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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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: 001-39592

Kronos Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**82-1895605**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1300 So. El Camino Real, Suite 400
San Mateo, California 94402
(650) 781-5200
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	KRON	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 or ☐ 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 or ☐ No.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See 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	☐	Smaller reporting company	☒
Non-accelerated filer	☒	Accelerated filer	☐
		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 or ☒ No

As of November 8, 2023 the registrant had 58,316,520 shares of common stock, $0.001 par value per share, outstanding.

TABLE OF CONTENTS

		Page
	PART I. FINANCIAL INFORMATION	
Item 1.	Condensed Financial Statements:	
	Condensed Balance Sheets as of September 30, 2023 (unaudited) and December 31, 2022	3
	Condensed Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2023 and 2022 (unaudited)	4
	Condensed Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2023 and 2022 (unaudited)	5
	Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2023 and 2022 (unaudited)	7
	Notes to Condensed Financial Statements (unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4.	Controls and Procedures	38
	PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings	39
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	99
Item 5.	Other Information	99
Item 6.	Exhibits	100
	Signatures	101

PART 1. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

KRONOS BIO, INC.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022[1]
Assets		
Current assets:		
Cash and cash equivalents	$ 57,599	$ 75,973
Short-term investments	129,114	162,212
Prepaid expenses and other current assets	4,850	6,106
Total current assets	191,563	244,291
Long-term investments	11,670	9,762
Property and equipment, net	11,310	12,985
Operating lease right-of-use assets	20,454	24,707
Restricted cash	2,026	2,026
Other noncurrent assets	970	1,167
Total assets	$ 237,993	$ 294,938
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,082	$ 5,047
Accrued expenses	9,151	12,963
Current portion of operating lease liabilities	3,263	2,347
Current portion of deferred revenue	8,577	—
Current portion of other liabilities	599	1,129
Total current liabilities	25,672	21,486
Noncurrent operating lease liabilities	26,279	28,744
Deferred revenue, net of current portion	7,422	—
Other noncurrent liabilities	—	209
Total liabilities	59,373	50,439
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.001 par value, 200,000,000 authorized as of September 30, 2023 and December 31, 2022; 58,180,739 and 56,967,436 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	58	57
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued and outstanding.		
Additional paid-in capital	662,358	641,422
Accumulated deficit	(483,541)	(396,188)
Accumulated other comprehensive income (loss)	(255)	(792)
Total stockholders' equity	178,620	244,499
Total liabilities and stockholders' equity	$ 237,993	$ 294,938

(1) The balance sheet as of December 31, 2022 is derived from the audited financial statements as of that date.

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

KRONOS BIO, INC.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue	$ 917	$ —	$ 4,002	$ —
Operating expenses:				
Research and development	25,344	23,403	67,675	70,547
General and administrative	9,398	10,135	30,813	32,886
Total operating expenses	34,742	33,538	98,488	103,433
Loss from operations	(33,825)	(33,538)	(94,486)	(103,433)
Other income, net:				
Interest and other income, net	2,451	1,282	7,133	2,011
Total other income, net	2,451	1,282	7,133	2,011
Net loss	(31,374)	(32,256)	(87,353)	(101,422)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	214	(389)	537	(1,011)
Net comprehensive loss	$ (31,160)	$ (32,645)	$ (86,816)	$ (102,433)
Net loss per share, basic and diluted	$ (0.54)	$ (0.57)	$ (1.52)	$ (1.81)
Weighted-average shares of common stock, basic and diluted	58,146,306	56,318,571	57,567,489	56,093,091

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

KRONOS BIO, INC.

