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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38682

KODIAK SCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001	KOD	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 October 31, 2019, the registrant had 37,058,168 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith beliefs as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, or similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth under the section of this Quarterly Report on Form 10-Q titled "Part II, Item 1A — Risk Factors" and elsewhere in this report. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies, clinical trials and regulatory filings;
- the translation of our preclinical results and data and early clinical trial results in particular relating to safety, efficacy and durability into future clinical trials in humans;
- the number, size and design of clinical trials that regulatory authorities may require to obtain marketing approval, including the order and number of clinical studies required to support an initial Biologics License Application, or BLA, in retinal vein occlusion, or RVO, and supplemental BLAs, or sBLAs, in wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and diabetic retinopathy, or DR;
- the timing or likelihood of regulatory filings and approvals, including the potential to achieve initial FDA approval of KSI-301 in 2022 for RVO and supplemental BLA submissions in 2022 for wet AMD, DME and DR;
- 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, manufacture 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;
- our ability to continue as a going concern;
- our ability to remain listed on The Nasdaq Stock Market;
- 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 proceeds of any offering.

All forward-looking statements are based on information available to us on the date of this Quarterly Report on Form 10-Q and we will not update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q, except as required by law. Our actual results could differ materially from those discussed in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, and 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. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within the section of this Quarterly Report on Form 10-Q titled "Part II, Item 1A — Risk Factors".

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Kodiak" the "Company," "we," "us," and "our" refer to Kodiak Sciences Inc.

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Item 1. Financial Statements (Unaudited).

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 37,033	$ 88,254
Marketable securities	23,571	—
Prepaid expenses and other current assets	440	2,195
Total current assets	61,044	90,449
Restricted cash	140	140
Property and equipment, net	1,114	1,097
Operating lease right-of-use asset	1,887	—
Other assets	4,731	503
Total assets	$ 68,916	$ 92,189
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,670	$ 1,050
Accrued and other current liabilities	5,210	3,776
Operating lease liability	421	—
Total current liabilities	7,301	4,826
Operating lease liability, net of current portion	1,616	—
Other liabilities	308	530
Total liabilities	9,225	5,356
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value, 490,000,000 shares authorized at September 30, 2019 and December 31, 2018; 37,008,997 and 36,829,857 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	4	4
Additional paid-in capital	202,183	197,595
Accumulated other comprehensive loss	19	—
Accumulated deficit	(142,515)	(110,766)
Total stockholders' equity	59,691	86,833
Total liabilities and stockholders' equity	$ 68,916	$ 92,189

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,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 10,115	$ 4,709	$ 24,676	$ 11,942
General and administrative	2,617	1,671	8,330	5,075
Total operating expenses	12,732	6,380	33,006	17,017
Loss from operations	(12,732)	(6,380)	(33,006)	(17,017)
Interest income	354	—	1,265	—
Interest expense (includes $1,076 and $2,944 attributable to related parties for the three and nine months ended September 30, 2018, respectively)	(2)	(1,982)	(8)	(5,329)
Other income (expense), net (includes $1,129 and $2,714 other expense attributable to related parties for the three and nine months ended September 30, 2018, respectively)	—	(2,090)	—	(4,435)
Net loss	$ (12,380)	$ (10,452)	$ (31,749)	$ (26,781)
Net loss per common share, basic and diluted	$ (0.33)	$ (1.33)	$ (0.85)	$ (3.45)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	37,330,066	7,851,560	37,291,328	7,764,888
Other comprehensive income				
Change in unrealized gains related to available-for-sale debt securities, net of tax	7	—	19	—
Total other comprehensive income	7	—	19	—
Comprehensive loss	$ (12,373)	$ (10,452)	$ (31,730)	$ (26,781)

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

Kodiak Sciences Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share and per share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	—	$ —	36,829,857	$ 4	$ 197,595	$ —	$ (110,766)	$ 86,833
Issuance of common stock upon exercise of stock options	—	—	80,000	—	83	—	—	83
Stock-based compensation expense	—	—	—	—	1,157	—	—	1,157
Other comprehensive income	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(7,984)	(7,984)
Balances at March 31, 2019	—	—	36,909,857	4	198,835	6	(118,750)	80,095
Issuance of common stock upon exercise of stock options	—	—	21,284	—	59	—	—	59
Stock-based compensation expense	—	—	—	—	1,244	—	—	1,244
Other comprehensive income	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(11,385)	(11,385)
Balances at June 30, 2019	—	—	36,931,141	4	200,138	12	(130,135)	70,019
Issuance of common stock upon exercise of stock options	—	—	77,855	—	272	—	—	272
Issuance of common stock upon exercise of common stock warrant	—	—	1	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,773	—	—	1,773
Other comprehensive income	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	(12,380)	(12,380)
Balances at September 30, 2019	—	$ —	37,008,997	$ 4	$ 202,183	$ 19	$ (142,515)	$ 59,691

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2017	12,385,154	$ 50,017	7,936,434	$ 1	$ 584	$ —	$ (69,323)	$ (68,738)
Issuance of common stock upon exercise of stock options	—	—	300	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	92	—	—	92
Net loss	—	—	—	—	—	—	(8,920)	(8,920)
Balances at March 31, 2018	12,385,154	50,017	7,936,734	1	676	—	(78,243)	(77,566)
Issuance of restricted stock awards	—	—	27,500	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	748	—	—	748
Net loss	—	—	—	—	—	—	(7,409)	(7,409)
Balances at June 30, 2018	12,385,154	50,017	7,964,234	1	1,424	—	(85,652)	(84,227)
Issuance of common stock upon exercise of stock options	—	—	47,500	—	49	—	—	49
Stock-based compensation expense	—	—	—	—	800	—	—	800
Net loss	—	—	—	—	—	—	(10,452)	(10,452)
Balances at September 30, 2018	12,385,154	$ 50,017	8,011,734	$ 1	$ 2,273	$ —	$ (96,104)	$ (93,830)

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,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (31,749)	$ (26,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	405	367
Non-cash interest expense and amortization of debt discount and issuance cost	—	5,295
Change in fair value of redeemable convertible preferred stock warrant liability	—	2,700
Change in fair value of derivative instrument	—	1,914
Stock-based compensation	4,174	1,549
Accretion of discount on available-for-sale securities	(195)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,782	(503)
Operating lease right-of-use asset	276	—
Other assets	(4,365)	—
Accounts payable	620	(1,754)
Accrued and other current liabilities	1,480	(3,511)
Operating lease liability	(281)	—
Other liabilities	—	33
Net cash used in operating activities	(27,853)	(20,691)
Cash flows from investing activities		
Purchase of property and equipment	(284)	(56)
Purchase of available-for-sale securities	(40,231)	—
Proceeds from maturities of available-for-sale securities	16,800	—
Net cash used in investing activities	(23,715)	(56)
Cash flows from financing activities		
Proceeds from issuance of convertible notes (includes $9,560 from related parties for the nine months ended September 30, 2018)	—	33,000
Deferred offering costs	—	(1,815)
Debt issuance cost	—	(140)
Proceeds from issuance of common stock	414	49
Principal payments of capital lease	(41)	(81)
Principal payments of tenant improvement allowance payable	(26)	(71)
Net cash provided by financing activities	347	30,942
Net increase (decrease) in cash, cash equivalents and restricted cash	(51,221)	10,195
Cash, cash equivalents and restricted cash, at beginning of period	88,394	1,535
Cash, cash equivalents and restricted cash, at end of period	$ 37,173	$ 11,730
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position		
Cash and cash equivalents	$ 37,033	$ 11,590
Restricted cash	140	140
Cash, cash equivalents and restricted cash in statement of financial position	$ 37,173	$ 11,730
Supplemental disclosures of non-cash investing and financing information:		
Issuance of derivative instrument related to convertible notes payable	$ —	$ 6,603
Unpaid 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 chronic, high-prevalence retinal diseases. The Company devotes substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel.

Liquidity

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company has incurred significant losses and negative cash flows from operations since inception and had an accumulated deficit of $142.5 million as of September 30, 2019. The Company had $60.6 million in cash and cash equivalents and marketable securities as of September 30, 2019. The Company has historically financed its operations primarily through the sale of redeemable convertible preferred stock, convertible notes, warrants and the sale of common stock in its initial public offering ("IPO"). To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue from product sales. Management expects operating losses to continue for the foreseeable future. The Company currently plans to raise additional funding as required based on the status of its development programs and projected cash flows, and the Company believes that its cash and cash equivalents and marketable securities as of September 30, 2019 are sufficient to fund its existing operational commitments and objectives at least through the first half of 2020. If the Company is unable to obtain other financing, the Company would be forced to delay, reduce or terminate some or all of its development programs and clinical trials or sell or license rights to its product candidates in certain territories or indications to others that may not be favorable to the Company.

The uncertainties inherent in the Company's future operations and in its ability to obtain additional funding raise substantial doubt about its ability to continue as a going concern beyond one year from the date these financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") applicable to interim periods and, in the opinion of management, include all normal and recurring adjustments which are necessary to present fairly the Company's financial position and results of operations for the reported periods.

These condensed consolidated financial statements have been prepared on a basis substantially consistent with, and should be read in conjunction with the audited financial statements for the year ended December 31, 2018 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 27, 2019. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. Certain information and note disclosures normally included in the audited financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. The results of operations for any interim period are not necessarily indicative of the results for the year ending December 31, 2019, or for any future period.

The accompanying condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with 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. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2019 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, except as noted below with respect to the Company's lease and marketable securities accounting policies and as noted within the "Recent Accounting Pronouncements – Recently Adopted Accounting Pronouncements" section.

Leases

The Company determines if an arrangement is, or contains, a lease at inception and then classifies the lease as operating or financing based on the underlying terms and conditions of the contract. Leases with terms greater than one year are initially recognized on the balance sheet as right-of-use assets and lease liabilities based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term and in a similar economic environment. The Company has elected not to recognize leases with terms of one year or less on the balance sheet.

Marketable Securities

The Company invests excess cash balances in short-term marketable securities. The investments in marketable securities are classified as either held-to-maturity or available-for-sale based on facts and circumstances present at the time of purchase. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expensed over the life of the instrument. Equity securities with readily determinable fair values are also carried at fair value with unrealized gains and losses included in other income (expense), net. Realized gains and losses on both debt and equity securities are determined using the specific identification method and are included in other income (expense), net.

If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other-than-temporary" and, if so, marks the investment to market through a charge to the Company's statement of operations and comprehensive loss.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which set out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). 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 clarified certain provisions and corrected 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 provided 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") superseded the previous leases standard, ASC 840 *Leases*.

The Company adopted the new lease standards as of January 1, 2019 using the modified retrospective approach to recognize a cumulative-effect adjustment on the effective date and to not adjust financial information and disclosures required under the new lease standards for comparative prior periods. The Company did not elect for the package of practical expedients and assessed all contracts at the transition date. The Company did not utilize the practical expedient which allows the use of hindsight in determining lease term and assessing impairment in right-of-use assets. The Company elected to apply the practical expedient and accounted for each lease component and related non-lease component as one single component. The Company elected not to recognize leases with terms of one year or less on the balance sheet.

The adoption of the new lease standards on January 1, 2019 resulted in the initial recognition of right-of-use asset of $2.2 million and operating lease liability of $2.3 million related to the operating lease for the Company's office and laboratory space in Palo Alto, California on the consolidated balance sheets with no material impact to the consolidated statements of operations, stockholders' equity or cash flows. Refer to Note 6.

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. ASU 2017-11 is effective for interim and annual periods beginning after December 15, 2018. The Company adopted this new guidance as of January 1, 2019, which did not result in a material impact 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. ASU 2018-07 is effective for interim and annual periods beginning after December 15, 2018. The Company adopted this new guidance as of January 1, 2019, which did not result in a material impact on its consolidated financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements*, which intends to improve financial reporting by requiring earlier recognition of credit losses on certain financial assets, such as available-for-sale debt securities. The standard is effective for interim and annual periods after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures.

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 August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which clarifies the accounting for implementation, set-up, and other upfront costs incurred in cloud computing arrangements. The standard is effective for interim and annual periods beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures.

3. Accrued and Other Current Liabilities

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

	September 30, 2019	December 31, 2018
Accrued research and development	$ 3,090	$ 1,387
Accrued salaries and benefits	1,824	2,061
Accrued legal fees	91	82
Accrued professional fees	80	117
Accrued other liabilities	125	129
Total accrued and other current liabilities	$ 5,210	$ 3,776

4. Fair Value Measurements

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

	Fair Value Measurements at September 30, 2019			
	Quoted Price in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents:				
Money market funds	$ 36,654	$ —	$ —	$ 36,654
Marketable securities:				
Commercial paper	—	11,809	—	11,809
Corporate notes	—	11,762	—	11,762
Total	$ 36,654	$ 23,571	$ —	$ 60,225

	Fair Value Measurements at December 31, 2018			
	Quoted Price in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents:				
Money market funds	$ 87,957	$ —	$ —	$ 87,957
Total	$ 87,957	$ —	$ —	$ 87,957

5. Marketable Securities

The marketable securities are classified as available-for-sale and consist of corporate notes and commercial paper. The fair value measurement data for marketable securities is obtained from independent pricing services. The Company validates the prices provided by the third-party pricing services by understanding the valuation methods and data sources used and analyzing the pricing data in certain instances.

