UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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.)**
1200 Page Mill Road **Palo Alto, CA**	**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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 29, 2021, the registrant had 51,717,286 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", "hope" 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 continued durability, efficacy and safety of our product candidates;
- the portfolio of clinical trials planned for submission in our Biologics License Application, or BLA, of KSI-301;
- our ability to present clinical data across our pivotal trials beginning in early 2022;
- our and Lonza's ability to successfully execute on our manufacturing development plan;
- 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 a BLA in wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, retinal vein occlusion, or RVO, and diabetic retinopathy, or DR;
- our expectations regarding chemistry manufacturing and controls, or CMC, requirements of the United States Food and Drug Administration, or FDA, and other regulatory bodies to support our BLA submission and potential commercial launch;
- the timing or likelihood of regulatory filings and approvals, including the potential to achieve FDA approval of KSI-301 in wet AMD, DME, RVO 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;
- our expectation as to the concentration of retinal specialists in the United States and its impact on our sales and marketing plans;
- our expectations regarding our ability to enter into manufacturing-related commitments, and the timing thereof;
- 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 estimates regarding the impact of the novel coronavirus, or COVID-19, pandemic on our business and operations, the business and operations of our collaborators, and on the global economy;
- our aspirational goals and objectives related to our human capital resources and workforce objectives;
- our ability to attract and retain key managerial, scientific and medical personnel;
- the accuracy of our estimates regarding the sufficiency of our cash resources, expenses, future revenue, capital requirements and needs for additional financing; and
- our financial performance.

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. and its subsidiaries.

SELECTED RISKS AFFECTING OUR BUSINESS

Investing in our common stock involves numerous risks, including the risks described in "Part II—Other Information, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, among others, the following:

- We are in the 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 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.
- 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.
- Our prospects are heavily dependent on our KSI-301 product candidate, which is currently in clinical development for multiple indications.
- A failure of KSI-301 in clinical development may require us to discontinue development of other product candidates based on our ABC Platform.
- 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 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.
- We may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.
- Our clinical trials may fail to demonstrate substantial evidence of the durability, efficacy and safety of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- 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 manufacture of our product candidates is highly complex and requires substantial lead time to produce.
- 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 ability to provide the information needed in the regulatory dossiers for our BLA filing, or our ability to supply our products for patients, if approved, could be delayed or stopped, or we may be unable to establish a commercially viable cost structure.
- The regulatory approval processes of the FDA, EMA, NMPA 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.
- We plan to conduct clinical trials for our product candidates outside the United States, and the FDA, EMA, NMPA and applicable foreign regulatory authorities may not accept data from such trials.
- Our business is subject to complex and evolving U.S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.
- 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 expect to rely on third parties to conduct many aspects of 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.

- 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.
- 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.
- 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.
- 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.
- 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 business is currently affected and could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and could materially and adversely affect our operations, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business. Our manufacturers are also engaged in the manufacturing of COVID-19 related vaccines and therapeutic treatments, and the success of and demand for these vaccines and therapeutic treatments means we and our programs are competing for scarce manufacturing resources.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 799,247	$ 944,396
Marketable securities	—	24,578
Prepaid expenses and other current assets	6,259	3,031
Total current assets	805,506	972,005
Restricted cash	6,324	6,324
Property and equipment, net	22,939	5,136
Operating lease right-of-use asset	68,450	73,672
Other assets	54,987	10,210
Total assets	$ 958,206	$ 1,067,347
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,761	$ 8,646
Accrued and other current liabilities	39,016	20,402
Operating lease liability	1,619	2,374
Total current liabilities	54,396	31,422
Operating lease liability, net of current portion	77,338	75,028
Liability related to sale of future royalties	99,929	99,890
Other liabilities	223	256
Total liabilities	231,886	206,596
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.0001 par value, 490,000,000 shares authorized at September 30, 2021 and December 31, 2020; 51,698,775 and 51,112,302 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5	5
Additional paid-in capital	1,191,367	1,151,920
Accumulated other comprehensive income	—	53
Accumulated deficit	(465,052)	(291,227)
Total stockholders' equity	726,320	860,751
Total liabilities and stockholders' equity	$ 958,206	$ 1,067,347

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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 56,002	$ 29,306	$ 141,743	$ 70,033
General and administrative	11,533	7,357	32,259	19,132
Total operating expenses	67,535	36,663	174,002	89,165
Loss from operations	(67,535)	(36,663)	(174,002)	(89,165)
Interest income	40	645	270	2,551
Interest expense	(6)	(6)	(17)	(19)
Other income (expense), net	(25)	(98)	(76)	120
Net loss	$ (67,526)	$ (36,122)	$ (173,825)	$ (86,513)
Net loss per common share, basic and diluted	$ (1.30)	$ (0.80)	$ (3.36)	$ (1.92)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	51,875,315	45,119,885	51,722,611	44,972,085
Other comprehensive income (loss)				
Change in unrealized gains related to available-for-sale debt securities, net of tax	—	(349)	(53)	235
Total other comprehensive income (loss)	—	(349)	(53)	235
Comprehensive loss	$ (67,526)	$ (36,471)	$ (173,878)	$ (86,278)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	51,112,302	$ 5	$ 1,151,920	$ 53	$ (291,227)	$ 860,751
Issuance of common stock upon exercise of stock options	113,559	—	1,483	—	—	1,483
Stock-based compensation expense	—	—	9,925	—	—	9,925
Other comprehensive loss	—	—	—	(35)	—	(35)
Net loss	—	—	—	—	(50,447)	(50,447)
Balances at March 31, 2021	51,225,861	5	1,163,328	18	(341,674)	821,677
Issuance of common stock upon exercise of stock options	131,276	—	2,228	—	—	2,228
Issuance of common stock upon vesting of restricted stock units, net of taxes withheld	72,976	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plans	4,295	—	305	—	—	305
Stock-based compensation expense	—	—	11,087	—	—	11,087
Other comprehensive loss	—	—	—	(18)	—	(18)
Net loss	—	—	—	—	(55,852)	(55,852)
Balances at June 30, 2021	51,434,408	5	1,176,948	—	(397,526)	779,427
Issuance of common stock upon exercise of stock options	103,585	—	2,042	—	—	2,042
Issuance of common stock upon vesting of restricted stock units, net of taxes withheld	10,799	—	—	—	—	—
Issuance of common stock upon exercise of common stock warrants	149,983	—	—	—	—	—
Stock-based compensation expense	—	—	12,377	—	—	12,377
Net loss	—	—	—	—	(67,526)	(67,526)
Balances at September 30, 2021	51,698,775	$ 5	$ 1,191,367	$ —	$ (465,052)	$ 726,320

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	44,413,404	$ 5	$ 503,475	$ 10	$ (158,131)	$ 345,359
Issuance of common stock upon exercise of stock options	39,297	—	159	—	—	159
Stock-based compensation expense	—	—	6,082	—	—	6,082
Other comprehensive income	—	—	—	479	—	479
Net loss	—	—	—	—	(24,392)	(24,392)
Balances at March 31, 2020	44,452,701	5	509,716	489	(182,523)	327,687
Issuance of common stock upon exercise of stock options	203,373	—	720	—	—	720
Issuance of common stock upon vesting of restricted stock units, net of taxes withheld	10,942	—	(206)	—	—	(206)
Stock-based compensation expense	—	—	6,890	—	—	6,890
Other comprehensive income	—	—	—	105	—	105
Net loss	—	—	—	—	(25,999)	(25,999)
Balances at June 30, 2020	44,667,016	5	517,120	594	(208,522)	309,197
Issuance of common stock upon exercise of stock options	93,497	—	813	—	—	813
Stock-based compensation expense	—	—	8,241	—	—	8,241
Other comprehensive loss	—	—	—	(349)	—	(349)
Net loss	—	—	—	—	(36,122)	(36,122)
Balances at September 30, 2020	44,760,513	$ 5	$ 526,174	$ 245	$ (244,644)	$ 281,780

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,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (173,825)	$ (86,513)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	722	317
Stock-based compensation	33,389	21,213
Amortization (accretion) of premium (discount) on marketable securities	25	(145)
Amortization of operating lease right-of-use asset	5,811	1,793
Amortization of issuance costs	39	36
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(3,228)	1,518
Other assets	(936)	(3,654)
Accounts payable	3,255	1,616
Accrued and other current liabilities	10,547	7,566
Operating lease liability	966	(156)
Net cash used in operating activities	(123,235)	(56,409)
Cash flows from investing activities		
Purchase of property and equipment	(8,598)	(1,855)
Deposits on property and equipment	(43,841)	—
Purchase of marketable securities	—	(86,317)
Maturities of marketable securities	24,500	134,148
Net cash provided by (used in) investing activities	(27,939)	45,976
Cash flows from financing activities		
Proceeds from issuance of common stock upon options exercise	5,753	1,692
Payments for restricted stock units, net of taxes withheld	—	(206)
Proceeds from issuance of common stock pursuant to employee stock purchase plans	305	—
Proceeds from sale of future royalties, net of issuance costs	—	99,643
Principal payments of capital lease	—	(5)
Principal payments of tenant improvement allowance payable	(33)	(28)
Net cash provided by financing activities	6,025	101,096
Net increase (decrease) in cash, cash equivalents and restricted cash	(145,149)	90,663
Cash, cash equivalents and restricted cash, at beginning of period	950,720	211,937
Cash, cash equivalents and restricted cash, at end of period	$ 805,571	$ 302,600
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets		
Cash and cash equivalents	$ 799,247	$ 291,585
Restricted cash	6,324	11,015
Cash, cash equivalents and restricted cash in consolidated balance sheets	$ 805,571	$ 302,600
Supplemental disclosures of non-cash investing and financing information:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 583	$ 75,545
Purchase of property and equipment under accounts payable and accruals	$ 10,730	$ 1,034

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 committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases in the United States and additional international markets. The Company devotes substantially all of its resources to the research and development of its product platforms and product candidates including activities to conduct clinical studies of its product candidates, manufacture product candidates and provide general and administrative support for these operations.

Liquidity

As of September 30, 2021, the Company had cash and cash equivalents of $799.2 million. Although the Company has incurred significant operating losses since inception and expects to continue to incur operating losses and negative operating cash flows for the foreseeable future, the Company believes that the cash and cash equivalents will be sufficient to meet the anticipated operating and capital expenditure requirements for the 12 months following the date of this Form 10-Q.

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. The condensed consolidated financial statements, in the opinion of management, include all normal and recurring adjustments 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, 2020 and notes thereto, the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 1, 2021. 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. The results of operations for any interim period are not necessarily indicative of the results for the year ending December 31, 2021, 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.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation. Such reclassifications had no impact on subtotals in the prior year condensed consolidated financial statements.

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. The impact of the ongoing COVID-19 pandemic continues to evolve. As a result, certain estimates and assumptions required increased judgment and carried a higher degree of variability and volatility, including but not limited to, the fair value of marketable securities, performance-based equity awards, and research and development accruals for the three and nine months ended September 30, 2021. As events continue to unfold and additional information becomes available, these estimates may change materially in future periods. Actual results could differ from those estimates.

Risks and Uncertainties

In March 2020, the World Health Organization declared a pandemic due to the global COVID-19 outbreak. The significant uncertainties caused by the ongoing COVID-19 pandemic may negatively impact the Company's operations, liquidity, and capital resources and will depend on certain evolving developments, including the duration and spread of the outbreak, regulatory and private sector responses and the impact on employees and vendors including supply chain and clinical partners, all of which are uncertain and cannot be predicted. During this pandemic, the Company continues to work closely with clinical sites towards maximal patient safety and the lowest number of missed visits and study discontinuations. The Company has taken and continues to take proactive measures to maintain the integrity of its ongoing clinical studies. Despite these efforts, the ongoing COVID-19 pandemic could significantly impact clinical trial enrollment and completion of its clinical studies. During this pandemic, the Company continues to work closely with its manufacturing suppliers, partners and facilities to maintain the supply of its product candidates needed for the expansion of clinical trials and to retain the number, scale and design of manufacturing runs that regulatory authorities may require to obtain marketing approval, including those required to support a BLA submission. Despite these efforts, the ongoing COVID-19 pandemic could significantly impact the timing or likelihood of clinical resupply and of regulatory filings and approvals. The Company will continue to monitor the COVID-19 situation and its impact on the ability to continue the development of, and seek regulatory approvals for, the Company's product candidates, and begin to commercialize any approved products.

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, 2021, respectively, 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, 2020, except as noted within the "Recent Accounting Pronouncements – Recently Adopted Accounting Pronouncements" section.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), under its Accounting Standards Codification 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 October 2020, the FASB issued Accounting Standards Update 2020-10, *Codification Improvements*, which updates various codification topics and disclosure requirements to improve alignment with the SEC's regulations. The Company adopted this new guidance as of January 1, 2021, and this guidance did not have a material impact on its consolidated financial statements and related disclosures.

New Accounting Pronouncements Not Yet Adopted

The Company continues to monitor new accounting pronouncements issued by the FASB. All other newly issued accounting pronouncements issued through the date of this report have been deemed either immaterial or not applicable.

3. Accrued and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Accrued clinical trial and related costs	$ 21,762	$ 11,119
Accrued leasehold improvements	7,470	19
Accrued salaries and benefits	4,790	5,094
Accrued research and development	3,392	3,082
Accrued legal fees	582	252
Accrued professional fees	223	253
Accrued other liabilities	797	583
Total accrued and other current liabilities	$ 39,016	$ 20,402

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, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 762,550	$ —	$ —	$ 762,550
Total	$ 762,550	$ —	$ —	$ 762,550

	Fair Value Measurements at December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 917,485	$ —	$ —	$ 917,485
Marketable securities:				
U.S. treasury securities	—	10,006	—	10,006
Corporate notes	—	14,572	—	14,572
Total	$ 917,485	$ 24,578	$ —	$ 942,063

As of September 30, 2021 and December 31, 2020, the fair value of the liability related to sale of future royalties is based on the Company's current estimates of future royalties expected to be paid to Baker Bros. Advisors, LP ("BBA"), which are considered Level 3 inputs.

5. Marketable Securities

The marketable securities are classified as available-for-sale and consist of U.S. treasury securities and corporate notes. 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 Company had no marketable securities at September 30, 2021. The following table summarizes the marketable securities (in thousands):

As of December 31, 2020	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasury securities	$ 10,003	$ 3	$ —	$ 10,006
Corporate notes	14,522	50	—	14,572
Total marketable securities, current	$ 24,525	$ 53	$ —	$ 24,578

All marketable securities held at December 31, 2020 had effective 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 three and nine months ended September 30, 2021, respectively and, as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss. As of September 30, 2021 and December 31, 2020, the Company had no allowance for credit losses for available-for-sale debt securities. There were no impairment charges or recoveries recorded during each of the nine months ended September 30, 2021 and September 30, 2020, respectively.

6. Commitments and Contingencies

Embedded Lease

In August 2020, the Company and its wholly-owned subsidiary Kodiak Sciences GmbH entered into a manufacturing agreement with Lonza Ltd ("Lonza") for the clinical and commercial supply of drug substance for KSI-301. A custom-built manufacturing facility is planned to be completed and dedicated to the manufacture of the Company's drug substance. The manufacturing agreement has an initial term of eight years, and the Company has the right to extend the term up to a total of 16 years. The Company and Lonza each have the ability to terminate this agreement upon the occurrence of certain conditions.

In April 2021, the agreement was amended to provide for higher annual manufacturing capacity. The Company expanded and finalized the design and scope of the bioconjugate manufacturing facility with a revised estimated capital contribution of approximately 75.0 million Swiss Francs of which the Company has paid 35.0 million Swiss Francs of the capital contribution, equivalent to $38.7 million U.S. Dollars, which is recorded in other assets on the consolidated balance sheet as of September 30, 2021. Over the period from 2022 through 2029, manufacturing payments totaling approximately 150.0 million Swiss Francs may be incurred for potential commercial supply of KSI-301 drug substance.

The Company concluded that this agreement contains an embedded lease as the custom-built manufacturing suite will be dedicated for the Company's use. As of September 30, 2021, the Company did not have control of this manufacturing space and therefore, did not record a right-of-use asset and corresponding lease liability.

Manufacturing Agreements

The Company has entered into service and equipment purchase agreements in the normal course of business with various providers, pursuant to which such providers agreed to perform activities in connection with the manufacturing process of certain materials. These agreements, and any related amendments, state that planned activities and purchases that are included in the signed work orders are, in some cases, binding and, hence, obligate the Company to pay the full price of the work order upon satisfactory delivery of products and services or obligate the Company to the binding amount regardless of whether such planned activities are in fact performed. Per the terms of the agreements, the Company has the option to cancel signed orders at any time upon written notice, which may or may not be subject to payment of a cancellation fee. The level of cancellation fees may be dependent on the timing of the written notice in relation to the commencement date of the work, with the maximum cancellation amount dependent on the agreement or the work order.

Other Funding Commitments

In the normal course of business, the Company enters into agreements with third-parties for services to be provided to the Company. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the applicable agreement. The actual amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of services to be provided to the Company.

The Company has also entered into various cancellable license agreements for certain technology. The Company may be obligated to make payments on future sales of specified products associated with such license agreements. Such payments are dependent on future product sales and are not estimable.

