESENTATION OF SECURITIES OF OTHER ENTITIES

The chairperson of the board of directors, the chief executive officer, the president, any vice president, the treasurer, the secretary or assistant secretary of this corporation, or any other person authorized by the board of directors or the chief executive officer, the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares or other securities of any other entity or entities standing in the name of this corporation, including the right to act by written consent. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the board of directors.

ARTICLE VI - STOCK

6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Unless otherwise provided by resolution of the board of directors, every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of, the corporation by the chairperson of the board of directors or vice-chairperson of the board of directors, or the president or a vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose

facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the corporation in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the corporation shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; *provided*, *however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 156, 202(a), 218(a) or 364 of the DGCL or with respect to this Section 6.2 a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

6.3 LOST, STOLEN OR DESTROYED CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner’s legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 DIVIDENDS

The board of directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the corporation's capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock, subject to the provisions of the certificate of incorporation.

The board of directors may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the corporation, and meeting contingencies.

6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer; *provided*, *however,* that such succession, assignment or authority to transfer is not prohibited by the certificate of incorporation, these bylaws, applicable law or contract.

6.6 STOCK TRANSFER AGREEMENTS

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.7 REGISTERED STOCKHOLDERS

The corporation:

(i) shall be entitled to treat the person registered on its books as the owner of any share or shares as the person exclusively entitled to receive dividends, vote, receive notifications and otherwise exercise all the rights and powers of an owner of such share or shares; and

(ii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII - MANNER OF GIVING NOTICE AND WAIVER

7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the corporation's records. An affidavit of the secretary or an assistant secretary of the corporation or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

7.2 NOTICE BY ELECTRONIC TRANSMISSION

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if:

(i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent; and

(ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An "**electronic transmission**" means any form of communication, not directly involving the physical transmission of paper, including the use of, or participation in, one or more electronic networks or databases (including one or more distributed electronic networks or databases), that creates a record that may be retained, retrieved, and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

Notice by a form of electronic transmission shall not apply to Sections 164, 296, 311, 312 or 324 of the DGCL.

7.3 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within 60 days of having been given written notice by the corporation of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.

7.4 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.5 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, or the board of directors or a committee thereof, as the case may be, need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - INDEMNIFICATION

8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**") (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director or officer of the corporation, or is or was a director or officer of the corporation serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the corporation, or is or was a director or officer of the corporation serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

8.4 INDEMNIFICATION OF OTHERS

Subject to the other provisions of this Article VIII, the corporation shall have power to indemnify its employees and agents to the extent not prohibited by the DGCL or other applicable law. The board of directors shall have the power to delegate to such person or persons as it may designate the determination of whether employees or agents shall be indemnified.

8.5 ADVANCED PAYMENT OF EXPENSES

Expenses (including attorneys' fees) actually and reasonably incurred by an officer or director of the corporation in defending any Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) actually and reasonably incurred by former directors and officers or other current or former employees and agents of the corporation or by persons currently or formerly serving at the request of the corporation as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the corporation deems appropriate (including any expense guidelines established by the corporation). The right to advancement of expenses shall not apply to any Proceeding (or any part of any Proceeding) for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding (or any part of any Proceeding) referenced in Section 8.6(ii) or 8.6(iii) prior to a determination that the person is not entitled to be indemnified by the corporation.

8.6 LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 and the DGCL, the corporation shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

(i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(iii) for any reimbursement of the corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the corporation, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(iv) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the corporation under applicable law, (c) otherwise required to be made under Section 8.7 or (d) otherwise required by applicable law; or

(v) if prohibited by applicable law.

8.7 DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the corporation of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The corporation shall indemnify such person against any and all expenses that are actually and reasonably incurred by such person in connection with any action for indemnification or advancement of expenses from the corporation under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8 NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9 INSURANCE

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 EFFECT OF REPEAL OR MODIFICATION

A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to the certificate of incorporation or these bylaws after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "**corporation**" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article VIII, references to "**other enterprises**" shall include employee benefit plans; references to "**fines**" shall include any excise taxes assessed on a person with respect to an employee benefit plan (excluding those in respect of any "parachute payments" within the meanings of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended); and references to "**serving at the request of the corporation**" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the corporation**" as referred to in this Article VIII.

ARTICLE IX - GENERAL MATTERS

9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the board of directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

9.3 SEAL

The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors. The corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "**person**" includes both an entity and a natural person.

ARTICLE X - AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; *provided*, *however*, that the affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the corporation to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII, this Article X and Article XI (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other bylaw). The board of directors shall also have the power to adopt, amend or repeal bylaws.

ARTICLE XI - EXCLUSIVE FORUM

Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation's stockholders, (iii) any action arising pursuant to any provision of the DGCL or the certificate of incorporation or these bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten (10) days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court, or for which such court does not have subject matter jurisdiction.

Unless the corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933.

Any person or entity purchasing or otherwise acquiring any interest in any security of the corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

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, Victor Perlroth, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kodiak Sciences 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)):

   (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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: November 16, 2018

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and 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, John Borgeson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kodiak Sciences 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)):

   (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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: November 16, 2018

By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and 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 Kodiak Sciences Inc. (the "Company") on Form 10-Q for the period ending September 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: November 16, 2018

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chairman and 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 Kodiak Sciences Inc. (the "Company") on Form 10-Q for the period ending September 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: November 16, 2018

By: /s/ John Borgeson

John Borgeson
Senior Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)