The following table summarizes the marketable securities held at September 30, 2019 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 11,809	$ —	$ —	$ 11,809
Corporate notes	11,743	19	—	11,762
Total	$ 23,552	$ 19	$ —	$ 23,571

All marketable securities held at September 30, 2019 had contractual maturities of less than one year. There were no realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the nine months ended September 30, 2019 and as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss. There were no impairment charges related to marketable securities for the nine months ended September 30, 2019.

6. 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 which was effective March 2016 and extended the lease term until October 2023.

The Company recognized an operating lease right-of-use asset and corresponding liability on January 1, 2019 based on the present value of remaining lease payments discounted at the Company's estimated incremental borrowing rate of 8.5% over the remaining lease term of 4.83 years. For the three and nine months ended September 30, 2019, the operating lease cost was $0.1 million and $0.4 million, respectively. The operating cash flows used for operating leases was $0.4 million for the nine months ended September 30, 2019. The short-term lease costs were immaterial for the three and nine months ended September 30, 2019.

The following tables summarize the Company's future payments under the non-cancellable operating lease (in thousands):

Year ending December 31,	**As of September 30, 2019**
2019 (excluding the nine months ended September 30, 2019)	$ 96
2020	581
2021	598
2022	616
2023	526
Total undiscounted lease payments	2,417
Less: imputed interest	(380)
Total operating lease liabilities	$ 2,037

Year ending December 31,	**As of December 31, 2018**
2019	$ 564
2020	581
2021	598
2022	616
2023	526
Total payments	$ 2,885

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.

7. Stock-based Compensation

In January 2019, the number of shares of common stock available for issuance under the 2018 Equity Incentive Plan was increased by approximately 1.5 million shares as a result of the automatic increase provision in the 2018 Plan.

Stock Options

Stock option activity under the 2018 Plan and 2015 Equity Incentive 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, 2018	3,024,404	5,135,267	$ 5.99	9.07	$ 10,681
Shares authorized	1,473,194	—			
Options exercised	—	(80,000)	$ 1.04		290
Balance, March 31, 2019	4,497,598	5,055,267	$ 6.14	8.69	8,769
Options granted	(449,988)	449,988	$ 8.40		
Options forfeited or canceled	15,804	(15,804)	$ 7.00		
Options exercised	—	(21,284)	$ 2.77		190
Balance, June 30, 2019	4,063,414	5,468,167	$ 6.34	8.60	29,716
Options granted	(816,750)	816,750	$ 14.29		
Options forfeited or canceled	123,588	(123,588)	$ 7.91		
Options exercised	—	(77,855)	$ 3.49		848
Balance, September 30, 2019	3,370,252	6,083,474	$ 7.42	8.51	$ 42,842

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,	
	2019	2018	2019	2018
Research and development	$ 987	$ 528	$ 2,396	$ 892
General and administrative	786	272	1,778	600
Total stock-based compensation	$ 1,773	$ 800	$ 4,174	$ 1,492

As of September 30, 2019, the unrecognized stock-based compensation of unvested employee options and unvested RSAs and RSUs was $21.1 million and it is expected to be recognized over a weighted-average period of 2.47 years.

8. 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,	
	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders	$ (12,380)	$ (10,452)	$ (31,749)	$ (26,781)
Denominator:				
Weighted-average common shares outstanding	37,340,844	7,980,457	37,311,018	7,954,583
Less: weighted-average unvested restricted shares and shares subject to repurchase	(10,778)	(128,897)	(19,690)	(189,695)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	37,330,066	7,851,560	37,291,328	7,764,888
Net loss per share attributable to common stockholders, basic and diluted	$ (0.33)	$ (1.33)	$ (0.85)	$ (3.45)

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,	
	2019	2018
Options to purchase common stock	6,083,474	3,796,312
Redeemable convertible preferred stock	—	12,385,154
2017 convertible notes (1)	—	2,689,744
2018 convertible notes (2)	—	4,289,955
Redeemable convertible preferred stock warrants	—	500,000
Unvested restricted stock awards	7,385	108,174
Total	6,090,859	23,769,339

(1) Calculated as $10.0 million in principal and $3.5 million in accrued but unpaid interest as of September 30, 2018, 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.

9. Subsequent Events

On November 1, 2019, the Company filed a shelf registration statement on Form S-3 (File No. 333-234443) with the SEC covering the offer and sale of the Company's securities, from time to time and in such amounts and at such prices and terms to be determined at or prior to the time of the offerings, up to $400.0 million for a period up to three years from the date of effectiveness of the shelf registration statement.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this report and with our audited financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2018, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 27, 2019. This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section of this report titled "Part II, Item 1A — Risk Factors" and elsewhere in this report.

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 macular edema due to retinal vein occlusion, or RVO. KSI-301 could also be an important anti-VEGF therapy for other less-common retinal vascular or exudative diseases such as choroidal neovascularization due to pathologic myopia (myopic CNV or mCNV). KSI-301 and our ABC Platform were developed at Kodiak, and we own worldwide rights to these assets. We have applied our ABC Platform to develop additional product candidates beyond KSI-301 including KSI-501, our bispecific anti-IL-6/VEGF bioconjugate, and we are expanding our early research pipeline to include ABC Platform-based triplet inhibitors for multifactorial retinal diseases such as dry AMD and the neurodegenerative aspects of glaucoma. We intend to progress these and other product candidates to address high-prevalence ophthalmic diseases. Our overall objective is to develop our product candidates, seek U.S. FDA and worldwide health authority marketing authorization approvals and ultimately commercialize our product candidates.

In the third quarter of 2019 and into the early fourth quarter, highlights of our activities included:

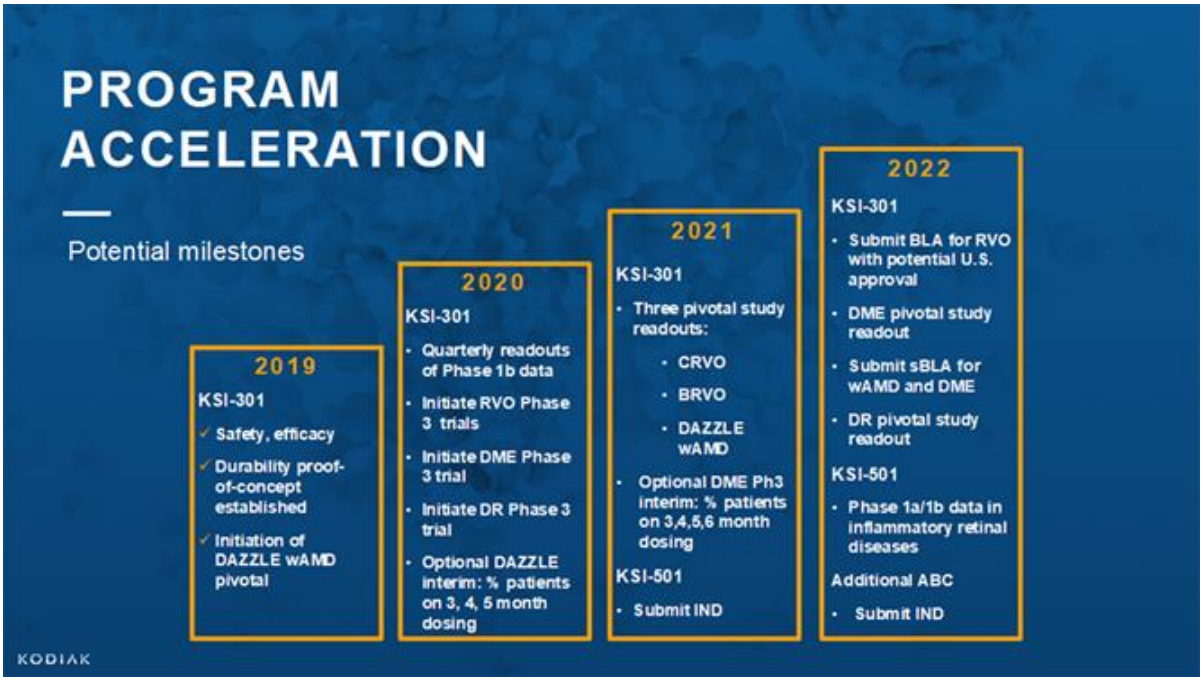
- Initiation of enrollment and recruitment in our pivotal 'DAZZLE' clinical trial of KSI-301 in patients with treatment naïve wet AMD;
- Presentation of promising clinical safety, efficacy, and durability data from the ongoing Phase 1b study of KSI-301 at the American Academy of Ophthalmology Annual Meeting Retina Subspecialty Day;
- Announcement of our accelerated development and registration strategy for KSI-301;
- Completion of a Type B (End of Phase 2 or EOP) meeting with FDA where we discussed and agreed on:
    - The recommended clinical, non-clinical, and manufacturing activities to support the licensure of KSI-301, and
    - The order and number of clinical studies required to support an initial Biologics License Application (BLA) in RVO and supplemental BLAs (sBLA) in wet AMD, DME, and DR; and
- Clarity on a capital efficient "2022 Vision" that, if successful, would result in an initial FDA approval of KSI-301 in 2022 for RVO and supplemental BLA submissions in 2022 for wet AMD, DME and potentially DR without DME.

Based on the emerging clinical data as well as our productive EOP meeting with FDA, we are accelerating the clinical development of KSI-301, with the goal of demonstrating a meaningfully-differentiated durability profile in each of wet AMD, RVO, DME, and DR, as compared to currently-marketed medicines and those known to be in clinical development.

We believe that we can achieve our “2022 Vision” of a BLA submission and initial US FDA approval for KSI-301 in RVO, and supplemental BLA (sBLA) submissions for wet AMD, DME and DR with a total of five pivotal trials– two in RVO, one in wet AMD, one in DME and one in DR without DME.

Consequently, we now intend to initiate at least four US/EU-based pivotal trials in 2020: one in central RVO (CRVO), one in branch RVO (BRVO), one in DME and one in DR. These studies, together with our ongoing pivotal study in wet AMD, will be the basis of our intended BLA and sBLA submissions.

Our 2022 Vision includes the following potential catalysts and milestones in 2019, 2020, 2021, and 2022:



Further details of our ongoing Phase 1b trial and our accelerating development strategy are discussed below.

Opportunity for Clinically Meaningful Differentiation

Current intravitreal anti-VEGF agents require frequent eye injections in order to achieve the best clinical results. When patients do not follow product labeling or miss treatments, improvements in their vision following treatment may be transient or decline over time. Real-world data demonstrate that most patients are not currently receiving their anti-VEGF therapy at the recommended intervals. We believe that our ABC Platform medicines could address this problem by requiring less frequent dosing, and the emerging Phase 1b clinical data with KSI-301 support meaningfully-differentiated clinical profiles of KSI-301 relative to standard of care in each of the major retinal diseases treated today with anti-VEGF therapy. The current and emerging standard of care treatment regimens and the dosing regimens Kodiak intends to test in its pivotal trials with KSI-301 are shown in the below Table.

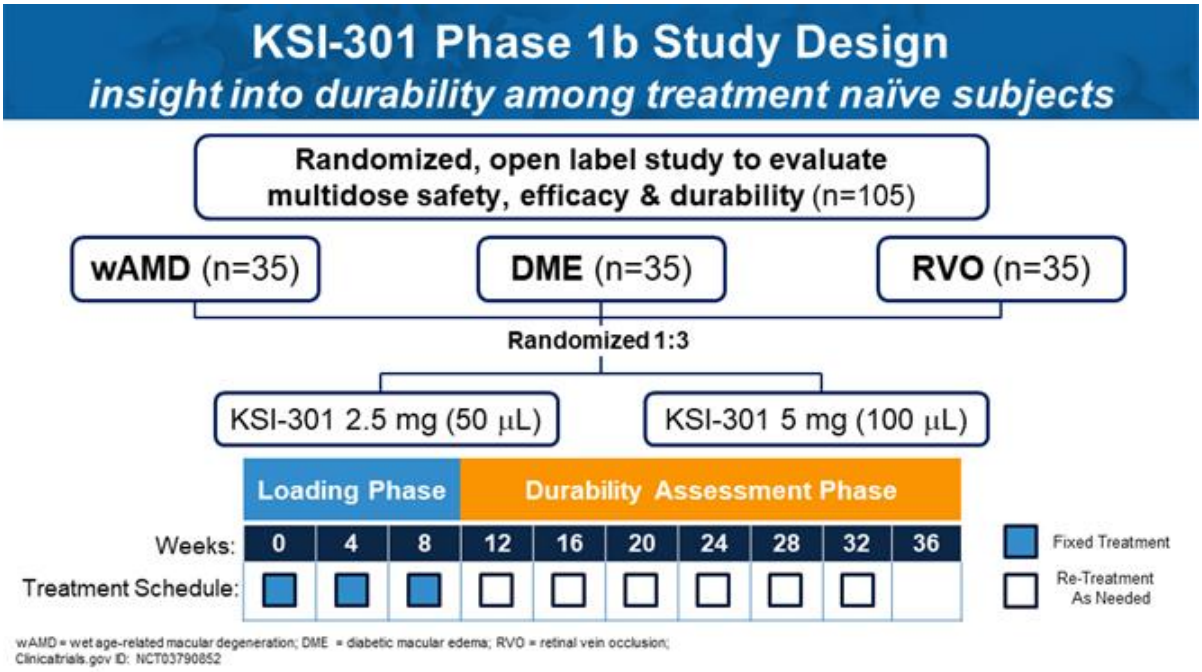
Retinal Disease:	**Wet AMD**	**Diabetic Macular Edema**	**Retinal Vein Occlusion**	**Non-Proliferative Diabetic Retinopathy**
Current and emerging standard of care	(Current:) Aflibercept once every 2 months, after 3 monthly loading doses (Emerging:) Brolucizumab once every 2-3 months, after 3 monthly loading doses	Aflibercept once every 2 months, after 5 monthly loading doses	Aflibercept once monthly	(Current:) None (Emerging:) Aflibercept once every 2 months, after 5 monthly loading doses
Kodiak's Dosing Regimen for KSI-301 (as studied in ongoing or anticipated pivotal trials)	KSI-301 once every 3, 4, or 5 months, after 3 monthly loading doses	KSI-301 once every 3, 4, 5, or 6 months, after 3 monthly loading doses	KSI-301 once every 2 months, after 2 monthly loading doses	KSI-301 once every 3, 4, or 6 months, with no loading doses