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 2021 and 2020, the number of shares of common stock available for issuance under the 2018 Equity Incentive Plan (the "2018 Plan") was increased by approximately 2.0 million and 1.8 million shares, respectively, 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 (the "2015 Plan") is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	6,897,276	$ 24.52	8.07	$ 841,704
Granted	1,478,994	$ 94.80		
Exercised	(348,420)	$ 17.06		
Forfeited or canceled	(228,118)	$ 41.86		
Outstanding at September 30, 2021	7,799,732	$ 37.62	7.74	$ 431,288

Restricted Shares

Restricted share activity, including restricted stock awards, restricted stock units, and performance-based restricted stock units, under the 2018 Plan and 2015 Plan is summarized as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2020	359,945	$ 59.54
Granted	170,150	$ 90.75
Vested	(83,775)	$ 57.98
Canceled	(34,033)	$ 61.24
Unvested at September 30, 2021	412,287	$ 72.59

Performance-Based Stock Options and Restricted Stock Units

The Company granted 669,581 performance-based stock options during the nine months ended September 30, 2021 (the "2021 PSAs"). The Company did not grant any performance-based equity awards during 2020. The Company granted 170,150 performance-based options and 128,900 performance-based restricted stock units to employees in 2019 (the "2019 PSAs").

The performance-based equity awards granted will vest one-quarter upon the achievement of specific clinical development milestones. The remaining shares will then vest ratably over three years thereafter. Performance-based stock options and performance-based restricted stock units are recorded as expense beginning when vesting events are determined to be probable.

The milestone for the 2019 PSAs was achieved during the second quarter of 2021. As of September 30, 2021, 42,536 performance-based stock options and 28,905 performance-based restricted stock units granted during 2019 have vested. The Company believes that the achievement of the requisite performance condition for 2021 PSAs granted in the first quarter of 2021 continues to be probable.

Stock-based compensation expense recognized was $2.1 million and $8.3 million during the three and nine months ended September 30, 2021, respectively, and $1.8 million and $5.5 million during the three and nine months ended September 30, 2020, respectively.

2018 Employee Share Purchase Plan

In August 2018, the Company adopted the 2018 Employee Share Purchase Plan ("ESPP"), which became effective on the business day prior to the effectiveness of the registration statement relating to the Company's initial public offering. A total of 460,000 shares of common stock were initially reserved for issuance under the ESPP. The initial offering period of the ESPP was authorized by the Company's board of directors and commenced on January 4, 2021. Each offering period is approximately twelve months long, with two purchase periods. ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the enrollment date or (2) the fair market value of the common stock on the exercise date.

The Company issued no shares and 4,295 shares under the ESPP during the three and nine months ended September 30, 2021, respectively. The stock-based compensation expense related to the ESPP was less than $0.1 million and $0.2 million during the three and nine months ended September 30, 2021, respectively.

Stock-Based Compensation Expense

Stock-based compensation for options, restricted shares, and ESPP 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,	
	2021	2020	2021	2020
Research and development	$ 6,429	$ 4,759	$ 17,598	$ 11,983
General and administrative	5,948	3,482	15,791	9,230
Total stock-based compensation	$ 12,377	$ 8,241	$ 33,389	$ 21,213

As of September 30, 2021, total unrecognized compensation cost related to the unvested share-based awards and ESPP was $122.4 million, which is expected to be recognized over a weighted-average period of 2.8 years.

8. Net Loss per Common Share

The following common share equivalents were excluded from the computation of diluted net loss per common share for the periods presented because their inclusion would have been antidilutive:

	As of September 30,	
	2021	2020
Outstanding stock options	7,799,732	7,238,363
Unvested restricted shares	412,287	363,195
Total	8,212,019	7,601,558

9. Subsequent Events

On October 13, 2021, stockholders of the Company approved the Kodiak Sciences Inc. 2021 Long-Term Performance Incentive Plan (the "LTPIP") as described in the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on September 13, 2021. Stock options were granted under the LTPIP, contingent on stockholder approval of the LTPIP, to named executive officers and other eligible employees at the vice president level who made a one-time election to participate in the LTPIP and agreed to forgo a portion of their annual long-term incentive awards over the seven-year performance period ending on August 11, 2028. A total of 5,502,334 shares of common stock were reserved for issuance under the LTPIP.

The options can be earned based on the achievement of the performance-based requirement and/or certain operational milestones. The performance-based requirement consists of seven tranches of options that are earned based on meeting or exceeding stock price goals between $200 and $800 per share for 90 consecutive trading days.

Up to 35% of the options may be earned through the attainment of certain operational milestones to the extent that number of options has not yet been earned from stock appreciation. A participant may earn up to 25% upon approval by the U.S. Food and Drug Administration of a Biologics License Application for KSI-301 in the three major anti-VEGF indications and up to 10% from generating sales of at least $2.5 billion in a fiscal year. Once earned, options are subject to a service-based requirement and will vest through the remainder of the seven-year performance period in equal monthly installments.

Performance-based stock options totaling 1,920,625 with the same terms and conditions as the LTPIP were also granted to employees below the vice president level under the 2018 Plan. These stock option awards were also contingent on stockholder approval of the LTPIP. As discussed above, the LTPIP was approved by the stockholders of the Company on October 13, 2021.

The Company is currently evaluating the LTPIP approved in October 2021 and its accounting impact as a modification of the portion of the annual long-term incentive awards granted in 2021 that were foregone.

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, 2020, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 1, 2021. 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

Since its founding in 2009, Kodiak Sciences Inc. ("Kodiak," the "Company," "we" or "our") has developed a new technology platform for retinal medicines. Our goal is to prevent and treat the major causes of blindness by developing and commercializing next-generation therapeutics for chronic, high-prevalence retinal diseases.

Kodiak has progressed its lead investigational therapy, KSI-301, into six registrational clinical trials. The comprehensive clinical program targets high prevalence anti-VEGF dependent retinal diseases with studies designed as a package to support a broad product label, which we hope will include the key diseases and the longest dosing intervals. KSI-301 is being developed as a first line therapy for use in any patient who may benefit from anti-VEGF therapy. At the same time, Kodiak is investing in commercial scale manufacturing with a capacity goal to supply 100% of today's branded anti-VEGF market. We hope to be able to provide a pre-filled syringe early in commercialization, with a stretch goal of having this available at launch. Combining these ambitious clinical and manufacturing efforts sets the stage for early market share capture when and if KSI-301 is approved.

In addition, Kodiak is investing in its pipeline. The Company is progressing its Antibody Biopolymer Conjugate (or ABC) Platform™ towards suboptimal anti-VEGF responder patients, a group as large as 30% of treated patients, with its bispecific conjugate KSI-501. And beyond today's anti-VEGF market, Kodiak's new triplet medicines are being designed on its ABC Platform in an effort to bring new capabilities to treat the retina in the even higher prevalence diseases of dry AMD and glaucoma.

Notably, up to this point, Kodiak has retained all global rights to make, use and sell its products, preserving future value and allowing for agile decision-making.

While engaged in these research and development efforts, the Company has also demonstrated a disciplined and creative approach to building and financing the company, so Kodiak today is well capitalized with more than $799.2 million in cash as of September 30, 2021.

Our objective is to develop our retina-focused product candidates, seek FDA and worldwide health authority marketing authorization approvals, and ultimately commercialize our product candidates.

Following from these efforts, we believe Kodiak has the potential to achieve our ambition of becoming a significant incumbent retinal development and commercialization franchise on a global basis.

Recent Updates

KSI-301 Clinical Program Highlights

We are engaged in a broad development program for KSI-301 with concurrent late-stage development activities across all of the major disease indications for which intravitreal anti-VEGF therapies are used and have made considerable progress in prosecuting the KSI-301 pivotal study program over this past quarter. We expect to include the results of all our pivotal clinical trials in wet AMD, DME and RVO in a single initial BLA. The ambitious program for KSI-301 reflects our conviction in KSI-301 (and our ABC Platform) and seeks labeling at launch that is supportive of a broad range of individualized dosing intervals, from every 4-week dosing up to once every 20-week dosing for wet AMD patients; from every 4-week dosing up to once every 24-week dosing for DME patients; and from every 4-week dosing up to once every 8-week dosing for RVO patients.

- DAZZLE – Phase 2b/3 Study in Patients with Treatment-Naïve Wet Age-Related Macular Degeneration (Wet AMD)

  The Phase 2b/3 DAZZLE study is a global, multi-center, randomized pivotal study designed to evaluate the durability efficacy and safety of KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on an individualized dosing regimen as infrequently as every five months and no more often than every three months or to receive aflibercept on its labeled every eight-week dosing regimen, each after three monthly initiating doses.

We initiated the DAZZLE pivotal study in October 2019 and completed enrollment in November 2020 with over 550 patients enrolled globally. We expect the last patient's primary endpoint visit to occur in the fourth quarter of 2021 and to announce topline data in the first quarter of 2022.

- BEACON – Phase 3 Study in Patients with Treatment-Naïve Retinal Vein Occlusion (RVO)

We began enrolling patients into BEACON in the third quarter of 2020. With over 475 patients randomized, we believe we are on track to complete enrollment into BEACON before the end of this year. Based on the 24-week primary endpoint for BEACON, we expect to announce topline data in mid-2022.

- GLEAM / GLIMMER – Paired Phase 3 Studies in Patients with Treatment-Naïve Diabetic Macular Edema (DME)

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized pivotal studies designed to evaluate the durability, efficacy and safety of KSI-301 in patients with treatment-naïve diabetic macular edema (DME). In each study, patients are randomized to receive either intravitreal KSI-301 on an individualized dosing regimen every eight to 24 weeks after only three loading doses or intravitreal aflibercept every eight weeks after five loading doses per its label. Each study is expected to enroll approximately 450 patients worldwide. The primary endpoint for both studies is at one year, and patients will be treated and followed for a total of two years.

We initiated GLEAM and GLIMMER in the third quarter of 2020. Continued elevated COVID-19 transmission rates globally have impacted enrollment rates for patients with treatment naïve DME. With GLEAM more than two-thirds enrolled and GLIMMER more than three-quarters enrolled, we expect to complete enrollment in the first quarter of 2022.

- DAYLIGHT – Phase 3 Study in Patients with Treatment-Naïve Wet AMD

The Phase 3 DAYLIGHT study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of high-frequency KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on a monthly dosing regimen or to receive standard-of-care aflibercept. The study is expected to enroll approximately 500 patients worldwide. The primary endpoint is at 40 weeks, and the study is being planned and executed to allow for inclusion of its results in the initial BLA for KSI-301.

In June 2021, we randomized the first patients into DAYLIGHT. Study enrollment has been strong with recruitment now underway both in the US and EU. Additional global study sites will be activated through the fourth quarter of 2021, and we believe we can complete enrollment in the first half of 2022.

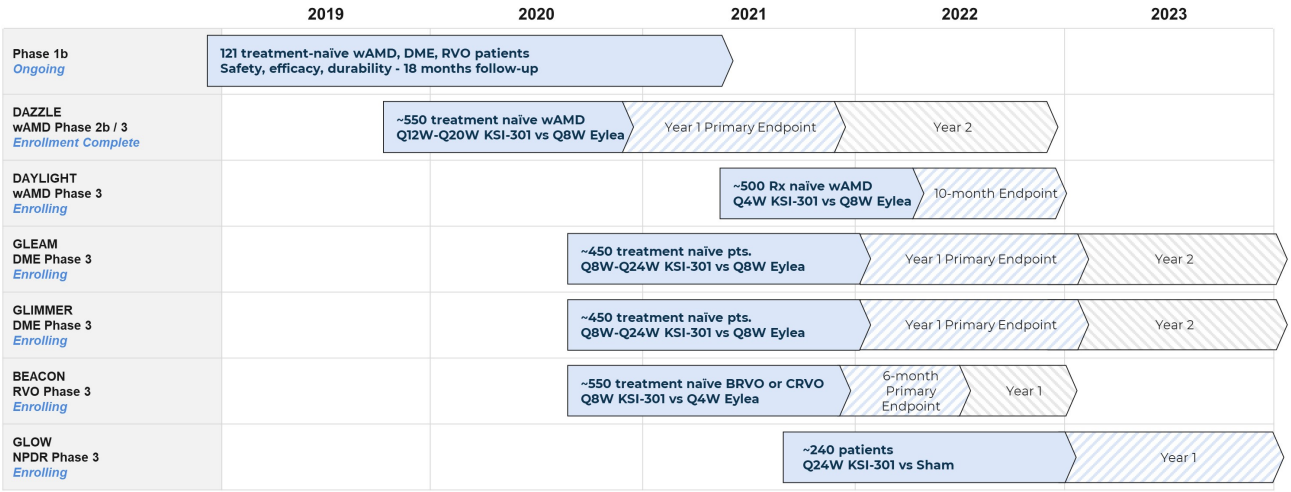
- GLOW – Phase 3 Study in Patients with Non-Proliferative Diabetic Retinopathy without DME

We began screening patients into GLOW in the second quarter of 2021 and randomized the first patients in September. We are not planning for this study and indication to be included in our initial BLA filing given our expectations for a longer recruitment timeframe. We are excited to be recruiting patients in this chronic, more preventive disease indication and believe KSI-301 can be a new longest-interval therapeutic option for patients with diabetic retinopathy.

To date, we are pleased with the continued operational progress across our pivotal program. We believe we are on track for a series of KSI-301 topline data readouts beginning in early 2022 with DAZZLE in the first quarter of 2022, BEACON in mid-2022 and then DAYLIGHT and GLEAM/GLIMMER tracking towards early 2023.

KSI-301 Development Strategy

5 Pivotals to support initial BLA with all 3 major anti-VEGF indications (NPDR in sBLA)



KODIAK

RVO: retinal vein occlusion; BRVO: branch RVO; CRVO: central RVO; wAMD: wet age-related macular degeneration; DME: diabetic macular edema; DR: diabetic retinopathy; FPI: first patient in

Our KSI-301 pivotal program is designed to support a full range of individualized dosing regimens and we hope to position KSI-301 to be the therapy of choice for all patients with retinal vascular disease and which can meet the distinct needs of patients, physicians, caregivers and payors.

KSI-301 program includes a wide range of dosing intervals to maximize flexibility and reimbursement confidence for physicians and patients

KODIAK

1. NCT04049266. 2. NCT04964089. 3. NCT04611152 and NCT04603937. 4. NCT04592419. 5. NCT05066230 6. Based on study design; sBLA: supplemental BLA

Kodiak Stockholder Approval of the Kodiak 2021 Long-term Performance Incentive Plan (LTPIP)

On August 12, 2021, the Board of Directors of Kodiak Sciences Inc. approved the Kodiak 2021 Long-Term Performance Incentive Plan (LTPIP), subject to approval by Kodiak stockholders. The LTPIP was approved by Kodiak's stockholders on October 13, 2021, with 75% of all votes cast voting in favor of approving the LTPIP, excluding votes cast by any participant in the LTPIP.

We believe the LTPIP aligns management incentives to significant value creation. The plan covers the next seven years and was open to a significant number of our existing employees – not just senior management. Employees had a one-time opportunity to "opt-in" to the plan by agreeing to forego up to 75% of their annual equity incentive compensation for the next seven years via a one-time election. Shares can be earned based on significant stock price appreciation over the seven-year performance period, with the possibility to earn up to 35% of the award based on achieving substantive operational goals. Earned awards begin vesting once earned and vest through the remainder of the seven-year period in equal monthly increments, ensuring what we believe is a true long-term incentive program.

China INDs

In March 2021, our investigational new drug (IND) applications for KSI-301 in RVO and DME were approved by China's National Medicinal Products Administration (NMPA). The IND approval allows Kodiak to enroll patients from China into the BEACON and GLIMMER studies; we believe that inclusion of patients from China in these studies could be beneficial for the potential future approval of KSI-301 in China.

The first Chinese patients are expected to be randomized in the fourth quarter of 2021. We are excited to embark on this important milestone in China as we believe there is substantial clinical unmet need in China for the type of long-interval dosing which KSI-301 and our ABC Platform may provide.

KSI-301 Phase 1b Study

In February 2021, we presented Year 1 durability, efficacy and safety data from our ongoing Phase 1b trial of KSI-301 in patients with treatment naïve wet AMD, DME or RVO at the Angiogenesis, Exudation, and Degeneration 2021 – Virtual Edition meeting. The data showed 2 in every 3 patients are on a 6-month or longer treatment-free interval at Year 1 in each of the three major retinal vascular diseases after only three loading doses. Robust vision gains (particularly notable in the context of very good baseline vision) and robust retinal drying (when baseline anatomical characteristics are considered) were seen across all three diseases being studied. Strong anti-VEGF efficacy (achieving at Year 1 approximately 20/40 eye chart vision on average in wet AMD and approximately 20/32 vision on average in DME and RVO) and an encouraging safety profile continued to be observed across all three diseases. We believe the data support the "anti-VEGF Generation 2.0" profile of KSI-301.