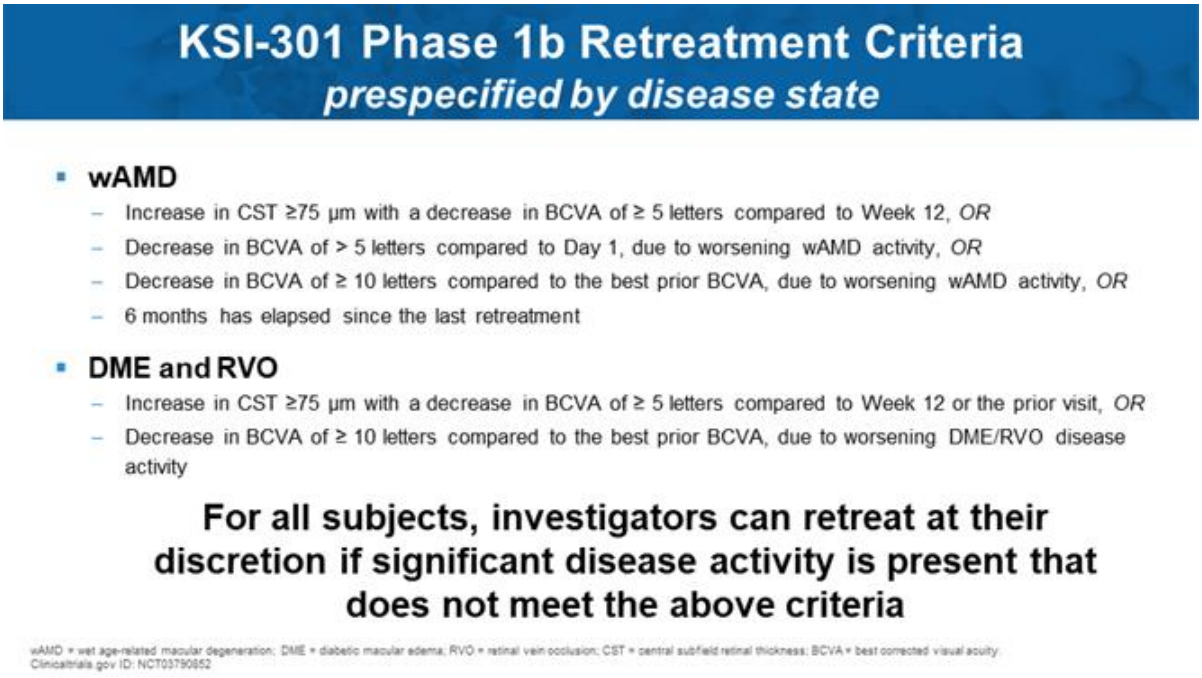
Emerging Phase 1b Data Support A Differentiated Profile of KSI-301 in Each Disease

In the fourth quarter of 2019, we reported emerging safety, efficacy and durability data of KSI-301 in patients with treatment-naïve wet AMD, DME, and RVO treated in our ongoing, open-label, multiple-dose Phase 1b study of KSI-301. This Phase 1b study was initiated in the United States in the fourth quarter of 2018 and followed a successful first-in-human, single ascending dose Phase 1a clinical study of KSI-301 that was also undertaken in 2018. The Phase 1b study is designed to provide a scientific and clinical proof of concept for the safety, efficacy and durability of KSI-301 and the ABC Platform in patients with retinal vascular disease. As of October 10, 2019, 104 patients had been enrolled in the Phase 1b study. In the study, patients are being treated with three monthly doses of either 2.5 mg or 5 mg KSI-301 and followed thereafter, with additional treatments according to disease-specific, protocol-specified retreatment criteria.

On October 11, 2019, we presented interim data from the ongoing Phase 1b study of KSI-301 at the American Academy of Ophthalmology (AAO) Annual Meeting Retina Subspecialty Day. We are observing promising clinical durability in the emerging data in each of the retinal diseases under study. We believe the Phase 1b data we are generating in treatment naïve patients with wet AMD, DME, or RVO lend confidence to the design of our current and proposed pivotal studies of KSI-301, and that these pivotal studies, if successful, will demonstrate meaningfully differentiated profiles in each of the four retinal vascular diseases as compared to current agents. On October 14, 2019, we hosted an R&D Day where we discussed the data together with a set of leading clinical and market experts. The AAO presentation and the R&D Day slides and recorded webcast are available on the Kodiak Investor Relations website.

The Phase 1b study design, retreatment criteria, and patient baseline characteristics are described in the below Figures. In the Phase 1b study, treatment-naïve patients with wet AMD, DME, or RVO receive three monthly loading doses of KSI-301 at either the 2.5 mg or 5 mg dose levels and are followed thereafter; retreatment with KSI-301 is administered as per the protocol-specified retreatment criteria.





KSI-301 Phase 1b Baseline Characteristics

Variable	wAMD Cohort (n=35)	DME Cohort (n=34)	RVO Cohort (n=35)
Age, mean (SD), years	77.2 (11.0)	60.7 (10.4)	63.6 (12.6)
Gender, n (%), female	25 (71.4)	13 (38.2)	13 (37.1)
Race, n (%), White	32 (91.4)	28 (82.4)	31 (88.6)
BCVA, mean (SD), ETDRS letters	64.5 (11.1)	66.8 (10.3)	54.9 (15.4)
BCVA, Snellen 20/40 or better, n (%)	14 (40.0)	16 (47.1)	6 (17.1)
OCT CST, mean (SD), microns	426 (176)	449 (109)	675 (237)

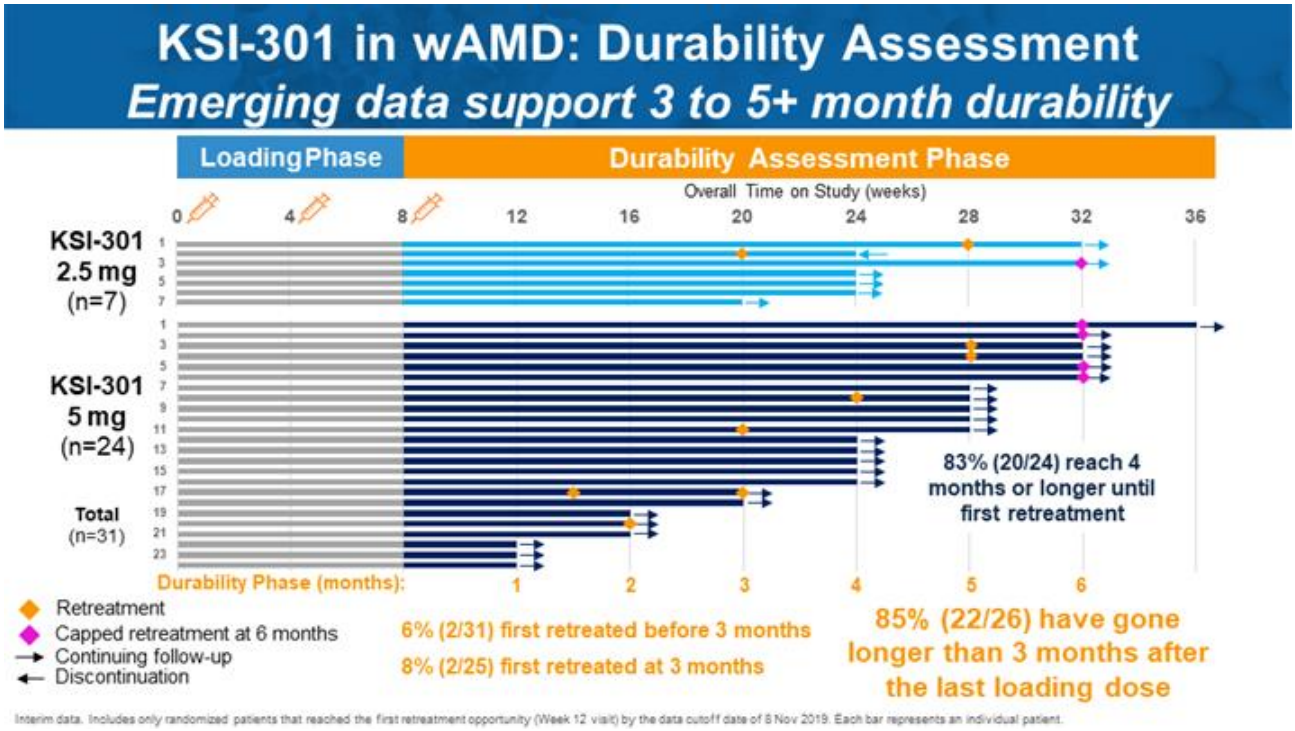
Includes all patients randomized as of 10 October 2019. SD= standard deviation; BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

The Figures below present additional new data on durability and efficacy outcomes from the ongoing Phase 1b study beyond those presented at the AAO and R&D Day, as the patients have, through November 8, 2019, been followed for approximately one additional month each. Across all three diseases under the study, improvements in vision and retinal anatomy were observed through 20 weeks of patient follow-up, with stability in OCT and BCVA over time in the monthly follow-up intervals following the three mandatory loading doses. Vision is measured as change in best corrected visual acuity, or BCVA, on a standardized eye chart, and retinal anatomy is measured as change in retinal central subfield thickness, or CST, using optical coherence tomography, or OCT, imaging.

Wet AMD

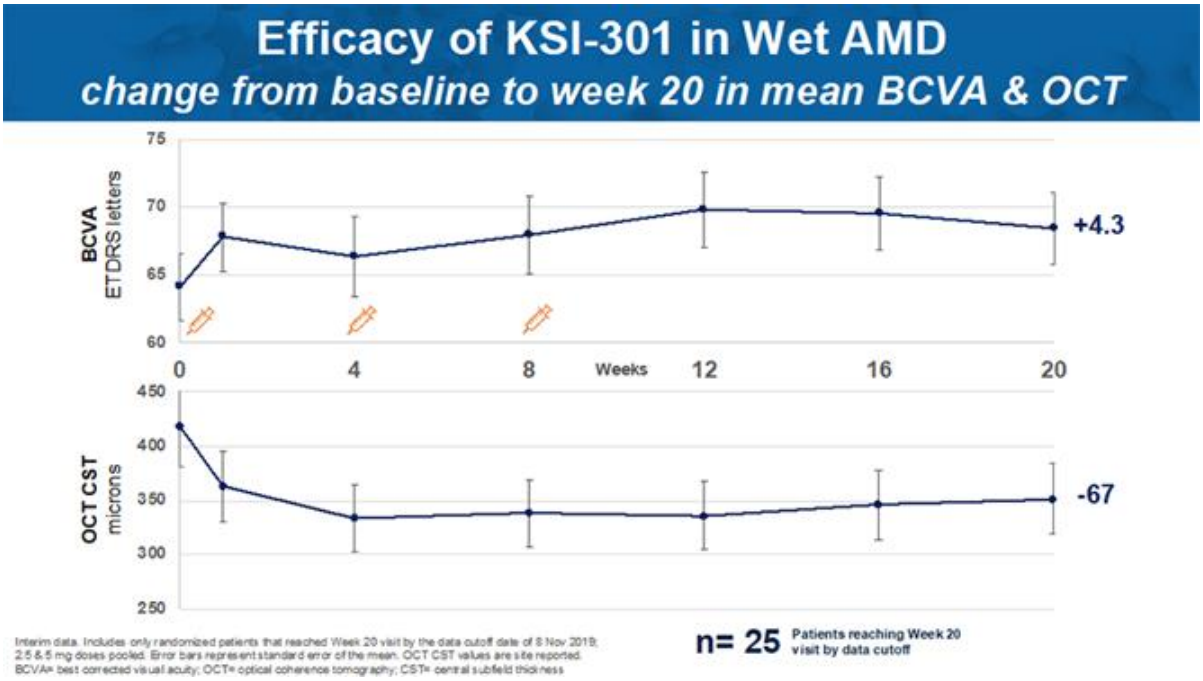
In wet AMD, with current agents, only approximately 40% of patients can be maintained on an every 12-week (3 month) dosing interval over a two-year period. The remaining 60% of patients require either every other month therapy, monthly therapy, or even on occasion treatment as often as every two weeks. Our objective with KSI-301 in wet AMD is to develop a therapy where the vast majority of patients are on every 12-week dosing or better, with at least 50% of patients maintained on an every four or five month dosing regimen.