Track Record of KSI-301 Safety

We believe the safety profile of KSI-301 continues to be very encouraging. In the pivotal study program, in which the data remain masked (blinded) as the studies are ongoing, we estimate that over 4,500 KSI-301 injections have been given. Additionally, more than 750 injections have been given in the open-label Phase 1a/1b program. The total safety database now includes an estimated >800 patient-years of exposure to KSI-301. Our ongoing reviews of safety data from the open-label Phase 1b study and the masked pivotal studies continue to suggest that the safety of KSI-301 is tracking with the expectations set by the safety profile of the current standard of care intravitreal medicines.

COVID-19

We are continuing to monitor the global ongoing COVID-19 pandemic. We and our key clinical and manufacturing partners have been able to continue to advance our operations. Through this pandemic, we continue to work closely with our clinical sites towards patient safety and low number of missed visits and study discontinuations. The overall rate of missed study visits remains <5%.

In response to the COVID-19 pandemic with regards to business operations, clinical trials, and manufacturing activities, we have taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention, or CDC, and the State of California to protect the health and safety of our employees and our community.

We will continue to monitor the COVID-19 situation closely. The ultimate impact of the ongoing COVID-19 pandemic on our business operations remains uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. See also the section titled "Risk Factors" for additional information on risks and uncertainties related to the evolving COVID-19 pandemic.

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 conduct our Phase 3 clinical studies, complete our clinical program, pursue regulatory approval of our drug candidates and prepare for a possible commercial launch. Predicting the timing or the final cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our drug candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with requirements of the stock exchange listing and Securities and Exchange Commission, or SEC, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Other Income (Expense), Net

Other income (expense), net consists primarily of accretion income and amortization expense on marketable debt securities net of amortized issuance costs from the liability related to the future sale of royalties to BBA in 2019.

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,		
	2021	2020	Change	2021	2020	Change
Operating expenses						
Research and development	$ 56,002	$ 29,306	$ 26,696	$ 141,743	$ 70,033	$ 71,710
General and administrative	11,533	7,357	4,176	32,259	19,132	13,127
Loss from operations	(67,535)	(36,663)	(30,872)	(174,002)	(89,165)	(84,837)
Interest income	40	645	(605)	270	2,551	(2,281)
Interest expense	(6)	(6)	—	(17)	(19)	2
Other income (expense), net	(25)	(98)	73	(76)	120	(196)
Net loss	$ (67,526)	$ (36,122)	$ (31,404)	$ (173,825)	$ (86,513)	$ (87,312)

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,		
	2021	2020	Change	2021	2020	Change
KSI-301 program expenses	$ 38,371	$ 15,415	$ 22,956	$ 89,557	$ 37,587	$ 51,970
KSI-501 program expenses	951	453	498	4,357	922	3,435
ABC Platform and other program expenses	1,745	2,174	(429)	5,173	5,345	(172)
Payroll and personnel expenses	10,679	8,104	2,575	30,483	20,850	9,633
Facilities and other research and development expenses	4,256	3,160	1,096	12,173	5,329	6,844
Total research and development expenses	$ 56,002	$ 29,306	$ 26,696	$ 141,743	$ 70,033	$ 71,710

KSI-301 program expenses increased $23.0 million and $52.0 million during the three and nine months ended September 30, 2021, respectively, as compared to 2020. The increase was primarily due to clinical trial costs to support ongoing trials, as well as manufacturing progress for KSI-301. We initiated two pivotal Phase 3 clinical studies in DME (GLEAM and GLIMMER) and one pivotal Phase 3 clinical study in RVO (BEACON) in the third quarter of 2020. In June 2021, we randomized the first patients into an additional Phase 3 study in wet AMD (DAYLIGHT) designed to broaden KSI-301's product labeling.

KSI-501 program increased $0.5 million and $3.4 million during the three and nine months ended September 30, 2021, respectively, as compared to 2020, primarily due to increased research and development activities for KSI-501.

Payroll and personnel expenses increased $2.6 million and $9.6 million during the three and nine months ended September 30, 2021, respectively, as compared to 2020, due to increased headcount and stock-based compensation expense.

Facilities and other research and development expenses increased $1.1 million and $6.8 million during the three and nine months ended September 30, 2021, respectively, as compared to 2020, primarily due to lease costs for our Palo Alto and Switzerland facilities expansion.

General and Administrative Expenses

General and administrative expenses increased $4.2 million and $13.1 million during the three and nine months ended September 30, 2021, respectively, as compared to 2020, primarily driven by increased headcount and stock-based compensation expense, professional services related to consulting, legal and accounting, and lease costs for Palo Alto facilities expansion.

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, warrants and the sale of royalties. As of September 30, 2021, we had cash and cash equivalents of $799.2 million.

Future Funding Requirements

We have incurred net losses since our inception. For the three and nine months ended September 30, 2021, we had net loss of $67.5 million and $173.8 million, respectively, and we expect to continue to incur additional losses in future periods. As of September 30, 2021, we had an accumulated deficit of $465.1 million.

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.

We have based these estimates on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. The timing and amount of our operating expenditures and capital requirements will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; 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.

The significant uncertainties caused by the evolving effects of the ongoing COVID-19 pandemic may also negatively impact our operations and capital resources. We and our key clinical and manufacturing partners have been able to continue to advance our operations, and we continue to monitor the impact of COVID-19 on our ability to continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. This pandemic may ultimately have a material adverse effect on our liquidity and operating plans, although we are unable to make any prediction with certainty given the spread and rapidly changing nature of the pandemic and the evolving global actions taken to contain and treat the novel coronavirus.

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 for each of the periods presented below, in thousands:

	Nine Months Ended September 30,	
	2021	**2020**
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (123,235)	$ (56,409)
Investing activities	(27,939)	45,976
Financing activities	6,025	101,096
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (145,149)	$ 90,663

Cash Flows from Operating Activities

Net cash used in operating activities was $123.2 million for the nine months ended September 30, 2021, primarily attributable to a net loss during this period due to increased payroll and personnel expenses and manufacturing and clinical trial costs to support overall growth. Cash used in operating activities was also driven by changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $27.9 million for the nine months ended September 30, 2021, primarily related to maturities of marketable securities net of purchases of and deposits related to property and equipment during the quarter.

Cash Flows from Financing Activities

Net cash provided by financing activities was $6.0 million for the nine months ended September 30, 2021, primarily due to the proceeds from stock option exercises and proceeds from issuances of common stock pursuant to employee stock purchase plans.

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, 2020, which was filed with the SEC on March 1, 2021. There have been no material changes in our contractual obligations and commitments since December 31, 2020, except as otherwise described in Note 6 to our unaudited condensed consolidated financial statements included in this report.

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 nine months ended September 30, 2021, 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, 2020, which was filed with the SEC on March 1, 2021, except as otherwise described in Note 2 to our unaudited condensed consolidated financial statements included in this report.

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.

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.

During the nine months ended September 30, 2021, there were no material changes to our market risk disclosures as reported in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 1, 2021.

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.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2021. Based upon such evaluation, our principal executive officer and principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2021.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

You should 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 the Discovery, Development and Commercialization of Our Product Candidates

Our prospects are heavily dependent on our KSI-301 product candidate, which is currently in clinical development for multiple indications.

KSI-301 is our only product candidate currently in clinical trials. It may be years before a registrational-type trial is completed, if at all. Further, we cannot be certain that either KSI-301 or any of our product candidates will be successful in clinical trials.

Our early encouraging preclinical and Phase 1/1b clinical trial results for KSI-301 in the respective indications are not necessarily predictive of the results of our ongoing or future discovery programs or any future preclinical or clinical studies. Our ability to demonstrate efficacy, safety and clinical durability in pivotal studies may be affected by the patient populations sampled and the design of our pivotal 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 or unobserved adverse events as more patients are treated with KSI-301 and followed for longer periods of time.

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. If approved, KSI-301 clinical study designs and data are not necessarily predictive of KSI-301's final marketed product label. FDA may not approve a label for once every five or six months even if we believe the data demonstrate that type of durability.

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 such as KSI-501 and KSI-601 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 on 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 receive regulatory approval in one or more of our four planned key clinical indications 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;
- If a product candidate obtains regulatory approval, approval may be for indications, dosage and administration or patient populations that are not as broad as intended or desired;
- 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, for example a positive benefit-risk profile;
- 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 occurs, 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 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 in time to meet the current and identified market opportunity. 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, dosage and administration 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, China National Medical Products Administration, or NMPA, 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, NMPA or any other regulatory authority concerns about risk to patients of the technology broadly; or if the FDA, EMA, NMPA 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, NMPA 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 and for use in regulatory filings 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, NMPA 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, NMPA 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. We may also face delays if we are unable to reach agreement with the FDA, EMA, NMPA or other regulatory authorities regarding CMC matters, including methodologies for, and assessment of, comparability of manufacturing procedures and lots.

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, NMPA 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. For example, the safety profile we have observed in the Phase 1a/1b study of KSI-301 and in the masked (blinded) pivotal data thus far may not be representative of the safety profile we observe when data is unmasked. We may still observe significant safety events that may negatively impact the KSI-301 program and the ABC platform. Even with a safety database through pivotal studies of approximately 1,500 patients, a safety profile for KSI-301 in line with today’s standard of care agents may not be sustained when administered to 100,000s of patients at varying dose intervals after commercialization.

Our most advanced product candidate, KSI-301, is an anti-VEGF biologic that we are studying 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, vasculitis, artery occlusion 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, as attributable to molar dose. 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. KSI-301 is also being explored clinically with higher frequency dosing**.** Although not predicated with today's standard of care agents historically, higher frequency dosing may increase the risk of potential adverse events. Our expectation is for KSI-301 to be used at high frequency (for example, monthly dosing) in a minority of patients, yet any additional toxicology signal observed, be it real or perceived, may negatively impact perceptions of KSI-301 in broader populations and impact clinical trial enrollment, regulatory approval and commercial success.

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 REMS 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 effects of health epidemics, including the ongoing COVID-19 pandemic and the resulting shelter-in-place, travel or similar restrictions;
- the design of the trial;
- new safety events may cause physicians to decrease patient enrollment in our studies;
- 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 or trials of a different design could be required before we submit our product candidates for approval. Our KSI-301 pivotal study program relies on a single active arm in each study at a single dose (5 mg), such that if a safety observation is observed there is no fallback position at a lower dose to rely on. 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. Even if trial results are successful at the primary endpoint, clinical trial results may be different or worse in the extended treatment periods following the primary endpoint, and such data may negatively impact perceptions by regulatory authorities, the clinical community or commercial payors of the benefits of our product candidate.

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, DME/DR, and RVO. 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, Regeneron and Novartis for the treatment of wet AMD, DME/DR, and RVO. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to educate these parties on the benefits of switching 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, AbbVie/Allergan, Mylan, Momenta, and Samsung Bioepis. 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.

The first Lucentis biosimilar was approved this year in the USA, and its approval may impact market dynamics and payor policies negatively for KSI-301. Roche's product candidate, faricimab, was filed for approval in May 2021 for wet AMD and DME and is currently enrolling pivotal studies in RVO. We believe faricimab's clinical profile together with physician enthusiasm for a new branded anti-VEGF will make it an important product in the marketplace. Even if KSI-301 presents a compelling clinical profile, we may not be able to market our product candidates as effectively as our competitors. For example, entrenched franchises may seek to impede adoption of KSI-301 through significant discounts or rebates.

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, NMPA 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 the manufacture of multiple components that require a diverse knowledge base and specialized personnel. Commercial manufacturing scale-up timelines may be negatively affected by material shortages, construction delays and supply chain challenges due to, among other factors, global supply chain shortages due to COVID-19 or other reasons.

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.

We rely on third parties for raw materials needed for manufacturing KSI-301. We may not be able to obtain adequate amounts in the future. 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, the United States and Switzerland. For example, the effects of health epidemics, including the ongoing COVID-19 pandemic and the resulting shelter-in-place, travel or similar restrictions may impact the timing of clinical resupply facing and BLA facing manufacturing activities.

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 and regulatory applications 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, NMPA and foreign regulatory authority approval processes and continuous oversight. We will need to contract with manufacturers who can meet all applicable FDA, EMA, NMPA 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, NMPA 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, NMPA 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. Our manufacturers are also engaged in the manufacturing of COVID-19 related vaccines and therapeutic treatments, and the success of and demand for these vaccines and therapeutic treatments means we and our programs are competing for scarce manufacturing resources. We aim to distribute KSI-301 in a prefilled syringe early in our commercial rollout. We may not be able to complete our prefilled syringe activities in a timely manner, or we may fail technically to design and develop a prefilled syringe for KSI-301. If we require large volumes of glass vials, we may not be able to secure a sufficient supply due to COVID-19 related shortages of glass and vials. 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 of our product or product label as 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, NMPA or other regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA, NMPA 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.

Drug pricing and access policies in the U.S. and abroad may change and negatively impact KSI-301's commercial viability. Proposed policy changes, including the potential for Medicare to negotiate with drug manufacturers, may limit our ability to competitively price KSI-301. Further, commercial insurers may limit patient access to KSI-301 and other branded therapies. 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, NMPA 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. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Our inability to promptly obtain and maintain 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 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, NMPA 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, NMPA 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, NMPA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or the portfolio of clinical trials planned for submission in our BLA;
- the FDA, EMA, NMPA 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, NMPA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication(s), when compared to the standard of care, is acceptable;
- the FDA, EMA, NMPA 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 a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- study data may not be positive in all clinical trials demonstrating a mix of positive and negative clinical trial results;
- the FDA, EMA, NMPA or comparable foreign regulatory authorities may fail to approve the chemistry, manufacturing and controls processes, test procedures and specifications, or facilities or third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA, NMPA 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 (or the respective jurisdictions of other regulatory authorities), and the FDA, (or EMA, NMPA 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 global clinical trials by the FDA, EMA, NMPA 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, NMPA or any applicable foreign regulatory authority will accept data from trials conducted outside of their respective jurisdictions. If the FDA, EMA, NMPA 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 NMPA 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, NMPA 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 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 REMS), 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, NMPA 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 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the 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 numerous challenges to the ACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress 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. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or

Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures as part of the budget reconciliation process. In addition, Congress is considering additional health reform measures, such as capping the costs for prescription drugs covered by Medicare Part D and by setting the annual out-of-pocket limit at $2,000 beginning in 2024, as part of the budget reconciliation process.

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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN Model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements or insider trading violations, which could significantly harm our business.

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, NMPA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA, NMPA 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. Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the course of clinical studies, which could result in regulatory sanctions and 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 and entities 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;
- 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. 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;
- 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 and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payments 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 CMS under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information related to payments or other transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;
- 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.

Our business is subject to complex and evolving U.S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.

A wide variety of provincial, state, national, and foreign laws and regulations, as well as policies, contracts and other obligations apply to the collection, use, retention, protection, disclosure and transfer of personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions.

For example, the European Union's General Data Protection Regulation, or GDPR, which took effect on May 25, 2018, imposes stringent data protection requirements and provides for material penalties for noncompliance. The GDPR applies to processing operations carried out in the context of the activities of an establishment in the European Economic Area, or EEA, and any processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA. Also, notwithstanding the United Kingdom's withdrawal from the EU, by operation of the so-called UK GDPR, the GDPR continues to apply in substantially equivalent form to processing operations carried out in the context of the activities of an establishment in the United Kingdom and any processing relating to the offering of goods or services to individuals in the United Kingdom and/or monitoring of their behavior in the United Kingdom—so, when we refer to the GDPR in this section, we are also making reference to the UK GDPR in the context of the United Kingdom, unless the context requires otherwise. These laws may apply in the context of our processing of personal data related to the conduct of clinical trials in the EEA and/or UK.

The GDPR requires organizations to give detailed disclosures about how they collect, use and share personal information; in certain cases, obtain explicit consent to process special categories of personal data, such as the health or genetic information referred to above; contractually require vendors to meet data protection requirements; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information.

European data protection laws, including the GDPR, also restrict transfers of personal data from Europe, including the EEA, the United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards that allowed U.S. companies to import personal data from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the European Union, or CJEU, adopted a decision in July 2020 that invalidated the EU U.S. Privacy Shield. Following this decision, the United Kingdom government has similarly invalidated use of the EU U.S. Privacy Shield as a mechanism for lawful personal data transfers from the United Kingdom to the United States under the UK GDPR; and the Swiss Federal Data Protection and Information Commissioner announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. The CJEU's decision in this case also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or other third countries that are not the subject of an adequacy decision of the European Commission. While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle, it made clear that reliance on the Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. Despite updated forms of the Standard Contractual Clauses having been issued by the European Commission following this case, use of the Standard Contractual Clauses must be assessed on a case-by-case basis. In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and/or applicable European data protection laws, the CJEU's decision in this case, subsequent guidance from the European Data Protection Board, or EDPB, and those updated Standard Contractual Clauses, would require the parties to that transfer to implement supplementary technical, organizational and/or contractual measures in order to rely on the Standard Contractual Clauses as a compliant 'transfer mechanism.' However, the EDPB draft guidance appears to conclude that no combination of supplementary measures could be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data 'in the clear' to recipients in countries where the power granted to public authorities to access the transferred personal data goes beyond that which is 'necessary and proportionate in a democratic society' – which may, following the CJEU's conclusions in this case on relevant powers of United States public authorities and commentary in that EDPB guidance, include the United States in certain circumstances. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses.