In our Phase 1b study, we have observed thus far that 92% of wet AMD treated eyes have been extended to three months or longer after the last loading dose of KSI-301 without receiving retreatment, and 85% have been extended longer than three months after the last loading dose. Many patients have not received their first retreatment until five or even six months after the last loading dose. In the Phase 1b study, the maximum retreatment interval for wet AMD patients is capped at six months. The following results have been observed as of November 8, 2019:

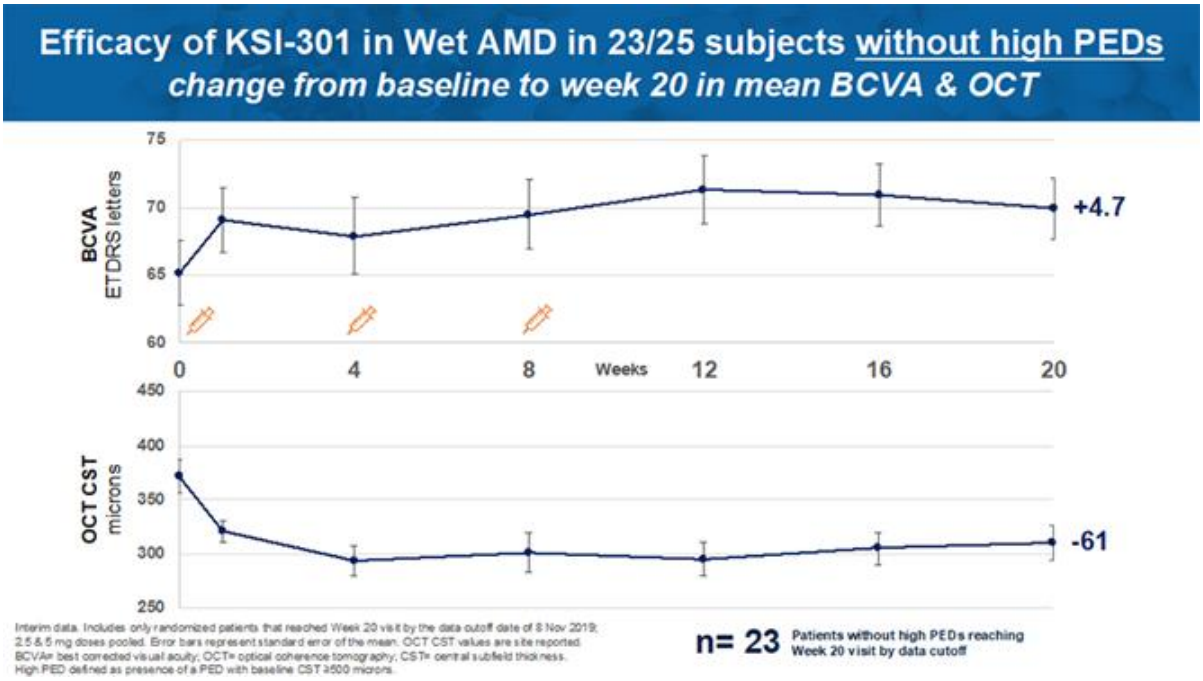


Intriguingly, we are observing that a high proportion of Phase 1b patients –approximately 50% as of November 8, 2019– are reaching or will reach six months without retreatment after the initial loading doses. Of the patients with sufficient follow-up and taking into consideration those retreated earlier as well as the patients who were examined and not retreated at the five month visit after the last loading dose, 8 of the 15 patients to date have reached or can reach six months without retreatment after the initial loading doses. These emerging data underscore the potential of KSI-301 and the ABC Platform to achieve truly long-interval dosing with an intravitreally-administered therapy.

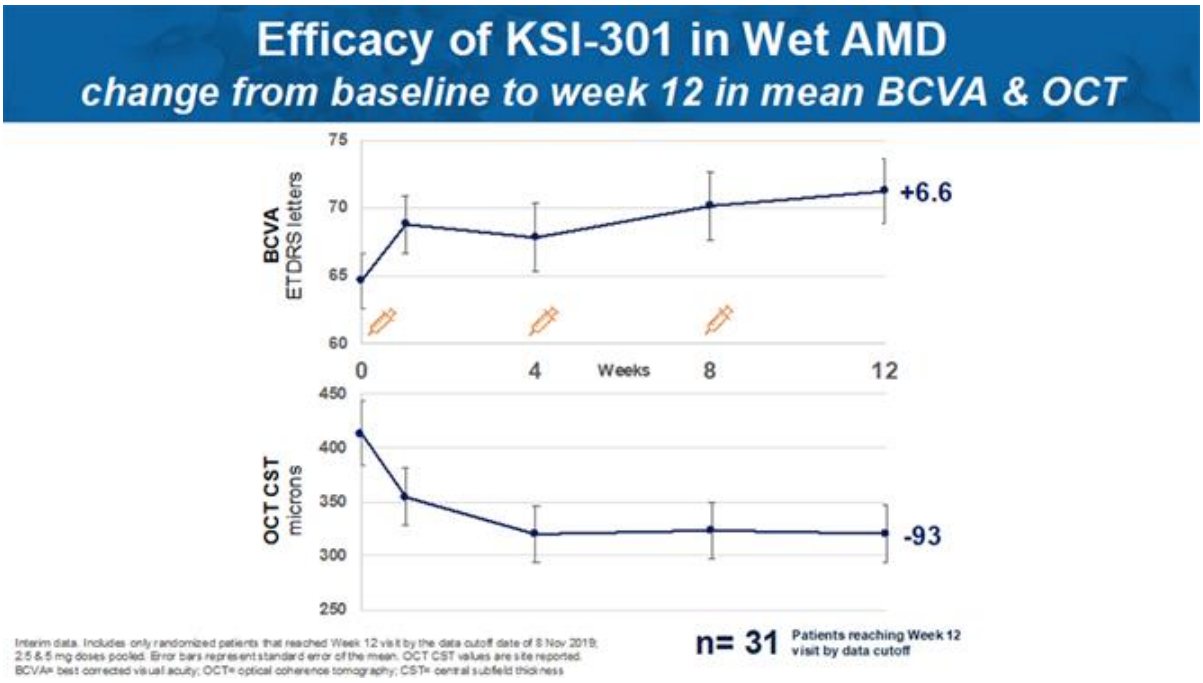
Visual acuity and retinal anatomy (OCT CST) improvements continue to be durable in the follow-up data as well. In the following graphs, the 25 wet AMD patients (pooled 2.5 mg and 5 mg dose levels) who reached the week 20 visit prior to the data cutoff date of November 8, 2019 are included. In the period between week 12 and week 20 (that is, months 1 to 3 after the loading phase), the treatment effect is maintained, with only a small (15.3 micron) change in average central subfield thickness on OCT was observed, and between weeks 16 and 20 this change was only 5.7 microns. This is consistent with an extended durability effect of KSI-301 and compares favorably to the OCT fluctuations observed with existing anti-VEGF agents on even shorter dosing intervals. Similarly, BCVA was also generally stable over these intervals, consistent with a prolonged duration of effect of KSI-301. BCVA tends to fluctuate by a small amount on a month-to-month basis in clinical trials.

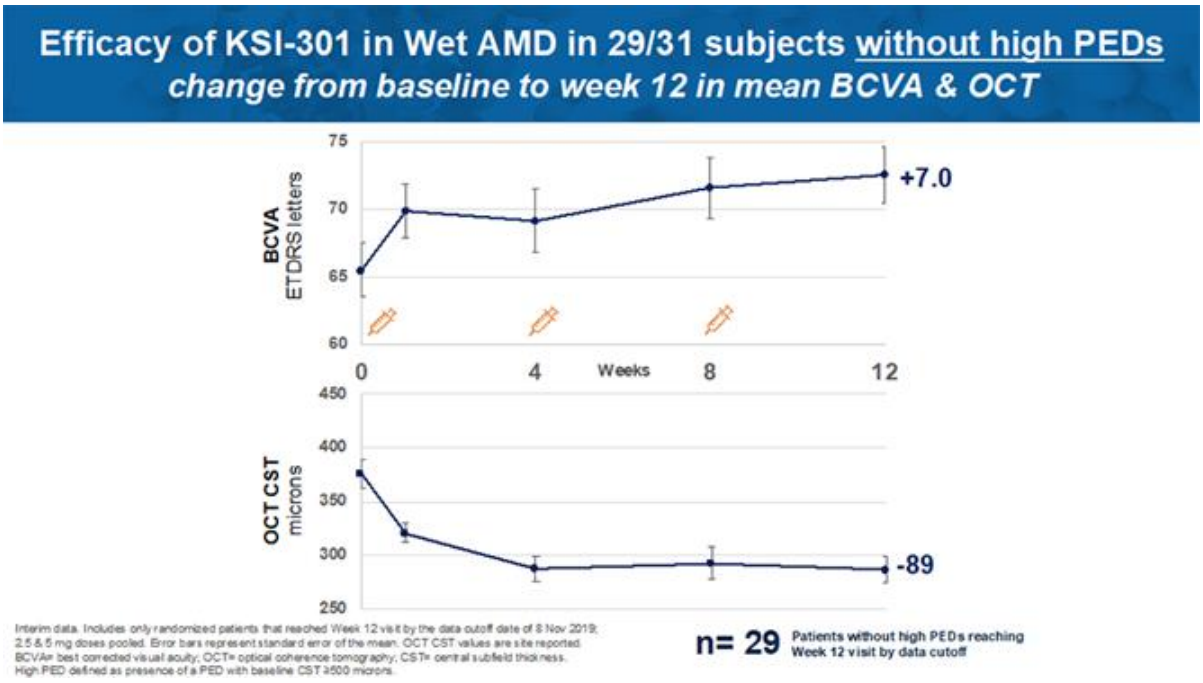


In the Phase 1b study, the average retinal thickness (OCT CST) data as reported by our clinical investigators includes the height of pigment epithelial detachments (PEDs). PEDs are an anatomic feature in some patients with wet AMD; treatment success in subjects with PEDs does not necessarily imply complete flattening of the PED, but rather eliminating the intraretinal and subretinal fluid, particularly when the PED is very high prior to anti-VEGF treatment. Additionally, comparison across studies of OCT mean CST values is difficult because it is often not clear or not disclosed in presentations and publications whether the data include or exclude the height of the PED, among other reasons. In the figure below, the graphs show the BCVA and OCT CST change in the wet AMD subjects excluding the 2/25 patients that presented with a very high (>500 microns of total CST) PED at baseline. The BCVA and OCT CST curves are similar to those of the full cohort, but the OCT CST values are lower at baseline and over time, and the standard error of the mean (SEM) error bars are narrower, demonstrating the relative weight these two patients have in a small cohort. In summary, these two patients appear to be outliers in baseline thickness but not in treatment response.



The data presented above include patients who reached the week 20 visit by the data cut-off date. When considering the larger group of patients who have data through the first 12 weeks of the ongoing study, the following results have been observed:



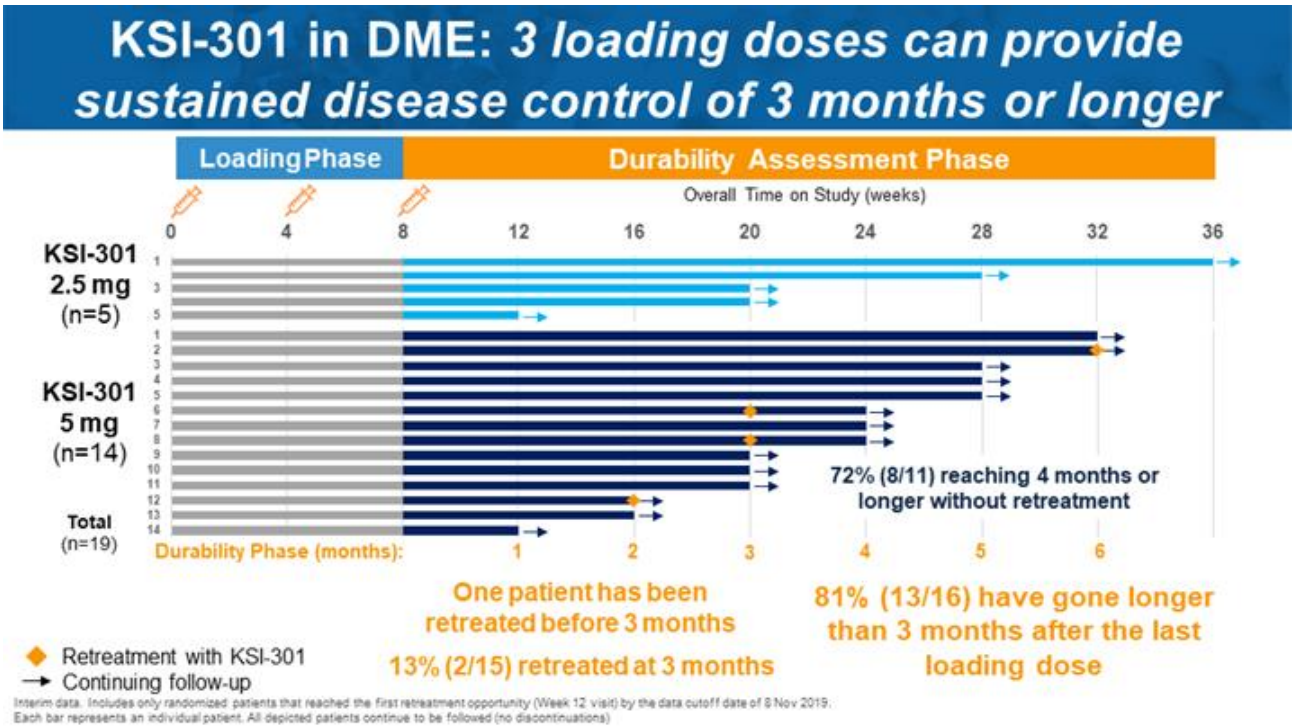


These data collectively demonstrate that KSI-301 has a potent anti-VEGF effect both on BCVA improvement and retinal drying in wet AMD patients. The clinical benefit appears in line with existing anti-VEGF agents (especially when considering differences in baseline characteristics), and we are observing substantially longer durability of clinical effect with KSI-301 than is expected from existing agents.

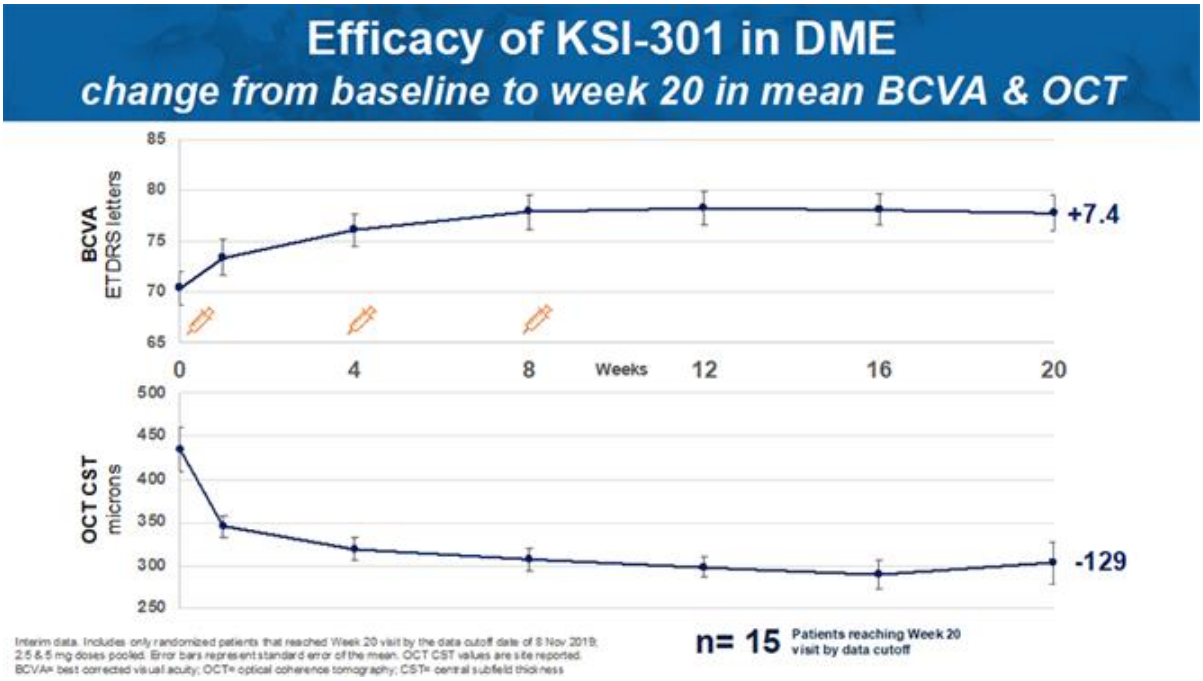
Although the Phase 1b study is open-label, we believe these results are representative both because patients in the study are randomized to two dose levels and because the key assessments (visual acuity and OCT) are measured objectively and in a standardized, reproducible manner. The very high proportion of Phase 1b patients who have been extended to 4, 5, or even 6 months without receiving retreatment also further supports the design of our ongoing pivotal study, DAZZLE, in which KSI-301 is administered to treatment-naïve wet AMD patients on an every 3, 4 or 5 month dosing regimen, as compared to aflibercept on an every 2 month regimen, each after three monthly loading doses.

Diabetic Macular Edema

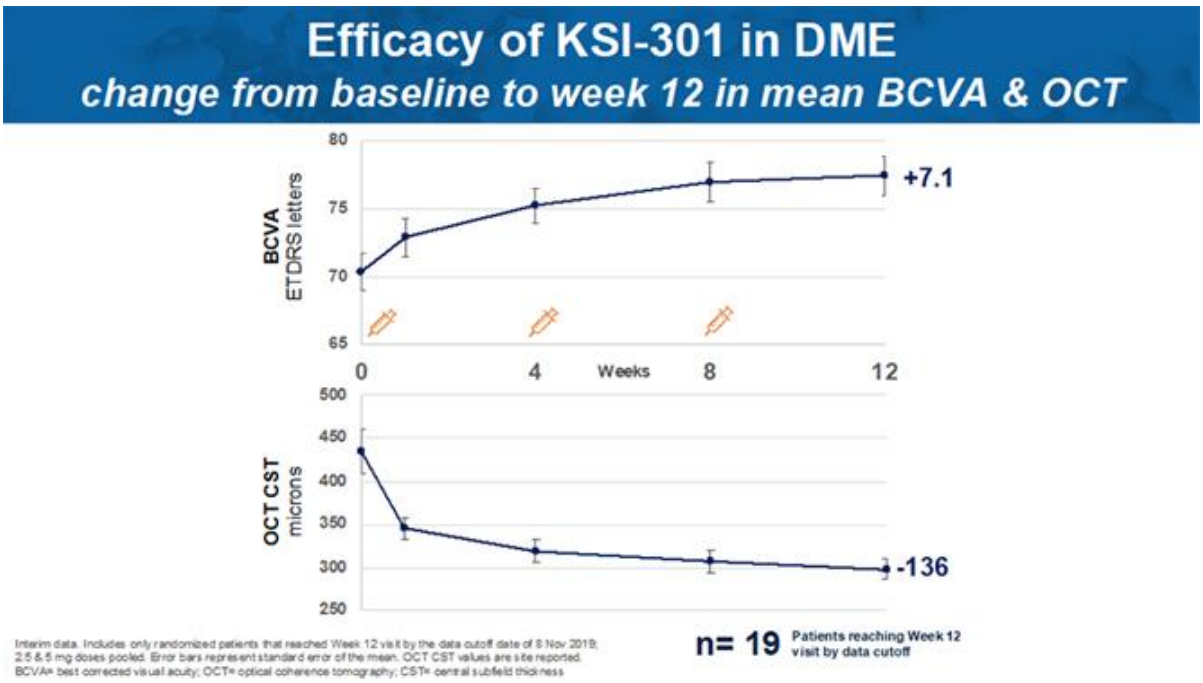
In DME, currently-approved anti-VEGF medicines are labeled for either monthly or every other month dosing after 5 monthly loading doses, and in a National Eye Institute-funded DRCR.net collaborative group study of DME patients, almost all patients required 6 initial monthly loading doses and a median of 9-10 doses were administered in the first year of therapy for all of the tested agents (aflibercept, bevacizumab, and ranibizumab). Our objective with KSI-301 in DME is thus twofold: first, to reduce the number of initiating or loading doses, and second to extend the treatment interval in the maintenance phase to 3 months and beyond. In our Phase 1b study, we have observed that 72% of DME treated eyes have been extended to four months or longer after the 3 loading doses of KSI-301 without receiving retreatment, with most patients not yet receiving any retreatment, including patients followed for as long as 5 to 7 months after the initiating doses. 81% of DME treated eyes have been extended longer than 3 months after the last loading dose (and 94% extended to 3 months or longer). The following results have been observed as of November 8, 2019:



Visual acuity and optical coherence tomography improvements continue to be durable in the follow-up data as well. In the following Figure, the 15 DME patients (pooled 2.5 mg and 5 mg dose levels) who reached the week 20 visit prior to the data cutoff date of November 8, 2019 are included. In the period between week 12 and week 20 (that is, months 1 to 3 after the loading phase), the treatment effect is maintained, with only a small (19.2 micron) change in average central subfield thickness on OCT was observed, and between weeks 16 and 20 this change was only 13.6 microns. This is consistent with the extended durability effect of KSI-301 and compares very favorably to existing anti-VEGF agents, particularly with a reduced number of loading doses. The change in OCT appeared largely driven by the two DME patients who required and received retreatment at week 20 under the protocol. Follow-up data at week 24 is available for both of these patients, and one month after they received retreatment at week 20, their OCT improved again by -97 and -255 microns respectively. Similarly, BCVA was also stable over these intervals, consistent with a prolonged duration of effect of KSI-301.



The data presented above include patients who reached the week 20 visit by the data cut-off date. When considering the larger group of patients who have data through the first 12 weeks of the ongoing study, the following results have been observed:

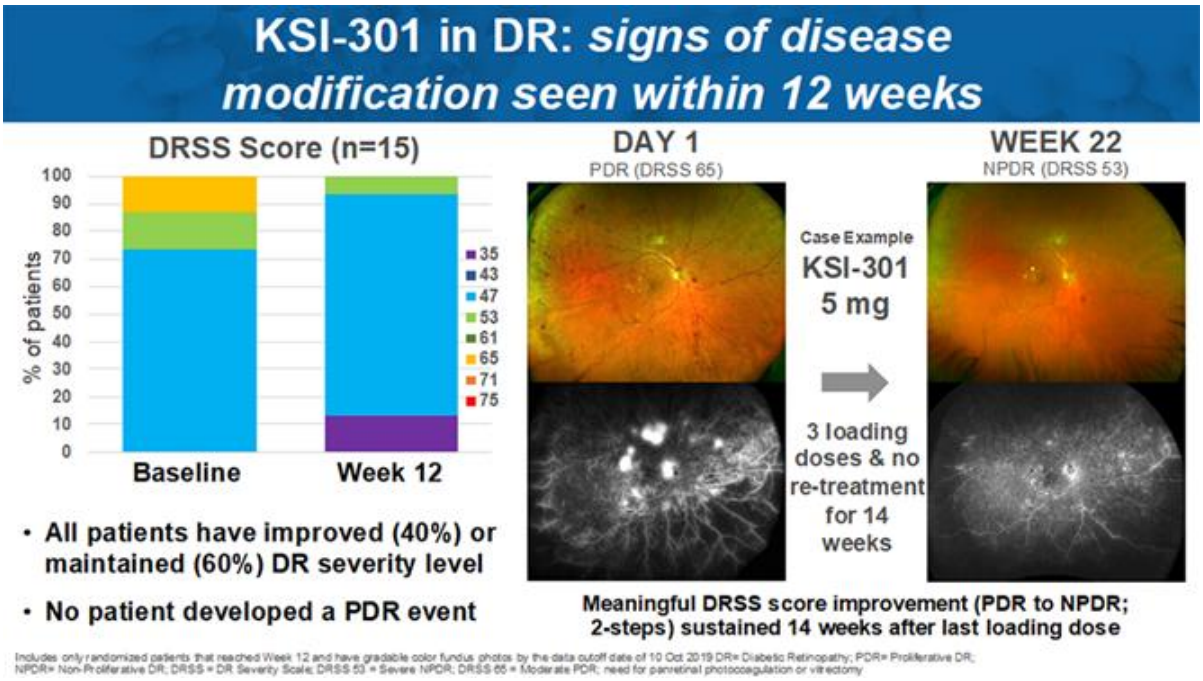


These data collectively demonstrate that KSI-301 has a potent anti-VEGF effect both on BCVA improvement and retinal drying in DME patients. The clinical benefit appears in line with existing anti-VEGF agents (especially when considering differences in baseline characteristics) and we are observing substantially longer durability of clinical effect with KSI-301 than with existing agents. Moreover, these results were achieved with fewer loading doses. These data support a pivotal study design where KSI-301 would be given on an every three- to six-month interval after three loading doses, compared to standard of care aflibercept on its approved every other month regimen after five loading doses.