On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of United Kingdom immigration control) of personal data from the EEA to the United Kingdom to continue without restriction for a period of four years ending June 27, 2025. After that period, the adequacy decision may be renewed only if the United Kingdom continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the United Kingdom and could intervene at any point if the United Kingdom deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the United Kingdom will require a valid 'transfer mechanism' and we may be required to implement new processes and put new agreements in place, such as Standard Contractual Clauses, to enable transfers of personal data from the EEA to the United Kingdom to continue, which could disrupt our operations.

If we are unable to implement a valid solution for personal data transfers from Europe, including, for example, obtaining individuals' explicit consent to transfer their personal data from Europe to the United States or other countries, we will face increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to import personal data from Europe, including the EEA, United Kingdom or Switzerland, may also (i) restrict our activities in Europe; (ii) limit our ability to collaborate with partners as well as other service providers, contractors and other companies subject to European data protection laws; or (iii) require us to increase our data processing capabilities in Europe at significant expense or otherwise cause us to change the geographical location or segregation of our relevant systems and operations—any or all of which could adversely affect our financial results.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

As noted above, the GDPR also provides for more robust regulatory enforcement and greater penalties for noncompliance than previously applicable data protection laws, including fines of up to €20 million or 4% of an undertaking's total worldwide annual turnover for the preceding financial year, whichever is higher. In addition to administrative fines, supervisory authorities have extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by noncompliant actors. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Additionally, as noted above, the United Kingdom has transposed the GDPR into the laws of the United Kingdom, which could expose us to two parallel regimes, each of which potentially authorizes similar fines, with the UK GDPR permitting fines of up to the higher of £17.5 million or 4% of global annual revenue of any noncompliant organizations for the preceding financial year, as well as other potentially divergent enforcement actions for certain violations.

Privacy laws in the U.S. are also increasingly complex and changing rapidly. For example, the California legislature enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA requires covered companies to provide new disclosures to California residents, and honor their requests to access, delete and opt-out of certain sharing of their personal information. The CCPA provides for civil penalties for violations. Since the enactment of the CCPA, new privacy and data security laws have been proposed in more than half of the states and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S. The CCPA itself will expand substantially as a result of California voters approving a November 2020 ballot measure that adopted the California Privacy Rights Act of 2020, or CPRA, which will, among other things, create a new administrative agency to implement and enforce California's privacy laws effective January 1, 2023. While certain clinical trial activities are exempt from the CCPA's requirements, other personal information that we handle may be subject to the CCPA, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities.

The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. We are working to comply with the privacy and data protection laws and regulations that apply to us, and we anticipate needing to devote significant additional resources to complying with these laws and regulations. It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices.

Our actual or perceived failure to adequately comply with applicable laws, regulations, policies, contracts and other obligations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory fines and bans on processing personal information, investigations and enforcement actions, penalties and other liabilities, interruptions to our development process, claims for damages by affected individuals, and damage to our reputation, any of which could materially affect our business, financial condition, results of operations and growth prospects.

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 UK 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 impede 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. We own a registered trademark for the mark "KODIAK" and "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. We have sent cease and desist letters to two companies and filed a trademark opposition proceeding against one company. If we deem it appropriate, we may decide to take further 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.

Developing and commercializing new medicines is a challenging exercise and requires diverse expertise in a variety of scientific, clinical, manufacturing, commercial, financial, people and legal functions. Failure to adequately develop these functions at Kodiak will hurt our ability to compete effectively.

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 U.S. operations at our facilities 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, 2021, we had 85 employees, all of whom were full-time. As our development plans and strategies develop, and as we continue 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.

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.

If our security measures, or those maintained on our behalf by CROs, service providers or other third parties, are compromised now, or in the future, or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, this could result in significant fines or other liability, interrupt our development programs, harm our reputation, or otherwise adversely affect our business.

In the course of our business, we collect, store and transmit proprietary, confidential and sensitive information, including personal information. The information and data processed and stored in our technology systems, and those of our research collaborators, CROs, contractors, consultants, and other third parties on which we depend to operate our business, may be vulnerable to security breaches, loss, damage, corruption, unauthorized access, use or disclosure, or misappropriation. Such incidents may also result from errors or malfeasance by our personnel or the personnel of the third parties with which we work, malware, viruses, software vulnerabilities, hacking, denial of service attacks, social engineering (including phishing), ransomware, credential stuffing or other cyberattacks, including attacks by state-sponsored organizations or sophisticated groups of hackers.

While we have developed systems and processes designed to protect the integrity, confidentiality and security of the confidential and personal information under our control, we cannot assure you that our security measures or those of the third parties we depend on will be effective in preventing cybersecurity incidents. There are many different and rapidly evolving cybercrime and hacking techniques, and we may be unable to anticipate attempted security breaches, identify them before our information is exploited, or react in a timely manner.

Additionally, as a result of the ongoing COVID-19 pandemic, certain employees remain in a remote work environment and outside of our corporate network security protection boundaries, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, any of which could have a material adverse effect on our business.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Although to our knowledge, we have not experienced a material system failure or cybersecurity incident 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.

Cybersecurity incidents and any unauthorized access or disclosure of our information or intellectual property could also compromise our intellectual property, expose sensitive business information, expose the personal information of our employees, require us to incur significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. Such incidents could also subject us to significant liability, harm our competitive position and delay the further development and commercialization of our product candidates.

Additionally, applicable data protection requirements, including, without limitation, laws, regulations, guidance as well as our internal and external policies and our contractual obligations, may require us to notify relevant stakeholders of security breaches, including affected individuals, partners, collaborators, regulators, law enforcement agencies, and others. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to litigation or other liability, fines, harm to our reputation, significant costs, or other materially adverse effects. There can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or protect us from liability or damages.

We cannot be certain that our insurance coverage will be adequate for cybersecurity liabilities, will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

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. For example, in connection to the ongoing COVID-19 pandemic, the various quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture product, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining clinical supplies of our product candidates. The extent to which the ongoing COVID-19 pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain the coronavirus or treat its impact, among others.

Our operations are located at facilities in Palo Alto, California and Switzerland. 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 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, pricing and reimbursement regimes 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.

Following the result of a referendum in 2016, the United Kingdom, or UK, left the European Union, or EU, on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union applied provisionally from January 1, 2021, and formally entered into force on May 1, 2021.

Since a significant proportion of the regulatory framework in the UK, is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime applicable to our operations, including with respect to our ability to obtain regulatory approvals of our product candidates in the EU. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency, or EMA, and a separate marketing authorization will be required to market our product candidates in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals, would restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the UK and the EU there are additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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

Our business is currently affected and could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and could materially and adversely affect our operations, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be materially and adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. For example, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In response, we delayed initiation of the next set of KSI-301 pivotal studies by one quarter from June to September 2020 in order to assess how best to minimize the impact of COVID-19 on clinical trial conduct. We implemented and continue to implement various enhancements into our ongoing study execution to help ensure the safety of patients, physicians, study site staff and Kodiak operations team members during the ongoing COVID-19 pandemic, including the use of remote study monitoring.

The COVID-19 pandemic continues to unfold, and we will continue to monitor our operations in response. We continue to observe government recommendations. Quarantines for COVID-19 or other viruses could impact personnel at third party manufacturing facilities, or the availability or cost of materials, which would disrupt our supply chain. While many of these materials may be obtained by more than one supplier, port closures and other restrictions resulting from the coronavirus outbreak in the region may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products. As we work towards commercial scale-up and manufacturing activities to support BLA submission, there is increasing competition with COVID-19 related vaccine and therapeutic programs for manufacturing related (i) materials such as resins, filters, sterile tubesets, pipette tips; (ii) personnel such as facility engineering and construction as well as plant engineers and workers; and (iii) production slots in cGMP facilities.

In addition, our current and future clinical trials may be materially and adversely affected by the COVID-19 outbreak in the future. Site initiation and patient enrollment may be further delayed due to prioritization of hospital resources toward the COVID-19 outbreak. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, and may adversely impact our clinical trial operations. Kodiak staff and/or our CRO partners may not be able to travel to study sites, impacting further site initiations and in-person monitoring of study data quality. Other Kodiak vendors on whom we depend, such as supply chain and logistics partners and our image reading centers may be disrupted, and our operations could be affected. Our clinical studies enroll patients who have underlying risk factors such as advanced age, hypertension and/or diabetes which could lead to higher than expected study discontinuation rates and/or missed visit rates if these patients are adversely affected by the COVID-19 outbreak. To date, we continue to see low levels of patient missed visits. Additionally, the pandemic could result in delayed recruitment in some or all of our clinical studies that are currently recruiting patients, for example if as a consequence of the pandemic patients are not willing to be seen by their physician as frequently as our study protocols require.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change.

The extent to which the risks and evolving effects of the COVID-19 pandemic impact our business and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease, including the effectiveness and timing of vaccine programs in the U.S. and worldwide. The COVID-19 pandemic may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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

As of December 31, 2020, the Company had $50.1 million of federal and $171.0 million of state net operating loss, or NOLs, that may be available to offset future taxable income. A portion of the federal NOL carryforwards begin to expire in 2035 and the state NOL carryforwards begin to expire in 2035, if not utilized. 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 NOL 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.

The Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") enacted in March 2020, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. Federal NOLs arising in tax years beginning after December 31, 2017 are permitted to be carried forward indefinitely, but carryback of such NOLs is generally permitted to the prior five taxable years only for NOLs arising in taxable years beginning before 2021. In addition, under the Tax Act, as modified by the CARES Act, the deductibility of federal NOLs incurred in taxable years beginning after December 31, 2017 is limited in taxable years beginning after December 31, 2020. For state income tax purposes, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. The new limitations on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

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 adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act, modified certain provisions of the Tax Act and proposals have recently been made in Congress (which have not yet been enacted) to increase the federal income tax rate applicable to corporate income and make other tax law changes that could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our net deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are in the 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 committed to researching, developing and commercializing transformative therapeutics to treat 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. Except for 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 losses of $173.8 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $465.1 million.

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

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

- progress our current and any future product candidates through preclinical and clinical development;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
- continue our research and discovery activities;
- continue the development of our ABC Platform;
- initiate and conduct additional preclinical, clinical or other studies for our current and any future product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates, including KSI-301;
- 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.

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 funded our operations primarily through the sale of equity securities. Developing our product candidates is expensive, and we expect to continue to increase our spending as we conduct the Phase 3 clinical trials for our KSI-301 product candidate. 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.

Our estimate as to how long we expect our existing cash, 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 currently have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

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

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

Risks Related to 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, including fluctuations attributable to the ongoing COVID-19 pandemic and other unforeseeable circumstances; 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.

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 principal 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, significant holders of outstanding common stock and their respective affiliates beneficially own a significant amount of our common stock. 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.

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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

General Risk Factors

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.

Future sales of our common stock in the public market could cause our share price to decline, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales, particularly sales by our directors, executive officers and significant stockholders, may have on the prevailing market price of our common stock. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, the shares of common stock subject to outstanding options under our equity incentive plans and the shares reserved for future issuance under our equity incentive plans, as well as shares issuable upon vesting of restricted stock unit awards, will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, certain holders of our common stock have the right, subject to various conditions and limitations, to request we include their shares of our common stock in registration statements we may file relating to our securities. 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.

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. Furthermore, 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. 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. Any failure to maintain effective internal controls could also have an adverse effect on our business, financial position and results of operations.

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

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
10.1	2021 Long-Term Performance Incentive Plan				
10.2	Letter Agreement, dated July 22, 2021, between Kodiak Sciences Inc., Kodiak Sciences GmbH and Edison ICAV, as assignee of Baker Bros. Advisors, LP	8-K	001-38682	10.1	7/23/2021
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	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* 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 9, 2021

By: /s/ Victor Perlroth

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

Date: November 9, 2021

By: /s/ John Borgeson

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

KODIAK SCIENCES INC.
2021 LONG-TERM PERFORMANCE INCENTIVE PLAN

1. GENERAL.

(a) Purpose. As part of its employee compensation program, Kodiak Sciences Inc. (the "Company") has adopted this 2021 Long-Term Performance Incentive Plan (the "Plan"), effective as of August 12, 2021 (the "Effective Date"), subject to Section 2 below. The purpose of the Plan is to help attract and retain key employees by providing them with additional incentives and to encourage such employees to contribute maximum effort towards supporting the Company's next phase of transformational performance and growth.

(b) Eligible Employees. An employee of the Company shall be eligible to participate in the Plan if (i) such employee is at Grade Level 10 or above at the Company and (ii) such employee has agreed to participate in the Plan by executing and returning an Election Form to the Company within the time period required therein. Notwithstanding the foregoing, the determination of whether an employee may participate in the Plan shall be made by the Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

2. STOCKHOLDER APPROVAL REQUIRED. The Plan shall be subject to stockholder approval at a special meeting of the Company's stockholders to be held as soon as practicable following the Effective Date. If such stockholder approval is not obtained, then each Award granted under the Plan will be forfeited and each Participant will receive 100% of his or her Annual LTI Awards for fiscal year 2021. If such stockholder approval is obtained, each Participant will forego a portion of each Annual LTI Award that may be granted by the Company to the Participant during the Performance Period, with such foregone portion being specified in his or her Election Form.

3. ADMINISTRATION OF THE PLAN.

(a) Powers of the Administrator. The Administrator shall have the authority, in its discretion:

(1) to select the employees to whom Awards may be granted pursuant to the Plan;

(2) to determine the number of Shares to be covered by each Award granted pursuant to the Plan;

(3) to approve the forms of Award Agreements for use under the Plan;

(4) to determine the terms and conditions, not inconsistent with the terms of the Plan, of any Award granted pursuant to the Plan. Such terms and conditions include, but are not limited to, the exercise price, the time or times when Awards may be exercised (which may be based on performance criteria), any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator shall determine;

(5) to construe and interpret the terms of the Plan and the Awards granted pursuant to the Plan;

(6) to modify or amend each Award, including but not limited to the discretionary authority to extend the post-termination exercisability period of Awards and to extend the maximum term of Awards;

(7) to authorize any person to execute on behalf of the Company any instrument required to effect the grant of an Award previously granted by the Administrator; and

(8) to make all other determinations deemed necessary or advisable for administering the Plan.

(b) Rule 16b-3. To the extent desirable to qualify transactions hereunder as exempt under Rule 16b-3, the transactions contemplated hereunder will be structured to satisfy the requirements for exemption under Rule 16b-3.

(c) Effect of Administrator's Decision. The Administrator's decisions, determinations and interpretations shall be final and binding on all Participants.

4. Stock Subject to the Plan. Subject to the provisions of Section 6 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan is 5,502,334 Shares. The Shares may be authorized, but unissued, or reacquired Common Stock.

5. Awards.

(a) Each Award granted under the Plan will be a Nonstatutory Stock Option.

(b) The term of each Award will be stated in the Award Agreement.

(c) Exercise Price.

(1) The per Share exercise price of each Award will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(2) At the time an Award is granted, the Administrator will fix the period within which the Award may be exercised and will determine any conditions that must be satisfied before the Award may be exercised.

(3) The Administrator will determine the acceptable form of consideration for exercising an Award, including the method of payment. Such consideration may consist entirely of: (1) cash; (2) check; (3) promissory note, to the extent permitted by Applicable Laws, (4) other Shares, provided that such Shares have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Award will be exercised and provided that accepting such Shares will not result in any adverse accounting consequences to the Company, as the Administrator determines in its sole discretion; (5) consideration received by the Company under a broker-assisted (or other) cashless exercise program (whether through a broker or otherwise) implemented by the Company in connection with the Plan; (6) by net exercise; (7) such other consideration and method of payment for the issuance of Shares to the extent permitted by Applicable Laws; or (8) any combination of the foregoing methods of payment.

(d) Exercise of Award.

(1) Any Award granted hereunder will be exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Administrator and set forth in the Award Agreement. An Award may not be exercised for a fraction of a Share.

(2) An Award will be deemed exercised when the Company receives: (i) a notice of exercise (in such form as the Administrator may specify from time to time) from the person entitled to exercise the Award, and (ii) full payment for the Shares with respect to which the Award is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Administrator and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Award will be issued in the name of the Participant or, if requested by the Participant, in the name of the Participant and his or her spouse, or, if approved by the Administrator, in the name of an estate planning vehicle established for the exclusive benefit of the Participant and the Participant's family members within the meaning of Instruction A.1.(a)(5) of Form S-8 under the Securities Act. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Award, notwithstanding the exercise of the Award. The Company will issue (or cause to be issued) such Shares promptly after the Award is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 6 of the Plan.

(3) Exercising an Award in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Award, by the number of Shares as to which the Award is exercised.

(4) If a Participant ceases to be a Service Provider, the Participant may exercise his or her Award, to the extent vested, within such period of time as is specified in the Award Agreement (but in no event later than the expiration of the term of such Award as set forth in the Award Agreement). If after termination the Participant does not exercise his or her Award within the time specified by the Administrator, the Award will terminate, and the Shares covered by such Award will revert to the Plan.

(e) Vesting of Award. A Participant's Award shall be subject to the vesting requirements set forth in the Award Agreement.