Diabetic Retinopathy

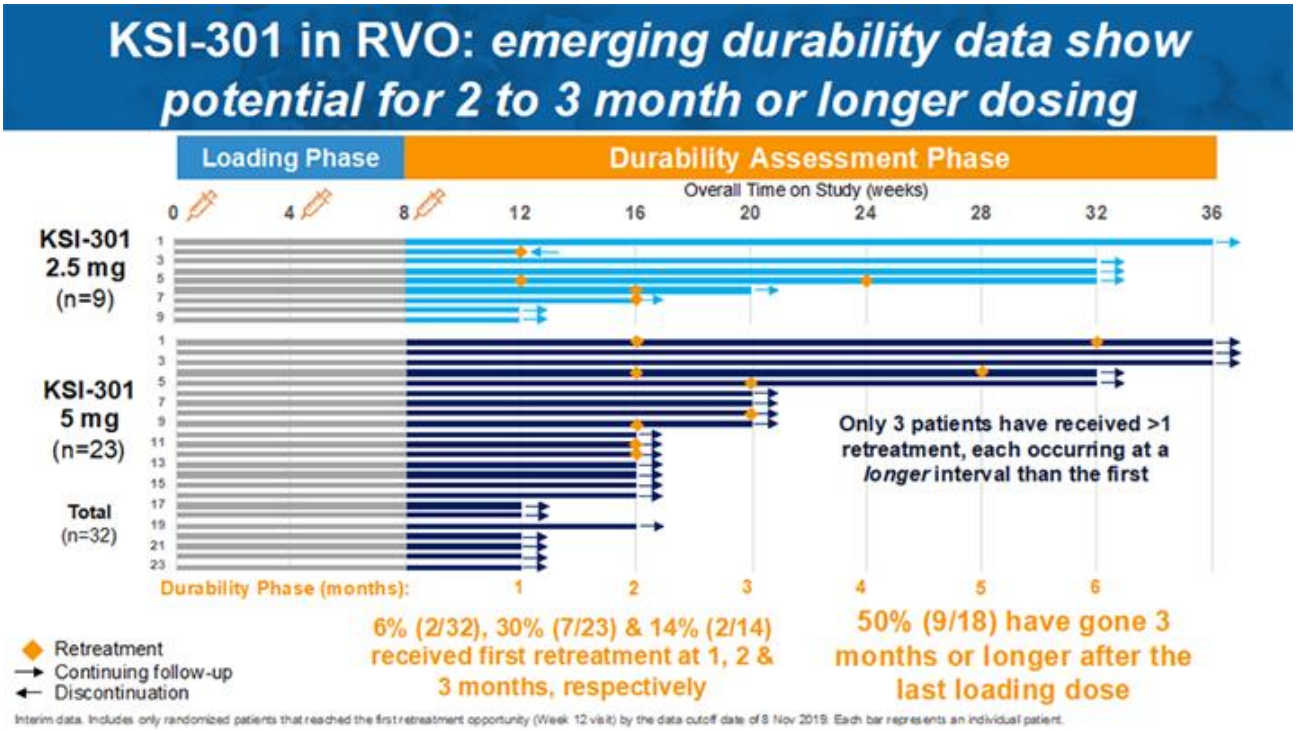
In DR, currently-approved medicines are labeled for either monthly or every other month dosing after five monthly loading doses. Use of anti-VEGF therapy in non-proliferative DR patients can significantly reduce the risk of developing sight-threatening complications, such as DME and proliferative DR. Because patients with non-proliferative DR without DME have not yet lost vision, an important benefit-risk consideration is the intensity of treatment required. We believe that the treatment burden required with currently-approved anti-VEGFs for DR is limiting the adoption of anti-VEGF therapy despite the demonstrated treatment benefits. Our objective with KSI-301 in NPDR is to develop a therapy that could be given on an infrequent basis, such as an every three-, four- or even every six-month interval, and without the loading doses required in the labeling of the currently-approved medicines.

In our Phase 1b study, we have observed early signs of improvement in diabetic retinopathy in the eyes of patients with concomitant DME: as of October 10, 2019, 40% of patients improved in DR severity level within the first 12 weeks of treatment and no patient worsening.

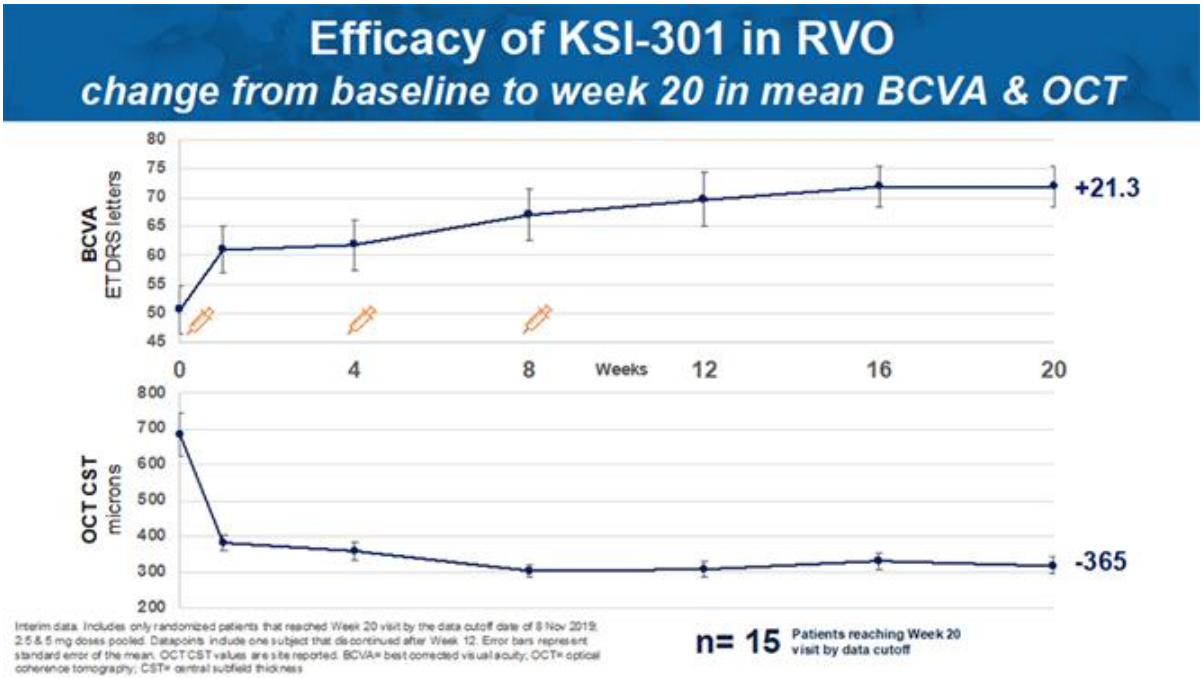


Retinal Vein Occlusion

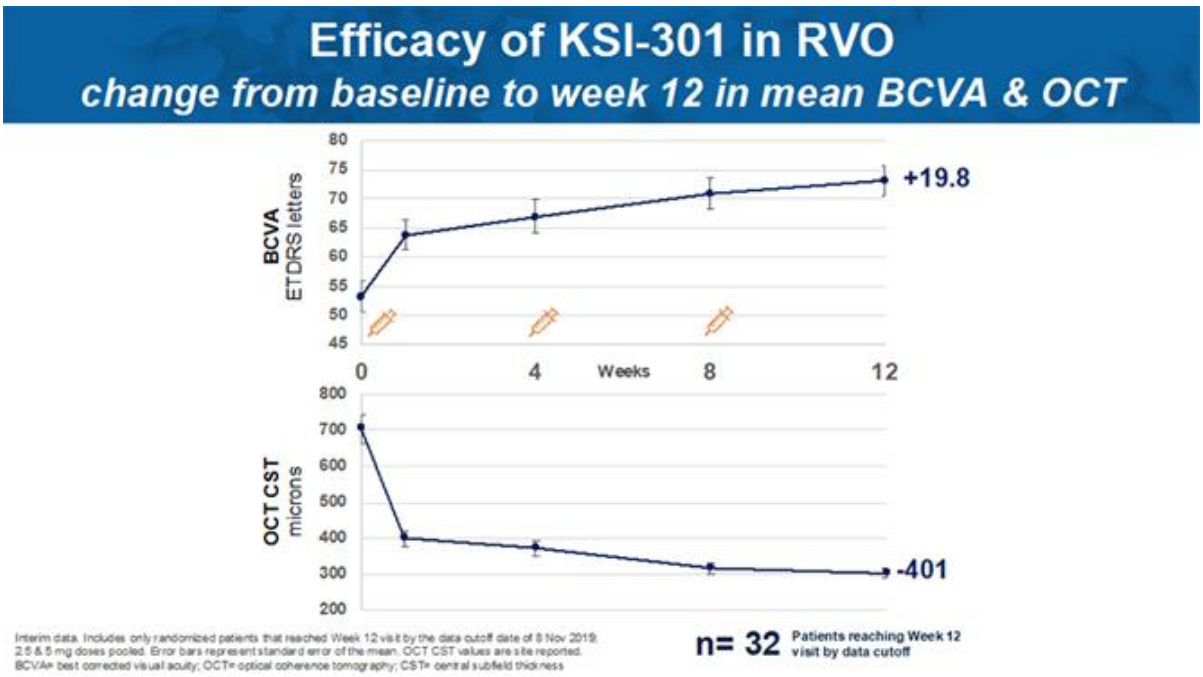
In RVO, a disease which has higher levels of intraocular VEGF on average than wet AMD and DME, the currently-approved medicines are labeled for monthly dosing. Moreover, a recent UK study in patients with central RVO demonstrated that less-than-monthly dosing can be associated with loss of maximal treatment effect on both OCT and VA outcomes. Our objective with KSI-301 in RVO is thus twofold: first, to reduce the number of initiating or loading doses, and second, to extend the treatment interval to 2 months and beyond. In our Phase 1b study, we have observed thus far that all RVO eyes treated with 5 mg KSI-301 have been extended to 2 months or longer after the last loading dose of KSI-301, with 50% of patients extended to 3 months or longer. The following results have been observed as of November 8, 2019:



Visual acuity and optical coherence tomography improvements continue to be durable in the follow-up data as well. In the following Figure, the 15 RVO patients (pooled 2.5 mg and 5 mg dose levels) who reached the week 20 visit prior to the data cutoff date of November 8, 2019 are included. In the period between week 12 and week 20 (that is, months 1 to 3 after the loading phase), the treatment effect is maintained, with only a small (9.5 micron) change in average central subfield thickness on OCT was observed, and between weeks 12 and 16 this change was only 21.6 microns, consistent with the observation that some patients required and received retreatment at week 16 (8 weeks after the last loading dose). This is consistent with the extended durability effect of KSI-301 and compares favorably existing anti-VEGF agents. Similarly, BCVA was also stable over these intervals, consistent with a prolonged duration of effect of KSI-301. An average improvement from baseline of +21.3 eye chart letters, which is over four eye chart lines, was observed at week 20.



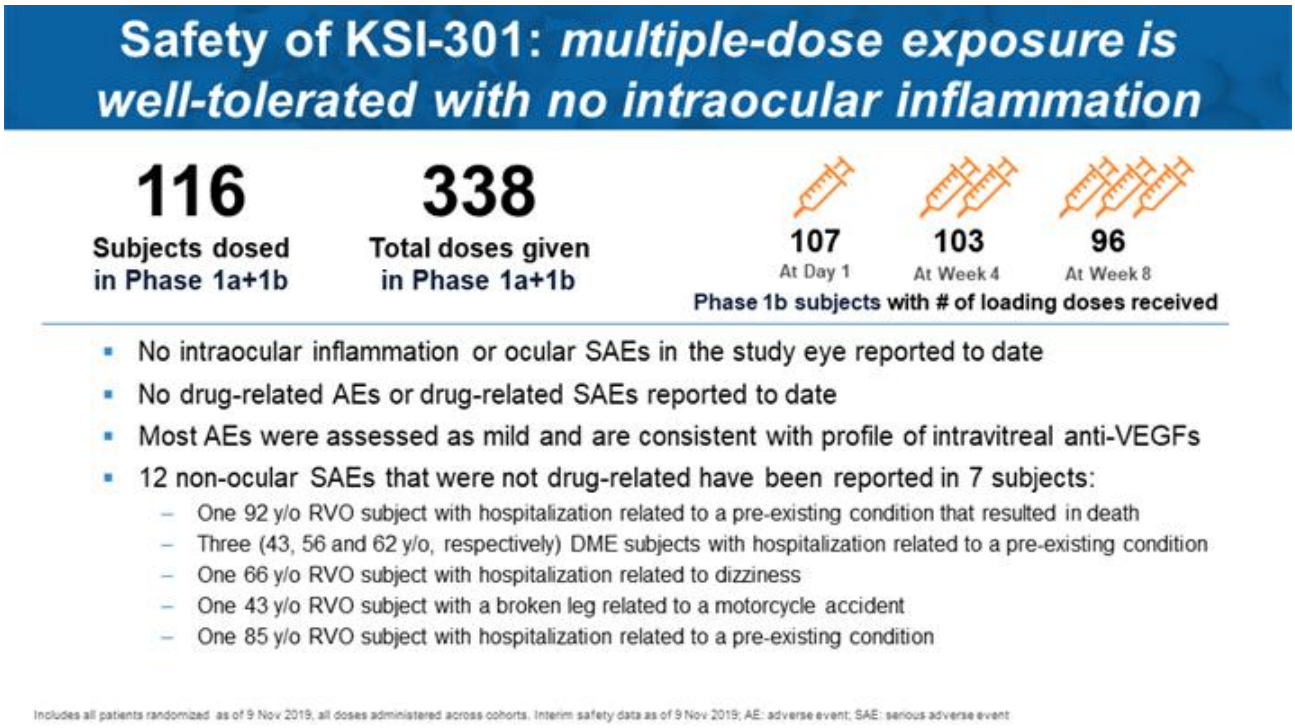
The data presented above includes patients who reached the week 20 visit by the data cut-off date. When considering the larger group of patients who have data through the first 12 weeks of the ongoing study, the following results have been observed:



These data collectively demonstrate that KSI-301 has a potent anti-VEGF effect both on BCVA improvement and retinal drying in RVO patients. The clinical benefit appears in line with existing anti-VEGF agents (especially when considering differences in baseline characteristics), with substantially longer durability than with existing agents, and the effects were achieved with fewer loading doses. These data support a pivotal study design where KSI-301 would be given on an every two month or longer interval, compared to standard of care aflibercept on its monthly regimen.