6. Adjustments; Dissolution or Liquidation; Merger or Change in Control.

(a) Adjustments. In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the Plan, will adjust the number and class of Shares that may be delivered under the Plan and/or the number, class, and price of Shares covered by each outstanding Award, and the numerical Share limits in Section 4 of the Plan.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Administrator will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an Award will terminate immediately prior to the consummation of such proposed action.

(c) Change in Control. In the event of a Change in Control, each outstanding Award will be treated as set forth in the applicable Award Agreement.

7. Tax.

(a) Withholding Requirements. Prior to the delivery of any Shares or cash pursuant to an Award (or exercise thereof) or such earlier time as any tax withholding obligations are due, the Company will have the power and the right to deduct or withhold, or require a Participant to remit to the Company, an amount sufficient to satisfy U.S. federal, state, or local taxes, non-U.S. taxes, or other taxes (including the Participant's FICA obligation) required to be withheld with respect to such Award (or exercise thereof).

(b) Withholding Arrangements. The Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a Participant to satisfy such tax withholding obligation, in whole or in part by (without limitation) (i) paying cash, (ii) electing to have the Company withhold otherwise deliverable cash or Shares having a fair market value not in excess of the maximum statutory amount required to be withheld, or (iii) delivering to the Company already-owned Shares having a fair market value not in excess of the maximum statutory amount required to be withheld. The fair market value of the Shares to be withheld or delivered will be determined as of the date that the taxes are required to be withheld.

(c) Compliance With Section 409A. Awards will be designed and operated in such a manner that they are either exempt from the application of, or comply with, the requirements of Section 409A such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Section 409A, except as otherwise determined in the sole discretion of the Administrator. The Plan and each Award Agreement under the Plan is intended to meet the requirements of Section 409A and will be construed and interpreted in accordance with such intent, except as otherwise determined in the sole discretion of the Administrator. To the extent that an Award or payment, or the settlement or deferral thereof, is subject to Section 409A the Award will be granted, paid, settled or deferred in a manner that will meet the requirements of Section 409A, such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Section 409A. In no event will the Company (or any Parent or Subsidiary of the Company, as applicable) reimburse a Participant for any taxes imposed or other costs incurred as a result of Section 409A.

8. Amendment and Termination of the Plan. Subject to Section 2 above, the Plan is effective as of the Effective Date and will continue in effect for a term of ten (10) years following the Effective Date, unless terminated earlier in accordance with this Section 8. The Board may modify, amend, or terminate the Plan at any time, provided that such modification, amendment or termination shall not cancel, reduce, or otherwise adversely affect the amount of any Award previously determined and granted to any Participant as of the date of any such modification, amendment, or termination, without the consent of the Participant unless such modification, amendment or termination is required to conform the Plan to Applicable Laws.

9. No Guarantee of Employment. Neither the Plan nor any Award shall confer upon a Participant any right with respect to continuing the Participant's relationship as a Service Provider, nor shall they interfere in any way with the

Participant's right or the right of the Company to terminate such relationship at any time, with or without cause, to the extent permitted by Applicable Laws.

10. Choice of Law. This Plan and any controversy arising out of or relating to this Plan shall be governed by, and construed in accordance with, the internal laws of the State of California, without regard to conflict of law principles that would result in any application of any law other than the law of the State of California.

11. Definitions. For purposes of the Plan, the following definitions shall apply. Capitalized terms used but not otherwise defined in the Plan will have the meanings ascribed to such terms in the Equity Plan.

(a) "Annual LTI Award" means an annual long-term incentive equity award that may be granted to a Participant with respect to any given fiscal year during the Performance Period.

(b) "Award" or means each Nonstatutory Stock Option granted to a Participant pursuant to the Plan.

(c) "Award Agreement" means an agreement between a Participant and the Company evidencing the terms and conditions of the Award, in substantially the form attached hereto as **Exhibit A**.

(d) "Award Notice" means the "Notice of Stock Option Grant" that accompanies the Award Agreement.

(e) "Election Form" means the Election Form for Special Equity Award in substantially the form attached hereto as **Exhibit B**.

(f) "Equity Plan" means the Kodiak Sciences Inc. 2018 Equity Incentive Plan, as amended from time to time, or any successor plan thereto.

(g) "Participant" means an Employee of the Company who meets the eligibility requirements set forth in Section 1 hereof to receive, and who has received, an Award.

(h) "Performance Period" shall mean the period commencing as of the Date of Grant and ending on August 11, 2028; provided, that the Performance Period may be extended as set forth in the Award Agreement.

EXHIBIT A

Award Agreement

KODIAK SCIENCES INC.

2021 LONG-TERM PERFORMANCE INCENTIVE PLAN

STOCK OPTION AGREEMENT

Unless otherwise defined herein, the terms defined in the Kodiak Sciences Inc. 2021 Long-Term Performance Incentive Plan (the "Plan") will have the same defined meanings in this Stock Option Agreement, which includes the Notice of Stock Option Grant (the "Notice of Grant"), the Terms and Conditions of Stock Option Grant attached hereto as Exhibit A, and all appendices and exhibits attached thereto (all together, the "Option Agreement").

NOTICE OF STOCK OPTION GRANT

Participant:

Address:

The undersigned Participant has been granted an Option to purchase Common Stock of Kodiak Sciences Inc. (the "Company"), subject to the terms and conditions of the Kodiak Sciences Inc. 2021 Long-Term Performance Incentive Plan attached hereto as Exhibit B (the "Plan") and this Option Agreement, as follows:

Date of Grant: _____

Number of Shares Granted: _____

Exercise Price per Share: $ _____

Total Exercise Price: $ _____

Type of Option: Nonstatutory Stock Option

Term/Expiration Date: _____

1. Vesting Schedule. The Option will be earned, vest and become exercisable based on the attainment of the Performance-Based Requirement and Service-Based Requirement, as described below. **[FOR CEO ONLY:** Notwithstanding the foregoing, the Option will be immediately exercisable pursuant to the Restricted Stock Purchase Agreement and related documents attached as Exhibit D hereto.**]**

(a) Performance-Based Requirement. Subject to the Participant continuing to be a Service Provider through each applicable date, the Option will be earned as to an applicable percentage of the Option based on the Stock Price meeting or exceeding the corresponding Stock Price Goal for a period of ninety (90) consecutive trading days during the Performance Period (such earned portion of the Option, the "Earned Option"), in accordance with the table below.

Option Tranche	Stock Price Goal	Tranche Earning Percentage	Cumulative Earning Percentage
Tranche 1	$200	7.5%	7.5%
Tranche 2	$300	12.5%	20%
Tranche 3	$400	25.0%	45%
Tranche 4	$500	25.0%	70%
Tranche 5	$600	20.0%	90%
Tranche 6	$700	5.0%	95%
Tranche 7	$800	5.0%	100%

(b) Service-Based Requirement. Following the attainment of the Stock Price Goal in accordance with Section 1(a) above, the Earned Option will be subject to additional time-based vesting and will vest in substantially equal monthly installments on the first day of each complete calendar month that occurs during the Service-Based Period, subject to the Participant continuing to be a Service Provider through each applicable vesting date.

(c) Operational and Sales Milestones.

(i) Notwithstanding Section 1(a) above, subject to the Participant continuing to be a Service Provider through each applicable date, the Option will be earned as to an applicable percentage of the Option based on the Company's achievement of the corresponding Operational Milestone or Sales Milestone during the Performance Period, in accordance with the table below. Any such portion of the Option that is earned based on the Company's achievement of the corresponding Operational Milestone or Sales Milestone during the Performance Period in accordance with this Section 1(c)(i) shall constitute the "Earned Option" for purposes of this Option Agreement.

Operational/Sales Milestone	Operational/Sales Milestone Earning Percentage
First Operational Milestone	15%
Second Operational Milestone	5%
Third Operational Milestone	5%
Sales Milestone	10%

(ii) Following the attainment of the Operational Milestone or Sales Milestone in accordance with Section 1(c)(i) above, the Earned Option will be subject to additional time-based vesting and will vest in substantially equal monthly installments on the first day of each complete calendar month that occurs during the Service-Based Period, subject to the Participant continuing to be a Service Provider through each applicable vesting date.

(iii) Notwithstanding anything herein to the contrary, the portion of the Option that is eligible to be earned based on the attainment of an Operational Milestone or Sales Milestone shall be inclusive of, and not in addition to, any portion of the Option that may be earned based on attainment of the Stock Price Goal. To the extent a portion of the Option becomes earned based on the attainment of an Operational Milestone or Sales Milestone, the subsequent tranche(s) of the Option that is eligible to be earned based on attainment of the Stock Price Goal shall be reduced by the excess, if any, of the number of Options earned over the "Cumulative Earning Percentage" set forth in the table in Section 1(a) above. For purposes of illustration only, (A) if fewer than 25% of the Option has been earned based on the Stock Price Goal, then up to 25% of the Option (inclusive of any portion previously earned based on the Stock Price Goal) shall be eligible to be earned based on attainment of the Operational Milestones and (B) if all three Operational Milestones are achieved following attainment of the Stock Price Goal for tranche 1 (i.e., $200) but prior to attainment of the Stock Price Goal for tranche 2 (i.e., $300) resulting in a Cumulative Earning Percentage equal to 25% of the Option, then (I) the portion of the Option eligible to be earned based on the Stock Price Goal in tranche 2 shall be reduced to zero and (II) the portion of the Option eligible to be earned based on the Stock Price Goal in tranche 3 shall be reduced to 20% in order to account for the 25% of the Option that has previously vested based on achievement of all three Operational Milestones. These principles are further illustrated in the table set forth below.

Option Tranche	Stock Price Goal	Tranche Earning Percentage	Cumulative Earning Percentage
Tranche 1	$200	7.5%	7.5%
Operational Milestones Achieved	-	17.5%	25%
Tranche 2	$300	~~*12.5%*~~	~~*20%*~~
Tranche 3	$400	~~*25.0%*~~ 20.0%	45%
Tranche 4	$500	25.0%	70%
Tranche 5	$600	20.0%	90%
Tranche 6	$700	5.0%	95%
Tranche 7	$800	5.0%	100%

2. Treatment Upon Termination of Employment.

(a) Termination for Cause. In the event that the Participant's employment with the Company is terminated by the Company for Cause, the Unvested Option shall immediately terminate and be forfeited without consideration.

(b) Voluntary Resignation. In the event that the Participant's employment with the Company is terminated due to the Participant's voluntary resignation other than for Good Reason, the Unvested Option shall immediately terminate and be forfeited without consideration.

(c) Termination without Cause/for Good Reason. Subject to the Participant's execution and delivery of a release and waiver of claims agreement drafted by and satisfactory to counsel for the Company, and such release and waiver of claims agreement must be executed and become effective within sixty (60) days following the employment termination date (the date such release and waiver of claims agreement becomes effective, the "Release Effective Date"), in the event that the Participant's employment with the Company is terminated by the Company without Cause or due to the Participant's resignation for Good Reason, a pro-rata portion of the Option that has been earned as of the date of such termination based on the attainment of the Stock Price Goal, Operational Milestones and/or Sales Milestone, as applicable, shall become vested and exercisable as of the Release Effective Date, based on a fraction the numerator of which is the number of completed Months of Service between the Date of Grant and the date of such termination and the denominator of which is eighty four (84). Any portion of the Option that remains unvested after giving effect to the preceding sentence shall immediately terminate and be forfeited without consideration.

(d) Retirement. In the event that the Participant's employment with the Company is terminated due to the Participant's Retirement, the portion of the Option that has been earned as of the date of such termination based on the attainment of the Stock Price Goal, Operational Milestones and/or Sales Milestone, as applicable, shall continue to vest and become exercisable based on the original monthly vesting schedule during the Service-Based Period as if such termination had not occurred. Any portion of the Option that is unearned as of the date of termination shall immediately terminate and be forfeited without consideration.

(e) Death/Severe Disability. In the event that the Participant's employment with the Company is terminated due to the Participant's death or Severe Disability, the portion of the Option that has been earned based on the attainment of the Stock Price Goal, Operational Milestones and/or Sales Milestone, as applicable, prior to the date of such termination shall become vested and exercisable as of the date of such termination. Any portion of the Option that is unearned as of the date of termination shall immediately terminate and be forfeited without consideration.

3. Post-Termination Exercise Period. The Option, to the extent earned and vested, will be exercisable for the following periods after the Participant ceases to be a Service Provider.

(a) Death. In the event of the death of the Participant during the period of continuous Service Provider status since the date of grant of the Option, or within three (3) months following termination of the Participant's continuous Service Provider status, the Vested Option may be exercised by the Participant's estate, or by a person who acquired the right to exercise the Option by bequest or inheritance, at any time within nine (9) months following the date of death or, if earlier, the date the Participant's continuous Service Provider status terminated.

(b) Severe Disability. In the event of termination of Participant's continuous Service Provider status as a result of the Participant's Severe Disability, the Participant may exercise the Vested Option at any time within six (6) months following such termination.

(c) Retirement. In the event of termination of Participant's continuous Service Provider status as a result of the Participant's Retirement, the Participant may exercise the Vested Option at any time prior to the first (1st) anniversary of the end of the Performance Period.

(d) Other Termination. In the event of termination of the Participant's continuous Service Provider status for any reason other than death, Severe Disability or Retirement, the Participant may exercise the Option at any time within three (3) months following such termination.

(e) Notwithstanding anything to the contrary in this Section 3, in no event may this Option be exercised after the Term/Expiration Date as provided above and may be subject to earlier termination as provided in Section 4 below.

4. Change in Control.

(a) In the event that a Change in Control occurs during the Performance Period, the Option will be earned as to an applicable percentage of the Option based on the per Share consideration received by the Company's shareholders in such Change in Control transaction meeting or exceeding the corresponding Stock Price Goal, in accordance with the table set forth in Section 1(a) above, subject to straight-line interpolation to the extent such per Share consideration falls between two Stock Price Goals. For the avoidance of doubt, to the extent that less than thirty five percent (35%) of the Option has vested in such Change in Control based on the Stock Price Goal, then the Option shall remain eligible to be earned based on the attainment of the Operational Milestones and Sales Milestone in accordance with Section 1(c) above. Thereafter, the earned portion of the Option shall vest and become exercisable in accordance with Section 1(b) above; provided, however, that if (i) on the date twenty-four (24) months immediately following the consummation of such Change in Control, the Participant is providing services to the acquiring company (or its subsidiaries or parent) as either an employee or a consultant or (ii) within twenty-four (24) months following the consummation of such Change in Control, the Participant's employment is terminated by the Company without Cause or by the Participant for Good Reason, then in either the case of (i) or (ii), one hundred percent (100%) of the Option that has previously been earned based on the Stock Price Goal, Operational Milestones and/or Sales Milestone but that remains unvested based on the Service-Based Period shall vest and become exercisable in full, subject to the Participant's execution and delivery of a release and waiver of claims agreement drafted by and satisfactory to counsel for the Company, and such release and waiver of claims agreement must be executed and become effective within sixty (60) days following the employment termination date or the second (2^{nd}) anniversary of the Change in Control, as applicable.

(b) Notwithstanding the foregoing, in the event that the successor corporation does not assume or substitute for the Option, the Participant will fully vest in and have the right to exercise the portion of the Option that has been earned as of the date of such Change in Control after giving effect to Section 4(a) above. In addition, if an Award is not assumed or substituted in the event of a Change in Control, the Administrator will notify the Participant in writing or electronically that the Award will be exercisable for a period of time determined by the Administrator in its sole discretion, and the Award will terminate upon the expiration of such period.

5. Stockholder Approval Required. Notwithstanding anything to the contrary in this Option Agreement, the Option is subject to approval of the Plan by the stockholders of the Company at a special meeting of the Company's stockholders to be held as soon as practicable following the Date of Grant. If such stockholder approval of the Plan is not obtained, then the Option granted hereunder will be forfeited and the Participant will receive 100% of the Participant's Annual LTI Award for fiscal year 2021. If such stockholder approval is obtained, the Participant will forego a portion of each Annual LTI Award that may be granted by the Company to the Participant during the Performance Period (including, for the avoidance of doubt, the Annual LTI Award for fiscal year 2021), with such foregone portion being specified in the Participant's Election Form.

6. Definitions. For purposes of this Option Agreement, the following definitions shall apply.

(a) "Annual LTI Award" means an annual long-term incentive equity award that may be granted to a Participant with respect to any given fiscal year during the Performance Period.

(b) "Cause" shall mean: (i) the Participant's conviction of, including pleading guilty or nolo contendere to, any felony or any crime involving dishonesty; (ii) the Participant's participation in any fraud or act of dishonesty against the Company that has caused or is reasonably expected to result in injury to the Company; (iii) a material violation by the Participant of any of the Company's written policies or other serious misconduct, in each case that results in or is reasonably likely to result in material harm to Company; (iv) the Participant's willful and continued failure substantially to perform any of the Participant's job duties (other than as a result of total or partial Severe Disability) that is not cured within thirty (30) days following written notice of Cause from the Company; (v) conduct by the Participant which, in the good faith and reasonable determination of the Administrator, demonstrates gross unfitness to serve; or (vi) the Participant's material breach of any agreement with the Company (or its subsidiaries or successors).