Safety of KSI-301 Injections

The safety profile of KSI-301 continues to be encouraging with no intraocular inflammation or study eye ocular serious adverse events reported across 338 injections given to 116 patients in the Phase 1a and Phase 1b program as of November 9, 2019. The systemic safety profile continues to be consistent with that expected for intravitreal anti-VEGF agents, as well.



Additionally, we have also started to evaluate anti-drug antibody (ADA) status in the Phase 1/1b program. As of October 28, 2019, a total of 362 samples from 103 subjects have been tested for the presence of ADAs. Only four samples from three subjects in Phase 1b were confirmed positive. These four samples all have low titers at or below the minimum required assay dilution. Of the 3/103 subjects testing positive, one subject tested positive at a low level at both Week 8 and Week 16. The second subject tested positive at a low level at Week 16, and no later time points have been tested yet. The third subject tested positive at a low level at Week 8 and was negative at Week 16. While the sample size is small, a review of the corresponding clinical and safety data for these three subjects did not show the ADA positivity to be correlated with loss of clinical efficacy (BCVA, OCT, earlier need for retreatment) or correlated with any ocular or non-ocular safety finding. Although these data are preliminary, they provide an additional window into the safety of KSI-301 as we accelerate the clinical development program.

Phase 1b Study Ongoing Status

We have extended the planned follow-up period of patients in the Phase 1b study from nine months to 18 months so that additional long-term durability and safety outcomes can be collected. We intend to continue to present ongoing safety, efficacy and durability data from the Phase 1b study at medical and investor meetings.

Accelerated Clinical Development Strategy for KSI-301

Based on the promising safety, efficacy and durability data observed to date in the Phase 1b study, we are accelerating the clinical development of KSI-301.

In the third quarter of 2019, we initiated enrollment in our pivotal DAZZLE clinical trial of KSI-301 in patients with treatment-naïve wet AMD. In this study, all patients will receive KSI-301 on an every three- to five- month dosing interval or standard-care aflibercept on an every two-month dosing interval, each after three initial monthly doses. We believe that an every three- to five- month dosing regimen with KSI-301 would represent a clinically-meaningful improvement compared to the currently-available standard of care for patients needing intraocular anti-VEGF therapy. A primary data readout is anticipated in 2021 depending on enrollment rates. This trial is currently recruiting patients in the United States and is additionally planned to enroll patients in several countries of the European Union as well as in Israel.

At our R&D Day event in October 2019, we announced our intention to initiate, in mid-2020, two Phase 3 studies of KSI-301 in RVO– one study in central RVO and one study in BRVO. These two studies would support an initial BLA for KSI-301 and could result in our achieving rapid market entry, because the primary endpoint for RVO studies is evaluated at six months.

Subsequently, in the fourth quarter of 2019, we held a Type B (EOP) meeting with FDA where we discussed and agreed upon the recommended clinical, non-clinical, and manufacturing activities to support the future licensure of KSI-301 in wet AMD, RVO, DME, and DR. In particular, we discussed and agreed with FDA on the sequence and number of clinical studies required to support an initial BLA and supplemental BLA to achieve approval in these four retinal diseases. FDA has indicated that approval in the four diseases of AMD, DME, RVO and DR without DME could be supported with a total of five pivotal trials – two in RVO, one in wet AMD, one in DME, and one in DR without DME. We also discussed with and received feedback from FDA on the designs of the proposed studies.

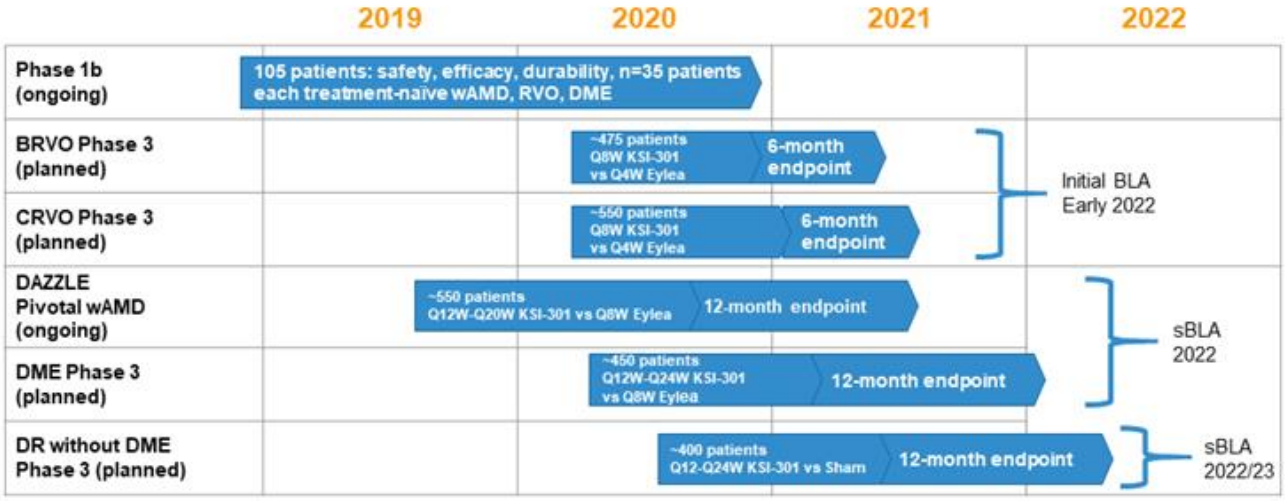
As a result of the supportive discussions with FDA, we now intend to initiate at least four US/EU-based pivotal trials in mid-2020: one in central RVO (CRVO), one in branch RVO (BRVO), one in DME, and one in DR without DME. These studies, together with our ongoing 'DAZZLE' pivotal study in wet AMD, will be the basis of our intended BLA and sBLA submissions. Each study will compare a differentiated KSI-301 dosing regimen head-to-head against standard of care: intravitreal anti-VEGF treatment in the case of wet AMD, DME, and RVO, and observation/sham injections for DR.

We believe the RVO studies can achieve primary data readouts in 2021 and support an initial BLA filing for KSI-301 in early 2022. We believe the DME study can achieve primary data readout in 2022 and, together with our DAZZLE wet AMD study, support a supplemental BLA for both DME and wet AMD in 2022. Likewise, we believe the DR study could achieve primary data readout in 2022 and support a supplemental BLA submission for DR in 2022 or 2023.

We are currently finalizing the designs of the RVO and DME Phase 3 studies following the discussions that we held with the FDA. For patients with RVO, we believe an every-other month or longer dose regimen for KSI-301, following two loading doses, can be meaningfully differentiated from that of other marketed and in-development anti-VEGF biologics that require monthly dosing in this disease. For patients with DME, we are planning a DAZZLE-like design, with all patients on an every 3-, 4-, 5- or 6- month regimen (after 3 monthly loading doses) compared to standard of care aflibercept dosed every 2 months (after 5 monthly loading doses). We believe this profile, with all patients on an every 3- month or longer dose regimen, can be meaningfully differentiated from that of other marketed and in-development anti-VEGF biologics.

We also expect to finalize the design of the DR Phase 3 study by early 2020. For DR patients, we believe that an every 3-, 4-, or 6- month regimen with no loading doses could offer an important and meaningfully-differentiated benefit for patients. Although anti-VEGF therapy is now approved in the US for DR, it is not standard of care for non-proliferative DR in most cases. Thus, a study of KSI-301 could compare against either placebo (sham injections) or anti-VEGF treatment.

Our anticipated US/EU clinical studies for KSI-301 are therefore as follows:



We additionally plan to initiate one or more clinical studies in China. We held our China pre-investigational new drug, or IND, meeting for KSI-301 with the China Center for Drug Evaluation, or CDE, in the second quarter of 2019. Based on this supportive meeting, as well as the progress with our clinical development of KSI-301 and the recent FDA feedback, we are now evaluating how the design and sequencing of our clinical studies in China can best support our China objectives and global objectives with the intention to submit one or more INDs for KSI-301 in China in the first quarter of 2020. The disease indications we explored in our pre-IND meeting included wet AMD, DME, and DR. Our IND submissions in China may include patients with wet AMD, DME/DR, RVO, and/or myopic CNV.

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 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 are evaluating investments in commercial manufacturing capacity. We do not have any products approved for sale and have not generated any product revenue since inception.

We have funded our operations primarily through the sale and issuance of equity securities. In October 2018, we completed our initial public offering, or IPO.

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 loss was $12.4 million and $31.7 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $142.5 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, RVO, DME or DR without DME or delay our efforts to advance and expand our product pipeline.

As of September 30, 2019, we had cash and cash equivalents and marketable securities of $60.6 million. Refer to the going concern evaluation under Note 1 to our unaudited condensed consolidated financial statements included in this report.

On November 1, 2019, we filed a shelf registration statement on Form S-3 (File No. 333-234443) with the SEC covering the offer and sale of the Company’s securities up to $400.0 million for a period up to three years from the date of effectiveness of the shelf registration statement.

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 continue to initiate and advance our Phase 2 studies, complete our clinical programs, 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 or our manufacturing activities, we could be required to expend significant additional financial resources and time on the completion of clinical development and launch-related manufacturing activities. 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 requirements of the stock exchange listing and the SEC, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists of interest income earned on investments for the three and nine months ended September 30, 2019 and 2018.

Interest Expense

Interest expense consists primarily of interest expense related to our convertible notes, including amortization of debt discount and debt issuance costs, for the three and nine months ended September 30, 2018. The convertible notes converted into shares of common stock upon the closing of our IPO.

Other Income (Expense), Net

Other income (expense), net consists of changes in the fair value of preferred stock warrants and derivative instruments for the three and nine months ended September 30, 2018. The preferred stock warrants converted into common stock warrants and the derivative liability was extinguished upon our IPO.

Results of Operations

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Operating expenses:						
Research and development	$ 10,115	$ 4,709	$ 5,406	$ 24,676	$ 11,942	$ 12,734
General and administrative	2,617	1,671	946	8,330	5,075	3,255
Loss from operations	(12,732)	(6,380)	(6,352)	(33,006)	(17,017)	(15,989)
Interest income	354	—	354	1,265	—	1,265
Interest expense (includes $1,076 and $2,944 attributable to related parties for the three and nine months ended September 30, 2018, respectively)	(2)	(1,982)	1,980	(8)	(5,329)	5,321
Other income (expense), net (includes $1,129 and $2,714 other expense attributable to related parties for the three and nine months ended September 30, 2018, respectively)	—	(2,090)	2,090	—	(4,435)	4,435
Net loss	$ (12,380)	$ (10,452)	$ (1,928)	$ (31,749)	$ (26,781)	$ (4,968)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated, in thousands:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
ABC Platform external expenses (1)	$ 440	$ 364	$ 76	$ 1,911	$ 912	$ 999
KSI-301 program external expenses (2)	5,808	1,684	4,124	11,691	5,173	6,518
KSI-501 program external expenses (3)	300	—	300	1,120	—	1,120
Payroll and personnel expenses (4)	2,898	2,075	823	8,147	4,288	3,859
Other research and development expenses (5)	669	586	83	1,807	1,569	238
Total research and development expenses	$ 10,115	$ 4,709	$ 5,406	$ 24,676	$ 11,942	$ 12,734

(1) ABC Platform external expenses primarily relates to manufacturing of biopolymer intermediate drug substance which can be used with multiple product candidates. These expenses are primarily for services provided by CMOs and CROs.

(2) KSI-301 program external expenses relates to development of KSI-301, including manufacturing and clinical trial costs. These expenses are primarily for services provided by CMOs and CROs.

(3) KSI-501 program external expenses relates to research and development of KSI-501.

(4) Payroll and personnel expenses includes salaries, benefits and stock-based compensation for our personnel involved in research and development activities. These expenses are separately classified and not allocated to specific programs because these expenses relate to multiple programs.

(5) Other research and development expenses includes direct costs related to research and development activities other than those listed above.