(c) "Corporate Transaction" shall mean any (i) consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization in which the members/shareholders of the Company prior to such consolidation, merger or reorganization shall own less than fifty percent (50%) of the voting equity of the continuing or surviving entity after such consolidation, merger or reorganization, (ii) any transaction or series of related transactions to which the Company is a party, in which in excess of fifty percent (50%) of the Company's voting equity securities is transferred, except for bona fide sales of the Company's equity securities to investors for primarily fundraising purposes, or (iii) a sale of substantially all of the assets of the Company.

(d) "Election Form" means the Election Form for Special Equity Award pursuant to which the Participant elected to forego a portion of each Annual LTI Award that may be granted by the Company to the Participant during the Performance Period.

(e) "Employment Agreement" shall mean the Executive Employment Agreement by and between the Company and Participant.

(f) "First Operational Milestone" shall mean U.S. Food and Drug Administration approval of a Biologics License Application in respect of a first major indication (RVO, DME and/or wAMD).

(g) "Good Reason" means the occurrence of any one or more of the following events without the prior written consent of Participant: (i) a material reduction in Base Salary or Targeted Incentive Bonus (as such terms are defined in the Employment Agreement) opportunity or benefits, provided that any reduction in Base Salary (and any reduction in the dollar amount of Participant's Targeted Incentive Bonus opportunity resulting from such reduction in Base Salary) that is related to a cross executive team base salary reduction shall not constitute "Good Reason"; (ii) a material reduction in Participant's title, duties, or responsibilities or change in reporting line; provided that a reassignment following a Corporate Transaction to a position that is substantially similar to the position held prior to the Corporate Transaction shall not constitute a material reduction in job responsibilities or duties; (iii) a relocation of Participant's primary work location that increases Participant's one-way commute by more than fifty (50) miles; (iv) failure of the successor company to assume obligations contained in this Option Agreement or any other equity compensation agreement in place between Participant and the Company at the time of the Corporate Transaction; (v) any written directive given to Participant by the Chief Executive Officer or the Board, as applicable, that is in conflict with Participant's professional obligations or otherwise in violation of applicable law or regulation, in all cases, of which the Chief Executive Officer or the Board, as applicable, has knowledge of such obligations or law or regulation prior to the issuance of such directive; or (vi) the Company's material breach of any terms of this Option Agreement, any other equity compensation agreement in place between Participant and the Company, or the Employment Agreement; provided, however, that no such event or condition shall constitute Good Reason unless (A) Participant gives the Company a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (B) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice, and (C) the termination date occurs within ninety (90) days following the Company's receipt of such notice.

(h) "Month of Service" shall mean a consecutive period of 30 calendar days during which the Participant is continuously employed with, and is actively providing service, to the Company or any Parent or Subsidiary of the Company.

(i) "Operational Milestone" shall mean each of the First Operational Milestone, Second Operational Milestone and Third Operational Milestone.

(j) "Performance Period" shall mean the period commencing as of the Date of Grant and ending on August 11, 2028; provided, that the Performance Period may be extended by up to ninety (90) trading days if as of the last day of the Performance Period (without regard to any extension) the Stock Price has reached or exceeded a Stock Price Goal for less than ninety (90) trading days.

(k) "Retirement" shall mean the Participant's voluntary resignation from the Company on or after the date on which the Participant attains 65 years of age.

(l) "Sales Milestone" shall mean the first completed fiscal year of the Company in which the Company has generated sales of at least $2.5 billion.

(m) "Second Operational Milestone" shall mean U.S. Food and Drug Administration approval of a Biologics License Application in respect of a second major indication (RVO, DME and/or wAMD).

(n) "Service-Based Period" shall mean the period commencing on either (i) the date on which the applicable Stock Price Goal was attained in accordance with this Option Agreement or (ii) the date on which the applicable Operational Milestone or Sales Milestone was attained in accordance with this Option Agreement and ending, in either case, on the last day of the Performance Period.

(o) "Severe Disability" shall mean that the Participant is unable, due to a physical or mental impairment, to perform the essential functions of the Participant's job position, with or without reasonable accommodation, for a period of two hundred seventy (270) consecutive calendar days. Any determination as to Severe Disability will be made by a licensed physician selected by the Administrator.

(p) "Stock Price" shall mean the closing sales price per share Common Stock as quoted on any established stock exchange or national market system (including without limitation the New York Stock Exchange, NASDAQ Global Select Market, the NASDAQ Global Market or the NASDAQ Capital Market of The NASDAQ Stock Market) on which the Common Stock is listed (or the closing bid, if no sales were reported), as reported in *The Wall Street Journal* in the Common Stock.

(q) "Stock Price Goal" shall mean each Stock Price target amount based on which the Option will be earned, as indicated in the table set forth in Section 1(a) above.

(r) "Third Operational Milestone" shall mean U.S. Food and Drug Administration approval of a Biologics License Application in respect of a third major indication (RVO, DME and/or wAMD).

(s) "Unvested Option" shall mean the portion of the Option other than the Vested Option.

(t) "Vested Option" shall mean the portion of the Option that has become earned and vested based on attainment of (i) the Stock Price Goal, Operational Milestone and/or Sales Milestone, as applicable, and (ii) the Participant's continued employment with the Company through the Service-Based Period.

[Signature page follows.]

By Participant's signature and the signature of the representative of the Company below, Participant and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan, attached hereto as Exhibit B, and this Option Agreement, including the Terms and Conditions of Stock Option Grant, attached hereto as Exhibit A, all of which are made a part of this document. Participant acknowledges receipt of a copy of the Plan. Participant has reviewed the Plan and this Option Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option Agreement, and fully understands all provisions of the Plan and this Option Agreement. Participant hereby agrees to accept as binding, conclusive, and final all decisions or interpretations of the Administrator upon any questions relating to the Plan and the Option Agreement. Participant further agrees to notify the Company upon any change in the residence address indicated below.

PARTICIPANT	KODIAK SCIENCES INC.
Signature	Signature
Print Name	Print Name
	Title

Address:

EXHIBIT A

TERMS AND CONDITIONS OF STOCK OPTION GRANT

1. Grant of Option. The Company hereby grants to the individual (the "Participant") named in the Notice of Stock Option Grant of this Option Agreement (the "Notice of Grant") an option (the "Option") to purchase the number of Shares, as set forth in the Notice of Grant, at the exercise price per Share set forth in the Notice of Grant (the "Exercise Price"), subject to all of the terms and conditions in this Option Agreement and the Plan, each of which is incorporated herein by reference. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Option Agreement, the terms and conditions of the Plan will prevail. The Option will be designated as a Nonstatutory Stock Option.

2. Vesting Schedule. Except as provided in Section 3, the Option awarded by this Option Agreement will vest in accordance with the vesting provisions set forth in the Notice of Grant. Shares scheduled to vest on a certain date or upon the occurrence of a certain condition will not vest in Participant in accordance with any of the provisions of this Option Agreement, unless Participant will have been continuously a Service Provider from the Date of Grant until the date such vesting occurs.

3. Administrator Discretion. The Administrator, in its discretion, may accelerate the vesting of the balance, or some lesser portion of the balance, of the unvested Option at any time, subject to the terms of the Plan. If so accelerated, such Option will be considered as having vested as of the date specified by the Administrator.

4. Exercise of Option.

(a) Right to Exercise. This Option may be exercised only within the term set out in the Notice of Grant, and may be exercised during such term only in accordance with the Plan and the terms of this Option Agreement.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice (the "Exercise Notice") in the form attached as Exhibit C or in a manner and pursuant to such procedures as the Administrator may determine, which will state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "Exercised Shares"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice will be completed by Participant and delivered to the Company. The Exercise Notice will be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares together and of any Tax Obligations (as defined in Section 6(a)). This Option will be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by the aggregate Exercise Price.

5. Method of Payment. Payment of the aggregate Exercise Price will be by any of the following, or a combination thereof, at the election of Participant:

(a) cash;

(b) check;

(c) consideration received by the Company under a formal cashless exercise program adopted by the Company in connection with the Plan; or

(d) if Participant is a U.S. employee, surrender of other Shares which have a Fair Market Value on the date of surrender equal to the aggregate Exercise Price of the Exercised Shares and that are owned free and clear of any liens, claims, encumbrances, or security interests, provided that accepting such Shares, in the sole discretion of the Administrator, will not result in any adverse accounting consequences to the Company.

6. Tax Obligations.

(a) Participant acknowledges that, regardless of any action taken by the Company or, if different, Participant's employer (the "Employer") or Parent or Subsidiary to which Participant is providing services (together, the Company, Employer and/or Parent or Subsidiary to which the Participant is providing services, the "Service Recipient"), the ultimate liability for any tax and/or social insurance liability obligations and requirements in connection with the Option, including, without limitation, (i) all federal, state, and local taxes (including the Participant's Federal Insurance Contributions Act (FICA) obligation) that are required to be withheld by the Company or the Service Recipient or other payment of tax-related items related to Participant's participation in the Plan and legally applicable to Participant, (ii) the Participant's and, to the extent required by the Company (or Service Recipient), the Company's (or Service Recipient's) fringe benefit tax liability, if any, associated with the grant, vesting, or exercise of the Option or sale of Shares, and (iii) any other Company (or Service Recipient) taxes the responsibility for which the Participant has, or has agreed to bear, with respect to the Option (or exercise thereof or issuance of Shares thereunder) (collectively, the "Tax Obligations"), is and remains Participant's responsibility and may exceed the amount actually withheld by the Company or the Service Recipient. Participant further acknowledges that the Company and/or the Service Recipient (A) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Option, including, but not limited to, the grant, vesting or exercise of the Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends or other distributions, and (B) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Option to reduce or eliminate Participant's liability for Tax Obligations or achieve any particular tax result. Further, if Participant is subject to Tax Obligations in more than one jurisdiction between the Date of Grant and the date of any relevant taxable or tax withholding event, as applicable, Participant acknowledges that the Company and/or the Service Recipient (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction. If Participant fails to make satisfactory arrangements for the payment of any required Tax Obligations hereunder at the time of the applicable taxable event, Participant acknowledges and agrees that the Company may refuse to issue or deliver the Shares.

(b) Tax Withholding. When the Option is exercised, Participant generally will recognize immediate U.S. taxable income if Participant is a U.S. taxpayer. If Participant is a non-U.S. taxpayer, Participant will be subject to applicable taxes in his or her jurisdiction. Pursuant to such procedures as the Administrator may specify from time to time, the Company and/or Service Recipient shall withhold the amount required to be withheld for the payment of Tax Obligations. The Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit Participant to satisfy such Tax Obligations, in whole or in part (without limitation), if permissible by applicable local law, by (i) paying cash, (ii) electing to have the Company withhold otherwise deliverable Shares having a fair market value equal to the minimum amount that is necessary to meet the withholding requirement for such Tax Obligations (or such greater amount as Participant may elect if permitted by the Administrator, if such greater amount would not result in adverse financial accounting consequences), (iii) withholding the amount of such Tax Obligations from Participant's wages or other cash compensation paid to Participant by the Company and/or the Service Recipient, (iv) delivering to the Company already vested and owned Shares having a fair market value equal to such Tax Obligations, or (v) selling a sufficient number of such Shares otherwise deliverable to Participant through such means as the Company may determine in its sole discretion (whether through a broker or otherwise) equal to the minimum amount that is necessary to meet the withholding requirement for such Tax Obligations (or such greater amount as Participant may elect if permitted by the Administrator, if such greater amount would not result in adverse financial accounting consequences). To the extent determined appropriate by the Company in its discretion, it will have the right (but not the obligation) to satisfy any Tax Obligations by reducing the number of Shares otherwise deliverable to Participant. Further, if Participant is subject to tax in more than one jurisdiction between the Date of Grant and a date of any relevant taxable or tax withholding event, as applicable, Participant acknowledges and agrees that the Company and/or the Service Recipient (and/or former employer, as applicable) may be required to withhold or account for tax in more than one jurisdiction. If Participant fails to make satisfactory arrangements for the payment of any required Tax Obligations hereunder at the time of the Option exercise, Participant acknowledges and agrees that the Company may refuse to honor the exercise and refuse to deliver the Shares if such amounts are not delivered at the time of exercise.

(c) Notice of Disqualifying Disposition of ISO Shares. If the Option granted to Participant herein is an ISO, and if Participant sells or otherwise disposes of any of the Shares acquired pursuant to the ISO on or before the later of (i) the date two (2) years after the Date of Grant, or (ii) the date one (1) year after the date of exercise, Participant will immediately notify the Company in writing of such disposition. Participant agrees that Participant may be subject to income tax withholding by the Company on the compensation income recognized by Participant.

(d) Code Section 409A. Under Code Section 409A, a stock right (such as the Option) that vests after December 31, 2004 (or that vested on or prior to such date but which was materially modified after October 3, 2004) that was granted with a per share exercise price that is determined by the Internal Revenue Service (the "IRS") to be less than the fair market value of an underlying share on the date of grant (a "discount option") may be considered "deferred compensation." A stock right that is a "discount option" may result in (i) income recognition by the recipient of the stock right prior to the exercise of the stock right, (ii) an additional twenty percent (20%) federal income tax, and (iii) potential penalty and interest charges. The "discount option" may also result in additional state income, penalty and interest tax to the recipient of the stock right. Participant acknowledges that the Company cannot and has not guaranteed that the IRS will agree that the per Share exercise price of this Option equals or exceeds the fair market value of a Share on the date of grant in a later examination. Participant agrees that if the IRS determines that the Option was granted with a per Share exercise price that was less than the fair market value of a Share on the date of grant, Participant shall be solely responsible for Participant's costs related to such a determination.

7. Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book entry form) will have been issued, recorded on the records of the Company or its transfer agents or registrars, and delivered to Participant (including through electronic delivery to a brokerage account). After such issuance, recordation, and delivery, Participant will have all the rights of a stockholder of the Company with respect to voting such Shares and receipt of dividends and distributions on such Shares.

8. No Guarantee of Continued Service. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF SHARES PURSUANT TO THE VESTING SCHEDULE HEREOF IS EARNED ONLY BY CONTINUING AS A SERVICE PROVIDER, WHICH UNLESS PROVIDED OTHERWISE UNDER APPLICABLE LAW IS AT THE WILL OF THE COMPANY (OR THE SERVICE RECIPIENT) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS OPTION OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS OPTION AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND WILL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE COMPANY (OR THE SERVICE RECIPIENT) TO TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER, SUBJECT TO APPLICABLE LAW, WHICH TERMINATION, UNLESS PROVIDED OTHERWISE UNDER APPLICABLE LAW, MAY BE AT ANY TIME, WITH OR WITHOUT CAUSE.

9. Nature of Grant. In accepting the Option, Participant acknowledges, understands and agrees that:

(a) the grant of the Option is voluntary and occasional and does not create any contractual or other right to receive future grants of options, or benefits in lieu of options, even if options have been granted in the past;

(b) all decisions with respect to future option or other grants, if any, will be at the sole discretion of the Company;

(c) Participant is voluntarily participating in the Plan;

(d) the Option and any Shares acquired under the Plan are not intended to replace any pension rights or compensation;

(e) the Option and Shares acquired under the Plan and the income and value of same, are not part of normal or expected compensation for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(f) the future value of the Shares underlying the Option is unknown, indeterminable, and cannot be predicted with certainty;

(g) if the underlying Shares do not increase in value, the Option will have no value;

(h) if Participant exercises the Option and acquires Shares, the value of such Shares may increase or decrease in value, even below the Exercise Price;

(i) for purposes of the Option, Participant's engagement as a Service Provider will be considered terminated as of the date Participant is no longer actively providing services to the Company or any Parent or Subsidiary (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is a Service Provider or the terms of Participant's employment or service agreement, if any), and unless otherwise expressly provided in this Option Agreement (including by reference in the Notice of Grant to other arrangements or contracts) or determined by the Administrator, (i) Participant's right to vest in the Option under the Plan, if any, will terminate as of such date and will not be extended by any notice period (*e.g.*, Participant's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where Participant is a Service Provider or Participant's employment or service agreement, if any, unless Participant is providing bona fide services during such time); and (ii) the period (if any) during which Participant may exercise the Option after such termination of Participant's engagement as a Service Provider will commence on the date Participant ceases to actively provide services and will not be extended by any notice period mandated under employment laws in the jurisdiction where Participant is employed or terms of Participant's engagement agreement, if any; the Administrator shall have the exclusive discretion to determine when Participant is no longer actively providing services for purposes of his or her Option grant (including whether Participant may still be considered to be providing services while on a leave of absence and consistent with local law);

(j) unless otherwise provided in the Plan or by the Company in its discretion, the Option and the benefits evidenced by this Option Agreement do not create any entitlement to have the Option or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the Shares; and

(k) the following provisions apply only if Participant is providing services outside the United States:

(i) the Option and the Shares subject to the Option are not part of normal or expected compensation or salary for any purpose;

(ii) Participant acknowledges and agrees that none of the Company, the Service Recipient, or any Parent or Subsidiary shall be liable for any foreign exchange rate fluctuation between Participant's local currency and the United States Dollar that may affect the value of the Option or of any amounts due to Participant pursuant to the exercise of the Option or the subsequent sale of any Shares acquired upon exercise; and

(iii) no claim or entitlement to compensation or damages shall arise from forfeiture of the Option resulting from the termination of Participant's engagement as a Service Provider (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is a Service Provider or the terms of Participant's employment or service agreement, if any), and in consideration of the grant of the Option to which Participant is otherwise not entitled, Participant irrevocably agrees never to institute any claim against the Company, any Parent, any Subsidiary or the Service Recipient, waives his or her ability, if any, to bring any such claim, and releases the Company, any Parent or Subsidiary and the Service Recipient from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, Participant shall be deemed irrevocably to have agreed not to pursue such claim and agrees to execute any and all documents necessary to request dismissal or withdrawal of such claim.

10. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant is hereby advised to consult with his or her own personal tax, legal and financial advisors regarding his or her participation in the Plan before taking any action related to the Plan.

11. **Data Privacy**. ***Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of Participant's personal data as described in this Option Agreement and any other Option grant materials by and among, as applicable, the Employer or other Service Recipient, the Company and any Parent or Subsidiary for the exclusive purpose of implementing, administering and managing Participant's participation in the Plan.***

Participant understands that the Company and the Employer may hold certain personal information about Participant, including, but not limited to, Participant's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any Shares or directorships held in the Company, details of all Options or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in Participant's favor ("Data"), for the exclusive purpose of implementing, administering and managing the Plan.

Participant understands that Data will be transferred to a stock plan service provider as may be selected by the Company in the future, which is assisting the Company with the implementation, administration, and management of the Plan. Participant understands that the recipients of the Data may be located in the United States or elsewhere, and that the recipient's country of operation (e.g., the United States) may have different data privacy laws and protections than Participant's country. Participant understands that if he or she resides outside the United States, he or she may request a list with the names and addresses of any potential recipients of the Data by contacting his or her local human resources representative. Participant authorizes the Company and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purposes of implementing, administering and managing Participant's participation in the Plan. Participant understands that Data will be held only as long as is necessary to implement, administer and manage Participant's participation in the Plan. Participant understands that if he or she resides outside the United States, he or she may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing his or her local human resources representative. Further, Participant understands that he or she is providing the consents herein on a purely voluntary basis. If Participant does not consent, or if Participant later seeks to revoke his or her consent, his or her engagement as a Service Provider and career with the Employer will not be adversely affected; the only adverse consequence of refusing or withdrawing Participant's consent is that the Company would not be able to grant Participant Options or other equity awards or administer or maintain such awards. Therefore, Participant understands that refusing or withdrawing his or her consent may affect Participant's ability to participate in the Plan. For more information on the consequences of Participant's refusal to consent or withdrawal of consent, Participant understands that he or she may contact his or her local human resources representative.

12. Address for Notices. Any notice to be given to the Company under the terms of this Option Agreement will be addressed to the Company at Kodiak Sciences Inc., 1200 Page Mill Road, Palo Alto, CA 94304, or at such other address as the Company may hereafter designate in writing.

13. Non-Transferability of Option. This Option may not be transferred in any manner otherwise than by will or by the laws of descent or distribution and may be exercised during the lifetime of Participant only by Participant; provided, that, if approved by the Administrator, the Option may be transferred to an estate planning vehicle established for the exclusive benefit of Participant and Participant's family members within the meaning of Instruction A.1.(a)(5) of Form S-8 under the Securities Act.

14. Successors and Assigns. The Company may assign any of its rights under this Option Agreement to single or multiple assignees, and this Option Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Option Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns. The rights and obligations of Participant under this Option Agreement may only be assigned with the prior written consent of the Company.

15. Additional Conditions to Issuance of Stock. If at any time the Company will determine, in its discretion, that the listing, registration, qualification or rule compliance of the Shares upon any securities exchange or under any state, federal or non-U.S. law, the tax code and related regulations or under the rulings or regulations of the United States Securities and Exchange Commission or any other governmental regulatory body or the clearance, consent or approval of the United States Securities and Exchange Commission or any other governmental regulatory authority is necessary or desirable as a condition to the purchase by, or issuance of Shares, to Participant (or his or her estate) hereunder, such purchase or issuance will not occur unless and until such listing, registration, qualification, rule compliance, clearance, consent or approval will have been completed, effected or obtained free of any conditions not acceptable to the Company. Subject to the terms of the Option Agreement and the Plan, the Company shall not be required to issue any certificate or certificates for Shares hereunder prior to the lapse of such reasonable period of time following the date of exercise of the Option as the Administrator may establish from time to time for reasons of administrative convenience.

16. Language. If Participant has received this Option Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

17. Interpretation. The Administrator will have the power to interpret the Plan and this Option Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret or revoke any such rules (including, but not limited to, the determination of whether or not any Shares subject to the Option have vested). All actions taken and all interpretations and determinations made by the Administrator in good faith will be final and binding upon Participant, the Company and all other interested persons. Neither the Administrator nor any person acting on behalf of the Administrator will be personally liable for any action, determination, or interpretation made in good faith with respect to the Plan or this Option Agreement.

18. Electronic Delivery and Acceptance. The Company may, in its sole discretion, decide to deliver any documents related to the Option awarded under the Plan or future options that may be awarded under the Plan by electronic means or request Participant's consent to participate in the Plan by electronic means. Participant hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through any on-line or electronic system established and maintained by the Company or a third party designated by the Company.

19. Captions. Captions provided herein are for convenience only and are not to serve as a basis for interpretation or construction of this Option Agreement.

20. Agreement Severable. In the event that any provision in this Option Agreement will be held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of this Option Agreement.

21. Amendment, Suspension or Termination of the Plan. By accepting this Option, Participant expressly warrants that he or she has received an Option under the Plan, and has received, read, and understood a description of the Plan. Participant understands that the Plan is discretionary in nature and may be amended, suspended or terminated by the Company at any time.

22. Governing Law and Venue. This Option Agreement will be governed by the laws of California, without giving effect to the conflict of law principles thereof. For purposes of litigating any dispute that arises under this Option or this Option Agreement, the parties hereby submit to and consent to the jurisdiction of the State of California, and agree that such litigation will be conducted in the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts, where this Option is made and/or to be performed.

23. Country Addendum. Notwithstanding any provisions in this Option Agreement, this Option shall be subject to any special terms and conditions set forth in the appendix (if any) to this Option Agreement for Participant's country (the "Country Addendum"). Moreover, if Participant relocates to one of the countries included in the Country Addendum (if any), the special terms and conditions for such country will apply to Participant, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Country Addendum constitutes part of this Option Agreement.

24. Modifications to the Agreement. This Option Agreement constitutes the entire understanding of the parties on the subjects covered. Participant expressly warrants that he or she is not accepting this Option Agreement in reliance on any promises, representations, or inducements other than those contained herein. Modifications to this Option Agreement or the Plan can be made only in an express written contract executed by a duly authorized officer of the Company. Notwithstanding anything to the contrary in the Plan or this Option Agreement, the Company reserves the right to revise this Option Agreement as it deems necessary or advisable, in its sole discretion and without the consent of Participant, to comply with Code Section 409A or to otherwise avoid imposition of any additional tax or income recognition under Section 409A of the Code in connection with the Option.

25. No Waiver. Either party's failure to enforce any provision or provisions of this Option Agreement shall not in any way be construed as a waiver of any such provision or provisions, nor prevent that party from thereafter enforcing each and every other provision of this Option Agreement. The rights granted both parties herein are cumulative and shall not constitute a waiver of either party's right to assert all other legal remedies available to it under the circumstances.

26. Tax Consequences. Participant has reviewed with its own tax advisors the U.S. federal, state, local and non-U.S. tax consequences of this investment and the transactions contemplated by this Option Agreement. With respect to such matters, Participant relies solely on such advisors and not on any statements or representations of the Company or any of its agents, written or oral. Participant understands that Participant (and not the Company) shall be responsible for Participant's own tax liability that may arise as a result of this investment or the transactions contemplated by this Option Agreement.

EXHIBIT B

KODIAK SCIENCES INC.

2021 LONG-TERM PERFORMANCE INCENTIVE PLAN

STOCK OPTION AGREEMENT

COUNTRY ADDENDUM

TERMS AND CONDITIONS

This Country Addendum includes additional terms and conditions that govern the Option granted to Participant under the Plan if Participant works in one of the countries listed below. If Participant is a citizen or resident of a country (or is considered as such for local law purposes) other than the one in which he or she is currently working or if Participant relocates to another country after receiving the Option, the Company will, in its discretion, determine the extent to which the terms and conditions contained herein will be applicable to Participant.

Certain capitalized terms used but not defined in this Country Addendum shall have the meanings set forth in the Plan, and/or the Stock Option Agreement to which this Country Addendum is attached.

NOTIFICATIONS

This Country Addendum also includes notifications relating to exchange control and other issues of which Participant should be aware with respect to his or her participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries listed in this Country Addendum, as of _____(except as otherwise noted below). Such laws are often complex and change frequently. As a result, the Company strongly recommends that Participant not rely on the notifications herein as the only source of information relating to the consequences of his or her participation in the Plan because the information may be outdated when Participant exercises the Option or sells Shares acquired under the Plan.

In addition, the notifications are general in nature and may not apply to Participant's particular situation, and the Company is not in a position to assure Participant of any particular result. Accordingly, Participant is advised to seek appropriate professional advice as to how the relevant laws in Participant's country may apply to Participant's situation.

Finally, if Participant is a citizen or resident of a country other than the one in which Participant is currently working (or is considered as such for local law purposes) or if Participant moves to another country after the Option is granted, the information contained herein may not be applicable to Participant.

EXHIBIT C

KODIAK SCIENCES INC.

2021 LONG-TERM PERFORMANCE INCENTIVE PLAN

EXERCISE NOTICE

Kodiak Sciences Inc.
1200 Page Mill Road
Palo Alto, CA 94304

Attention: Stock Administration

1. Exercise of Option. Effective as of today, _____, _____, the undersigned ("Purchaser") hereby elects to purchase _____ shares (the "Shares") of the Common Stock of Kodiak Sciences Inc. (the "Company") under and pursuant to the 2021 Long-Term Performance Incentive Plan (the "Plan") and the Stock Option Agreement, dated _____ and including the Notice of Grant, the Terms and Conditions of Stock Option Grant, and exhibits attached thereto (the "Option Agreement"). The purchase price for the Shares will be $_____, as required by the Option Agreement.

[**FOR CEO ONLY:** Exercise of Option. Effective as of today, _____, _____, the undersigned ("Purchaser") hereby elects to purchase _____ shares (the "Shares") of the Common Stock of Kodiak Sciences Inc. (the "Company") under and pursuant to the 2021 Long-Term Performance Incentive Plan (the "Plan") and the Stock Option Agreement, dated _____ and including the Notice of Grant, the Terms and Conditions of Stock Option Grant, the Restricted Stock Purchase Agreement and exhibits attached thereto (the "Option Agreement"). The Purchaser further acknowledges and agrees that the purchase of the Shares hereunder shall be subject to and conditioned upon the Participant entering into the Restricted Stock Purchase Agreement (in the form attached to the Option Agreement as Exhibit D) with respect to any Shares acquired by the Participant hereunder, and such Shares shall be subject to, and shall become vested and non-forfeitable in accordance with, the vesting schedule set forth in the Notice of Grant. The purchase price for the Shares will be $_____, as required by the Option Agreement.]

2. Delivery of Payment. Purchaser herewith delivers to the Company the full purchase price of the Shares and any Tax Obligations (as defined in Section 6(a) of the Option Agreement) to be paid in connection with the exercise of the Option.

3. Representations of Purchaser. Purchaser acknowledges that Purchaser has received, read and understood the Plan and the Option Agreement and agrees to abide by and be bound by their terms and conditions.

4. Rights as Stockholder. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the Shares, no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to the Option, notwithstanding the exercise of the Option. The Shares so acquired will be issued to Purchaser as soon as practicable after exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date of issuance, except as provided in Section 6 of the Plan.

5. Tax Consultation. Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser's purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted with any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

6. Entire Agreement; Governing Law. The Plan and the Option Agreement are incorporated herein by reference. This Exercise Notice, the Plan and the Option Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Purchaser with respect to the subject matter hereof, and may not be modified adversely to the Purchaser's interest except by means of a writing signed by the Company and Purchaser. This Option Agreement is governed by the internal substantive laws, but not the choice of law rules, of California.

Submitted by: Accepted by:

PURCHASER	KODIAK SCIENCES INC.
Signature	Signature
Print Name	Print Name
Address:	
	Title
	Date Received

EXHIBIT D-1

KODIAK SCIENCES INC.

2021 LONG-TERM PERFORMANCE INCENTIVE PLAN

RESTRICTED STOCK PURCHASE AGREEMENT

THIS RESTRICTED STOCK PURCHASE AGREEMENT (the "Agreement") is made between Victor Perlroth (the "Purchaser") and Kodiak Sciences Inc. (the "Company") or its assignees of rights hereunder as of _____, ____.

Unless otherwise defined herein, capitalized terms used in this Agreement shall have the meanings ascribed to such terms defined in the Company's 2021 Long-Term Performance Incentive Plan (the "Plan").

RECITALS

A. Pursuant to the exercise of the Option granted to Purchaser under the Plan and pursuant to the Stock Option Agreement (the "Option Agreement") dated as of _____, 2021 by and between the Company and Purchaser, which Plan and Option Agreement are hereby incorporated by reference, Purchaser has elected to purchase _____ of those Shares of Common Stock which have not become vested under the vesting schedule set forth in the Option Agreement ("Unvested Shares").

B. As required by the Option Agreement, as a condition to Purchaser's election to exercise the Option, Purchaser must execute this Agreement, which sets forth the rights and obligations of the parties with respect to Shares acquired upon exercise of the Option.

1. Repurchase Option.

(a) If Purchaser's status as a Service Provider is terminated for any reason, the Company shall have the right and option for one hundred and eighty (180) days from such date to purchase from Purchaser, or Purchaser's personal representative, as the case may be, all of the Purchaser's Unvested Shares as of the date of such termination at the price paid by the Purchaser for such Shares (the "Repurchase Option").

(b) Upon the occurrence of such termination, the Company may exercise its Repurchase Option by delivering personally or by registered mail, to Purchaser (or his or her transferee or legal representative, as the case may be) with a copy to the escrow agent described in Section 2 below, a notice in writing indicating the Company's intention to exercise the Repurchase Option and by delivering to the Purchaser (or the Purchaser's transferee or legal representative) a check in the amount of the aggregate repurchase price. Upon delivery of such notice and payment of the aggregate repurchase price, the Company shall become the legal and beneficial owner of the Unvested Shares being repurchased and the rights and interests therein or relating thereto, and the Company shall have the right to retain and transfer to its own name the number of Unvested Shares being repurchased by the Company.

(c) Whenever the Company shall have the right to repurchase Unvested Shares hereunder, the Company may designate and assign one or more employees, officers, directors or stockholders of the Company or other persons or organizations to exercise all or a part of the Company's Repurchase Option under this Agreement and purchase all or a part of such Unvested Shares.

(d) If the Company does not elect to exercise the Repurchase Option conferred above by giving the requisite notice within one hundred and eighty (180) days following the termination, the Repurchase Option shall terminate.

(e) The Repurchase Option shall terminate in accordance with the vesting schedule contained in Purchaser's Option Agreement.

2. Transferability of the Shares; Escrow.

(a) Purchaser hereby authorizes and directs the Secretary of the Company, or such other person designated by the Company, to transfer the Unvested Shares as to which the Repurchase Option has been exercised from Purchaser to the Company.

(b) To insure the availability for delivery of Purchaser's Unvested Shares upon repurchase by the Company pursuant to the Repurchase Option under Section 1, Purchaser hereby appoints the Secretary, or any other person designated by the Company as escrow agent (the "Escrow Agent"), as its attorney-in-fact to sell, assign and transfer unto the Company, such Unvested Shares, if any, repurchased by the Company pursuant to the Repurchase Option and shall, upon execution of this Agreement, deliver and deposit with the Escrow Agent, the share certificates representing the Unvested Shares, together with the stock assignment duly endorsed in blank, attached hereto as Exhibit D-2. The Unvested Shares and stock assignment shall be held by the Escrow Agent in escrow, pursuant to the Joint Escrow Instructions of the Company and Purchaser attached as Exhibit D-3 hereto, until the Company exercises its Repurchase Option, until such Unvested Shares are vested, or until such time as this Agreement no longer is in effect. Upon vesting of the Unvested Shares, the Escrow Agent shall promptly deliver to the Purchaser the certificate or certificates representing such Shares in the Escrow Agent's possession belonging to the Purchaser, and the Escrow Agent shall be discharged of all further obligations hereunder; provided, however, that the Escrow Agent shall nevertheless retain such certificate or certificates as Escrow Agent if so required pursuant to other restrictions imposed pursuant to this Agreement.

(c) Neither the Company nor the Escrow Agent shall be liable for any act it may do or omit to do with respect to holding the Shares in escrow and while acting in good faith and in the exercise of its judgment.

(d) Transfer or sale of the Shares is subject to restrictions on transfer imposed by any applicable state and federal securities laws. Any transferee shall hold such Shares subject to all the provisions hereof and the Exercise Notice executed by the Purchaser with respect to any Unvested Shares purchased by Purchaser and shall acknowledge the same by signing a copy of this Agreement.