ABC Platform external expenses increased $0.1 million and $1.0 million during the three and nine months ended September 30, 2019, respectively, as compared to 2018. The increase was primarily driven by manufacturing runs to support our product candidate pipeline.

KSI-301 program external expenses increased $4.1 million and $6.5 million during the three and nine months ended September 30, 2019, respectively, as compared to 2018. The increase was primarily due to clinical trial costs as well as manufacturing runs for KSI-301.

KSI-501 program external expenses increased $0.3 million and $1.1 million during the three and nine months ended September 30, 2019, respectively, due to ongoing research and development of KSI-501.

Payroll and personnel expenses increased $0.8 million and $3.9 million during the three and nine months ended September 30, 2019, respectively, as compared to 2018. The increase was a result of increased headcount and stock-based compensation expense.

Other research and development expenses remained relatively constant during the three and nine months ended September 30, 2019 as compared to 2018. Our other research and development expenses may fluctuate in future periods as we elect to develop other product candidates.

General and Administrative Expenses

General and administrative expenses increased $0.9 million during the three months ended September 30, 2019 as compared to 2018. The increase in general and administrative expenses was primarily attributable to increases of $0.6 million in salaries, including stock-based compensation, and $0.3 million in insurance fees associated with operating as a public company.

General and administrative expenses increased $3.3 million during the nine months ended September 30, 2019 as compared to 2018. The increase in general and administrative expenses was primarily attributable to increases of $1.5 million in salaries, including stock-based compensation, $0.8 million in insurance fees and $1.0 million in professional services and costs associated with operating as a public company.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

We have funded our operations primarily through the sale and issuance of common stock, redeemable convertible preferred stock, convertible notes and warrants. In October 2018, we completed our IPO.

As of September 30, 2019, we had cash and cash equivalents and marketable securities of $60.6 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of September 30, 2019, our funds are primarily held in corporate notes, commercial paper and money market accounts.

Future Funding Requirements

We have incurred net losses since our inception. For the three and nine months ended September 30, 2019, we had net loss of $12.4 million and $31.7 million, respectively, and we expect to continue to incur additional losses in future periods. As of September 30, 2019, we had an accumulated deficit of $142.5 million. Refer to the going concern evaluation under Note 1 to our unaudited condensed consolidated financial statements included in this report.

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.

To date, we have not generated any product revenue. We do not expect to generate any product 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.

We have based our 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 report titled “Part II, Item 1A — Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,	
	2019	**2018**
Net cash (used in) provided by:		
Operating activities	$ (27,853)	$ (20,691)
Investing activities	(23,715)	(56)
Financing activities	347	30,942
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (51,221)	$ 10,195

Cash Flows from Operating Activities

The $7.2 million increase in cash used in operating activities for the nine months ended September 30, 2019 as compared to 2018 was primarily driven by the increase in net loss during this period due to increased payroll and personnel expenses and manufacturing and clinical trial costs to support overall growth and by the change in other assets due to long-term advance payments for clinical trials.

Cash Flows from Investing Activities

The $23.7 million increase in cash used in investing activities for the nine months ended September 30, 2019 as compared to 2018 was driven by the net purchase of marketable securities.

Cash Flows from Financing Activities

The $30.6 million decrease in cash provided by financing activities for the nine months ended September 30, 2019 as compared to 2018 was due to the issuance of convertible debt in February 2018 offset by an increase in cash used for deferred offering costs related to our IPO.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations” in our Annual Report on Form 10-K for the year ended December 31, 2018. There have been no material changes in our contractual obligations and commitments since December 31, 2018.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these 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 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 three and nine months ended September 30, 2019, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 27, 2019, except as otherwise described in Note 2 to our unaudited condensed consolidated financial statements included in this report.

We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development;
- stock-based compensation expense; and
- income taxes.

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 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 this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate and foreign currency sensitivities. Our investment portfolio is used to preserve capital until it is required to fund operations, including research and development activities, and consists of money market funds, commercial paper, and corporate notes which would be affected by changes in the general level of U.S. interest rates. Due to the short-term maturities and low-risk profile of our investment portfolio, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our investments.

We do not believe that inflation and fluctuations in interest rates and foreign exchange rates had a significant impact on our results of operations for any period 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 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 SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, 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 officer, evaluated the effectiveness of our disclosure controls and procedures at the end of the period covered by this report. Based upon such evaluation, our principal executive officer and principal financial 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

During the nine months ended September 30, 2019, we implemented certain internal controls as a result of our adoption of the new lease standards on January 1, 2019. There were no other changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in 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 consider carefully the following risk factors, together with all the other information in this report, including the section of this report titled "Part I, Item 2 — Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed financial statements and notes thereto. The occurrence of any events described in the following risk factors and the risks described elsewhere in this report could harm our business, operating results, financial condition, and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements that we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

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 have enrolled over 100 patients with wet AMD, DME, or RVO in our Phase 1b multiple-dose clinical trial of KSI-301 and we are currently enrolling wet AMD patients in our Phase 2 'DAZZLE' clinical trial of KSI-301. We have not initiated clinical trials for any of our other product candidates. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product, 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 loss of $12.4 million and $31.7 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $142.5 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' equity 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, 2019, we had cash and cash equivalents and marketable securities of $60.6 million. Refer to the going concern evaluation under Note 1 to our unaudited condensed consolidated financial statements included in this report.

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 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.

As of September 30, 2019, we had cash and cash equivalents and marketable securities of $60.6 million. Refer to the going concern evaluation under Note 1 to our unaudited condensed consolidated financial statements included in this report. Our estimate as to how long we expect our existing cash and cash equivalents and marketable securities 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.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

As of September 30, 2019, we had cash and cash equivalents and marketable securities of $60.6 million. We expect these available cash resources to fund our existing operational commitments and objectives at least through the first half of 2020. The uncertainties inherent in our future operations and in our ability to obtain additional funding raise substantial doubt about our ability to continue as a going concern beyond one year from the date of filing this report. If we are unable to obtain sufficient funding, we may be forced to delay or reduce the scope of our development programs and clinical trials, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

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 our Phase 1a clinical trial of KSI-301 in July 2018, reached the primary endpoint in September 2018, and completed the last patient visit of that study in November 2018. Subsequently, beginning in December 2018, we have enrolled over 100 patients in our Phase 1b clinical trial of KSI-301 and continue to follow those patients for safety, efficacy and durability. In the third quarter of 2019, we began enrollment in our pivotal Phase 2 ‘DAZZLE’ study and the first patients were dosed in October 2019. It may be years before the pivotal trials required for approval are 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, Phase 1a, and ongoing Phase 1b 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 1a clinical trial was designed to evaluate safety and tolerability of KSI-301 after single doses, and our ongoing Phase 1b clinical trial was designed to evaluate safety, efficacy and durability of KSI-301 after multiple doses. Although the trials have yielded early evidence of safety, efficacy and durability, the data derive from a small number of subjects (a total of 113 as of October 10, 2019), and we expect that our pivotal trials will have materially different design parameters. For example, our Phase 1a and Phase 1b trials do not evaluate durability of KSI-301 across the planned 12-, 16- or 20- week dosing intervals in exactly the same manner as we are evaluating in our Phase 2 wet AMD trial. 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 late-stage 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 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 IND application 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 CROs 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 CMOs 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, DME/DR and RVO. 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 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 of this report 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 educate adequate numbers of physicians on the benefits of prescribing 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 Europe, China and other foreign countries. 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.

Since the ACA's enactment, there have been, and continue to be, numerous challenges to the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. In addition, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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, due to subsequent legislative amendments to the statute, 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.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contain further price control measures that could be enacted during the budget process or in other future legislation. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has started implementing some of these measures under its existing authority. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. 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, including the False Claims Act, which can be enforced by private citizens on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws, which impose criminal and civil penalties 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 Centers for Medicare & Medicaid 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; state and local laws that require the registration of pharmaceutical sales representatives; 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 significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, 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 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 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 "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 September 30, 2019, we had 34 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 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, it could result in a material disruption of our development programs and our business operations, whether due to a loss of 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 third-party research institution collaborators, CROs, other contractors and consultants for many aspects of our business, including research and development activities and manufacturing of our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business.

The secure maintenance of information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past few years, cyber-attacks have become more prevalent and much harder to detect and defend against.

Our network and storage applications and those of our collaborators, CROs and vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by them. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our employees. Cyber-attacks could cause us to incur significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our collaborators, CROs and vendors may not be adequate to protect against such security breaches and disruptions. 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.

The expected withdrawal of the United Kingdom from the EU, commonly referred to as "Brexit," may cause increased economic volatility, affecting our operations and business. Brexit may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

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, 2018, we had federal net operating loss carryforwards, or NOLs, of $21.9 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. 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.

Risks Related to Ownership of Our Common Stock

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 “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 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 could reduce the market price of our common stock. Approximately 27.5 million shares, or 74.5% of our shares outstanding after our IPO were prohibited from resale pursuant to the terms of lock-up agreements entered into by our stockholders with the underwriters in our IPO; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, the resale restrictions applicable to these shares pursuant to the lock-up agreements lapsed in April 2019.

Moreover, holders of an aggregate of approximately 13.3 million 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 all 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. 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 60.2% of our outstanding common stock as of September 30, 2019. 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 a "smaller reporting company," and the reduced disclosure requirements applicable us may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in 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 Section 404 of the Sarbanes-Oxley Act of 2002, or SOX, 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. In addition, to the extent that we continue to qualify as a "smaller reporting company," as defined in the Exchange Act, we may choose to provide the scaled disclosure available to smaller reporting companies. As a result, the information we provide stockholders may 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 continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX, 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 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 costly. 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 continually 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 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 SOX. 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 do not meet certain of The Nasdaq Stock Market continued listing requirements and therefore, we risk delisting, which may decrease our stock price and make it harder for our stockholders to trade our stock.

As previously disclosed, on October 4, 2019, we notified by The Nasdaq Stock Market that we were not in compliance with Nasdaq Listing Rule 5605(c)(2)(A), which requires the Audit Committee our board to consist of at least three independent directors. We have made a timely request for an appeal before the Nasdaq Hearings Panel, which is scheduled for November 21, 2019. The request for an appeal automatically stayed any suspension or delisting action pending the issuance of the decision of the Nasdaq Hearings Panel, and our board is committed to filling the third independent director position on the Audit Committee and to gain compliance with the audit committee composition requirements under Nasdaq Listing Rule 5605(c)(2)(A) in advance of the Nasdaq Hearings Panel.

There can be no assurance that the Nasdaq Hearings Panel will provide any grace period for compliance beyond the hearing date, or that we will be able to gain compliance with the Nasdaq Listing Rules. Also, we cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on The Nasdaq Stock Market. If The Nasdaq Stock Market delists our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We have broad discretion in the use of proceeds from any offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds received from any offering. Our management may spend a portion or all of the net proceeds from any offering 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 any offering in a manner that does not produce income or that loses value.

Delaware law and provisions in our certificate of incorporation and bylaws 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 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:

- 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 of 1933, as amended.

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. Our bylaws further provide that unless we otherwise consent in writing, 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, which we refer to as the Federal Forum Provision. However, on December 19, 2018, the Delaware Chancery Court issued an opinion in *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL, finding that provisions similar to the Federal Forum Provision are not valid under Delaware Law. As previously disclosed in a Current Report on Form 8-K we filed on January 28, 2019, in light of the *Sciabacucchi* decision, we do not currently intend to enforce the foregoing federal forum selection provision unless the *Sciabacucchi* decision, which is currently on appeal before the Delaware Supreme Court, is reversed. If the Delaware Supreme Court affirms the Chancery Court's decision, then we intend to amend the Bylaws to remove the invalid provision. Such amendment could cause us to incur additional costs, which could have an adverse effect on our business, financial condition or results of operations.

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

Recent Sales of Unregistered Securities

During the three months ended September 30, 2019, we issued 1 share of common stock through the exercise of 1 common stock warrant priced at $0.01 per share. The issuance of the common stock upon the cash exercise of the common stock warrant 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 share of common stock or common stock warrant.

Use of Proceeds from Registered Securities

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 $83.5 million, inclusive of the partial over-allotment option exercise, after deducting underwriting discounts and commissions and other offering costs. 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.

There has been no material change in the planned use of the net proceeds from our initial public offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 5, 2018.

Purchases of Equity Securities by the Issuer

None.

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
4.2	Investors' Rights Agreement, dated September 8, 2015, as amended, by and among the registrant and the investors and founders named therein	S-1/A	333-227237	4.2	9/24/2018
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal 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 attached as Exhibits 32.1 and 32.2 are deemed "furnished" and not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, 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 12, 2019 By: /s/ Victor Perlroth

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

Date: November 12, 2019 By: /s/ John Borgeson

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

Exhibit 31.1

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

I, 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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

5. The registrant's other certifying officer(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 12, 2019

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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

5. The registrant's other certifying officer(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 12, 2019

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, 2019 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 results of operations of the Company.

Date: November 12, 2019

By: /s/ Victor Perlroth

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

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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, 2019 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 results of operations of the Company.

Date: November 12, 2019 By: /s/ John Borgeson

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

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Kodiak Sciences Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.