3. Ownership, Voting Rights, Duties. This Agreement shall not affect in any way the ownership, voting rights or other rights or duties of Purchaser, except as specifically provided herein.

4. Legends. The share certificate evidencing the Shares issued hereunder shall be endorsed with the following legend (in addition to any legend required under applicable federal and state securities laws):

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS UPON TRANSFER AND RIGHTS OF REPURCHASE AS SET FORTH IN AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

5. Adjustment for Stock Split. All references to the number of Shares and the purchase price of the Shares in this Agreement shall be appropriately adjusted to reflect any stock split, stock dividend or other change in the Shares, which may be made by the Company pursuant to Section 6 of the Plan after the date of this Agreement.

6. Notices. Notices required hereunder shall be given in person or by registered mail to the address of Purchaser shown on the records of the Company, and to the Company at their respective principal executive offices.

7. Survival of Terms. This Agreement shall apply to and bind Purchaser and the Company and their respective permitted assignees and transferees, heirs, legatees, executors, administrators and legal successors.

8. Section 83(b) Election. Purchaser hereby acknowledges that he has been informed that, with respect to the exercise of an Option for Unvested Shares, an election (the "Election") may be filed by the Purchaser with the Internal Revenue Service, within thirty (30) days of the purchase of the exercised Shares, electing pursuant to Section 83(b) of the Code to be taxed currently on any difference between the purchase price of the exercised Shares and their Fair Market Value on the date of purchase. A form of Election under Section 83(b) is attached hereto as Exhibit D-4 for reference.

PURCHASER ACKNOWLEDGES THAT IT IS PURCHASER'S SOLE RESPONSIBILITY AND NOT THE COMPANY'S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b) OF THE CODE, EVEN IF PURCHASER REQUESTS THE COMPANY OR ITS REPRESENTATIVE TO MAKE THIS FILING ON PURCHASER'S BEHALF.

9. Representations. Purchaser has reviewed with his or her own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. Purchaser is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. Purchaser understands that he or she (and not the Company) shall be responsible for his or her own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

10. Entire Agreement; Governing Law. The Plan and Option Agreement are incorporated herein by reference. The Plan, the Option Agreement, the Exercise Notice, and this Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Purchaser with respect to the subject matter hereof, and may not be modified adversely to the Purchaser's interest except by means of a writing signed by the Company and Purchaser. This Agreement is governed by the internal substantive laws but not the choice of law rules of California.

Purchaser represents that he has read this Agreement and is familiar with its terms and provisions. Purchaser hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, this Agreement is deemed made as of the date first set forth above.

PURCHASER	KODIAK SCIENCES INC.
_____	_____
Signature	By
_____	_____
Print Name	Print Name
_____	_____
	Title
_____	
Residence Address	

Dated: _____, ____

EXHIBIT D-2

ASSIGNMENT SEPARATE FROM CERTIFICATE

FOR VALUE RECEIVED I, Victor Perlroth, hereby sell, assign and transfer unto Kodiak Sciences Inc. (the "Company") _____ shares of the common stock of the Company standing in my name of the books of the Company and represented by Certificate No. ___ herewith and do hereby irrevocably constitute and appoint the Company's Secretary to transfer the said stock on the books of the Company with full power of substitution in the premises.

This Stock Assignment may be used only in accordance with the Restricted Stock Purchase Agreement between the Company and the undersigned dated _____, _____ (the "Agreement").

Dated: _____ Signature:

Name: Victor Perlroth

INSTRUCTIONS: Please do not fill in any blanks other than the signature line. The purpose of this assignment is to enable the Company to exercise its "repurchase option," as set forth in the Agreement, without requiring additional signatures on the part of the Purchaser.

EXHIBIT D-3

JOINT ESCROW INSTRUCTIONS

_____, ____

Corporate Secretary
Kodiak Sciences Inc.
_____
_____

Dear _____:

As Escrow Agent for both Kodiak Sciences. (the "Company"), and the undersigned purchaser of stock of the Company (the "Purchaser"), you are hereby authorized and directed to hold the documents delivered to you pursuant to the terms of that certain Restricted Stock Purchase Agreement (the "Agreement") between the Company and the undersigned, in accordance with the following instructions:

1. In the event the Company and/or any assignee of the Company (referred to collectively for convenience herein as the "Company") exercises the Company's repurchase option set forth in the Agreement, the Company shall give to Purchaser and you a written notice specifying the number of shares of stock to be purchased, the purchase price, and the time for a closing hereunder at the principal office of the Company. Purchaser and the Company hereby irrevocably authorize and direct you to close the transaction contemplated by such notice in accordance with the terms of said notice.

2. At the closing, you are directed (a) to date the stock assignments necessary for the transfer in question, (b) to fill in the number of shares being transferred, and (c) to deliver the stock assignments, together with the certificate evidencing the shares of stock to be transferred, to the Company or its assignee, against the simultaneous delivery to you of the purchase price (by cash, a check, or some combination thereof) for the number of shares of stock being purchased pursuant to the exercise of the Company's repurchase option.

3. Purchaser irrevocably authorizes the Company to deposit with you any certificates evidencing shares of stock to be held by you hereunder and any additions and substitutions to said shares as defined in the Agreement. Purchaser does hereby irrevocably constitute and appoint you as Purchaser's attorney-in-fact and agent for the term of this escrow to execute with respect to such securities all documents necessary or appropriate to make such securities negotiable and to complete any transaction herein contemplated, including but not limited to the filing with any applicable state blue sky authority of any required applications for consent to, or notice of transfer of, the securities. Subject to the provisions of this paragraph 3, Purchaser shall exercise all rights and privileges of a stockholder of the Company while the stock is held by you.

4. Upon written request of the Purchaser, but no more than once per calendar year, unless the Company's repurchase option has been exercised, you shall deliver to Purchaser a certificate or certificates representing so many shares of stock as are not then subject to the Company's repurchase option. Within two hundred (200) days after cessation of Purchaser's continuous employment by or services to the Company, or any parent or subsidiary of the Company, you shall deliver to Purchaser a certificate or certificates representing the aggregate number of shares held or issued pursuant to the Agreement and not purchased by the Company or its assignees pursuant to exercise of the Company's repurchase option.

5. If at the time of termination of this escrow you should have in your possession any documents, securities, or other property belonging to Purchaser, you shall deliver all of the same to Purchaser and shall be discharged of all further obligations hereunder.

6. Your duties hereunder may be altered, amended, modified or revoked only by a writing signed by all of the parties hereto.

7. You shall be obligated only for the performance of such duties as are specifically set forth herein and may rely and shall be protected in relying or refraining from acting on any instrument reasonably believed by you to be genuine and to have been signed or presented by the proper party or parties. You shall not be personally liable for any act you may do or omit to do hereunder as Escrow Agent or as attorney-in-fact for Purchaser while acting in good faith, and any act done or omitted by you pursuant to the advice of your own attorneys shall be conclusive evidence of such good faith.

8. You are hereby expressly authorized to disregard any and all warnings given by any of the parties hereto or by any other person or corporation, excepting only orders or process of courts of law and are hereby expressly authorized to comply with and obey orders, judgments or decrees of any court. In case you obey or comply with any such order, judgment or decree, you shall not be liable to any of the parties hereto or to any other person, firm or corporation by reason of such compliance, notwithstanding any such order, judgment or decree being subsequently reversed, modified, annulled, set aside, vacated or found to have been entered without jurisdiction.

9. You shall not be liable in any respect on account of the identity, authorities or rights of the parties executing or delivering or purporting to execute or deliver the Agreement or any documents or papers deposited or called for hereunder.

10. You shall not be liable for the outlawing of any rights under the Statute of Limitations with respect to these Joint Escrow Instructions or any documents deposited with you.

11. You shall be entitled to employ such legal counsel and other experts as you may deem necessary properly to advise you in connection with your obligations hereunder, may rely upon the advice of such counsel, and may pay such counsel reasonable compensation therefor.

12. Your responsibilities as Escrow Agent hereunder shall terminate if you shall cease to be an officer or agent of the Company or if you shall resign by written notice to each party. In the event of any such termination, the Company shall appoint a successor Escrow Agent.

13. If you reasonably require other or further instruments in connection with these Joint Escrow Instructions or obligations in respect hereto, the necessary parties hereto shall join in furnishing such instruments.

14. It is understood and agreed that should any dispute arise with respect to the delivery and/or ownership or right of possession of the securities held by you hereunder, you are authorized and directed to retain in your possession without liability to anyone all or any part of said securities until such disputes shall have been settled either by mutual written agreement of the parties concerned or by a final order, decree or judgment of a court of competent jurisdiction after the time for appeal has expired and no appeal has been perfected, but you shall be under no duty whatsoever to institute or defend any such proceedings.

15. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail with postage and fees prepaid, addressed to each of the other parties thereunto entitled at the following addresses or at such other addresses as a party may designate by ten (10) days' advance written notice to each of the other parties hereto.

16. By signing these Joint Escrow Instructions, you become a party hereto only for the purpose of said Joint Escrow Instructions; you do not become a party to the Agreement.

17. This instrument shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and permitted assigns.

18. These Joint Escrow Instructions shall be governed by the internal substantive laws, but not the choice of law rules, of California.

[Signature page follows]

PARTICIPANT	KODIAK SCIENCES INC.
Signature	By
Print Name	Print Name
	Title
Residence Address	

ESCROW AGENT

Corporate Secretary

Dated:

EXHIBIT D-4

ELECTION UNDER SECTION 83(b)

OF THE INTERNAL REVENUE CODE OF 1986

The undersigned taxpayer hereby elects, pursuant to Section 83(b) of the Internal Revenue Code of 1986, as amended, to include in taxpayer's gross income or alternative minimum taxable income, as the case may be, for the current taxable year the amount of any compensation taxable to taxpayer in connection with taxpayer's receipt of the property described below.

1. The name, address and taxpayer identification (social security) number of the undersigned, and the taxable year in which this election is being made, are:

TAXPAYER'S NAME:

TAXPAYER'S SOCIAL SECURITY NUMBER:

ADDRESS:

TAXABLE YEAR:

The name, address and taxpayer identification (social security) number of the undersigned's spouse are (complete if applicable):

SPOUSE'S NAME:

SPOUSE'S SOCIAL SECURITY NUMBER:

ADDRESS:

2. The property with respect to which the election is made is described as follows: _____ shares (the "Shares") of the Common Stock of Kodiak Sciences Inc. (the "Company").

3. The date on which the property was transferred is:_____ ,_____.

4. The property is subject to the following restrictions:

The Shares may not be transferred and are subject to forfeiture under the terms of an agreement between the taxpayer and the Company. These restrictions lapse upon the satisfaction of certain conditions contained in such agreement.

5. The Fair Market Value at the time of transfer, determined without regard to any restriction other than a restriction which by its terms shall never lapse, of such property is: $_____.

6. The amount (if any) paid for such property is: $_____.

The undersigned has submitted a copy of this statement to the person for whom the services were performed in connection with the undersigned's receipt of the above-described property. The transferee of such property is the person performing the services in connection with the transfer of said property.

[Signature page follows]

The undersigned understands that the foregoing election may not be revoked except with the consent of the Commissioner.

Dated: _____

Taxpayer

EXHIBIT B

Election Form

KODIAK SCIENCES INC.

ELECTION FORM FOR SPECIAL EQUITY AWARD

The Compensation Committee (the "***Committee***") of the Board of Directors (the "***Board***") of Kodiak Sciences Inc. (the "***Company***") is providing you the opportunity to receive a one-time special equity award in the form of a stock option under the Kodiak Sciences Inc. 2018 Equity Incentive Plan (the "***Plan***"), pursuant to the terms and conditions set forth in this Election Form for Special Equity Award ("***Election Form***") and as described in the attached Q&A (the "***Special Award***").

Specifically, the Committee is giving you the opportunity in this Election Form to (1) elect whether you wish to receive the Special Award (such election, the "***Opt-In Election***"), which would be granted to you in lieu of a portion of each annual long term incentive award that may be granted by the Company to you during fiscal year 2021 and continuing through and including fiscal year 2027 (the "***Election Period***"), in each case subject to your continued status as a Service Provider (as defined in the Plan) on the applicable grant date (collectively, the "***Annual Long Term Incentive Awards***"), and, to the extent you make the Opt-In Election, (2) indicate your preference regarding the portion of the Annual Long Term Incentive Awards that you wish to forego (the "***Percentage Election***").

We will be sending a DocuSign to complete this Election Form. Please complete the DocuSign before 5:00 p.m., Pacific Time on _____. To the extent that your completed Election Form is not received by such time, you will be deemed to have declined the Special Award.

Opt-In Election. I hereby make the following election with respect to the Special Award:

☐ **Accept.** I wish to accept the Special Award and forego a percentage of my Annual Long Term Incentive Award for each of the next seven years. I have indicated my Percentage Election below.

☐ **Decline.** I wish to decline the Special Award.

Percentage Election. I hereby elect to forego the following percentage of each Annual Long Term Incentive Award in exchange for the Special Award:

☐ 0% of the Annual Long Term Incentive Awards in the form of the Special Award; or

☐ 25% of the Annual Long Term Incentive Awards in the form a Special Award of _____non-qualified stock options; or

☐ 50% of the Annual Long Term Incentive Awards in the form of a Special Award of _____non-qualified stock options; or

☐ 75% of the Annual Long Term Incentive Awards in the form of a Special Award of ____non-qualified stock options.

By signing below, you acknowledge that you understand that, after 5:00 p.m., Pacific Time on _____, you may not withdraw or change your elections.

_____ _____

Signature Date

_____

Name (please print)

(Exhibit A). – Special Award Q&A

Exhibit A

KODIAK SCIENCES INC.

SPECIAL AWARD Q&A

The following information in this Special Award Q&A ("***Q&A***") is intended as a summary. It may not answer all of the questions you may have about the Special Award and is not intended to go into every detail regarding the Special Award. Please note that if there are any inconsistencies between the information in this Q&A and the terms of the Special Award (as set forth in the documentation evidencing the Special Award that will, in the event you make the Opt-In Election, be provided to you upon grant), the terms of the Special Award will control. Capitalized terms not explicitly defined in this Q&A or the Election Form will have the same meanings ascribed to them in the Plan.

Why am I receiving the Election Form?

To motivate and reward the next phase of transformational performance and growth, the Committee is considering approving a new long-term incentive compensation program (the "***KSO Program***"), pursuant to which each participant will be granted a Special Award that will vest subject to both time-based and performance-based vesting conditions (as described further below). You are receiving the Election Form because you are grade-level six or above and the Committee believes you are in a position to lead and influence the Company's next phase of performance and growth, and therefore wants you to be a participant in the KSO Program. By electing to receive the Special Award, you will confirm your wish to participate in the KSO Program.

Is there an overview document to review details of KSO Program?

Eligible participants should read the "KSO Program 7-year Performance Award Participant Overview" . Please note that the KSO Program is subject to modification or cancellation based on shareholder voting from special proxy filing.

What is the potential value of the Special Award?

The Special Award is designed to provide approximately three times the value at the end of the seven year performance measurement period, based on assumptions used prior to grant date, as compared to the foregone portion of the Annual Long Term Incentive Awards.

How will the Special Award vest?

Subject to certain exceptions, the Special Award will be earned based upon the achievement of stock price performance objectives ranging from $200 to $800 over the next seven years. These performance objectives will need to be achieved, and sustained, over ninety (90) consecutive trading days at any time during the Election Period. Once earned, the Special Award will also be subject to time-based vesting conditions. Specifically, upon the achievement of any performance objective under the KSO Program, the underlying tranche of options will vest in equal monthly installments between the date of achievement of such performance objective and the end of the Election Period, subject to your continued status as a Service Provider through each such vesting date. Subject to certain exceptions, any stock price performance objectives that are not achieved by the end of the Election Period will result in the cancellation of any relevant tranches of the Special Award.

Are there any other ways for the Special Award to be earned and to vest?

A threshold level of the Special Award will be earned upon the attainment of certain operational performance objectives. Up to 25% of the Special Award will be earned upon the attainment of regulatory milestones tied to KSI-301. An additional 10% of the Special Award will be earned in the first fiscal year in which KSI-301 and/or KSI-501 has sales of $2.5 billion. To prevent double counting, the KSOs that are earned based on (Exhibit A). Please note that attainment of the stock price performance objectives (that is, the same KSOs cannot be earned twice).

Are there any other conditions applicable to the Special Award?

The Special Award will be subject to stockholder approval at a special meeting of the Company's stockholders to be held as soon as practicable following the Committee's approval of the KSO Program and the Special Award. If such shareholder approval is not obtained, then the Special Award will be forfeited and you will receive 100% of the value of your Annual Long Term Incentive Award for fiscal year 2021.

Who can I contact to answer any questions regarding the Special Award?

You are encouraged to direct questions to KSOQuestions@InfiniteEquity.com or contact John Borgeson at the Company to the extent you have any questions regarding the Special Award.

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2021

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2021

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, 2021 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, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By:

Date: November 9, 2021 /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, 2021 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, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By:

Date: November 9, 2021 /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.