Condensed Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	56,967,436	$ 57	$ 641,422	$ (792)	$ (396,188)	$ 244,499
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	386,318	—	305	—	—	305
Stock-based compensation expense	—	—	6,607	—	—	6,607
Net unrealized gain (loss) on available-for-sale securities	—	—	—	432	—	432
Net loss	—	—	—	—	(26,238)	(26,238)
Balance at March 31, 2023	57,353,754	$ 57	$ 648,334	$ (360)	$ (422,426)	$ 225,605
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	521,497	1	332	—	—	333
Stock-based compensation expense	—	—	6,906	—	—	6,906
Employee stock purchase plan	247,048	—	348	—	—	348
Net unrealized gain (loss) on available-for-sale securities	—	—	—	(109)	—	(109)
Net loss	—	—	—	—	(29,741)	(29,741)
Balance at June 30, 2023	58,122,299	$ 58	$ 655,920	$ (469)	$ (452,167)	$ 203,342
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	58,440	—	142	—	—	142
Stock-based compensation expense	—	—	6,296	—	—	6,296
Net unrealized gain (loss) on available-for-sale securities	—	—	—	214	—	214
Net loss	—	—	—	—	(31,374)	(31,374)
Balance at September 30, 2023	58,180,739	$ 58	$ 662,358	$ (255)	$ (483,541)	$ 178,620

KRONOS BIO, INC.

Condensed Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	55,703,327	$ 56	$ 608,064	$ (39)	$ (262,984)	$ 345,097
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	361,182	—	529	—	—	529
Stock-based compensation expense	—	—	7,788	—	—	7,788
Net unrealized gain (loss) on available-for-sale securities	—	—	—	(131)	—	(131)
Net loss	—	—	—	—	(36,263)	(36,263)
Balance at March 31, 2022	56,064,509	$ 56	$ 616,381	$ (170)	$ (299,247)	$ 317,020
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	142,189	—	375	—	—	375
Stock-based compensation expense	—	—	8,207	—	—	8,207
Employee stock purchase plan	12,539	—	35	—	—	35
Net unrealized gain (loss) on available-for-sale securities	—	—	—	(491)	—	(491)
Net loss	—	—	—	—	(32,903)	(32,903)
Balance at June 30, 2022	56,219,237	$ 56	$ 624,998	$ (661)	$ (332,150)	$ 292,243
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	220,391	—	628	—	—	628
Stock-based compensation expense	—	—	7,461	—	—	7,461
Net unrealized gain (loss) on available-for-sale securities	—	—	—	(389)	—	(389)
Net loss	—	—	—	—	(32,256)	(32,256)
Balance at September 30, 2022	56,439,628	$ 56	$ 633,087	$ (1,050)	$ (364,406)	$ 267,687

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

KRONOS BIO, INC.
Condensed Statements of Cash Flows
(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (87,353)	$ (101,422)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,658	1,692
Net amortization (accretion) on available-for-sale securities	(4,103)	185
Change in accrued interest on available-for-sale securities	363	856
Stock-based compensation expense	19,809	23,456
Noncash lease expense	1,982	1,628
Impairment of long-lived assets	2,916	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,266	1,433
Other noncurrent assets	197	—
Accounts payable	(945)	409
Accrued expenses	(3,812)	6,161
Right-of-use operating assets and lease liabilities, net	(1,549)	(1,997)
Deferred revenue	15,999	—
Current portion of other liabilities and other noncurrent liabilities	14	(799)
Net cash provided by (used in) operating activities	(53,558)	(68,398)
Cash flows from investing activities:		
Purchase of property and equipment	(648)	(525)
Purchase of available-for-sale marketable securities	(170,816)	(307,181)
Maturities of marketable securities	206,272	243,248
Sale of marketable securities	—	500
Net cash provided by (used in) investing activities	34,808	(63,958)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	28	1,532
Proceeds from issuance of common stock under the employee stock purchase plan	348	35
Net cash provided by (used in) financing activities	376	1,567
Net increase (decrease) in cash and cash equivalents	(18,374)	(130,789)
Cash, cash equivalents and restricted cash at beginning of period	77,999	200,296
Cash, cash equivalents and restricted cash at end of period	$ 59,625	$ 69,507
Supplemental disclosures of non-cash activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ —	$ 51
Cash and cash equivalents at end of period	$ 57,599	$ 67,481
Restricted cash at end of period	2,026	2,026
Cash, cash equivalents and restricted cash at end of period	$ 59,625	$ 69,507

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

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Kronos Bio, Inc. (Kronos or the Company), a Delaware corporation, was incorporated on June 2, 2017. The Company is an integrated discovery through clinical development biopharmaceutical company, with a focus on developing therapeutics that target the dysregulated transcription that causes cancer and other serious diseases.

The Company operates in one business segment: the development of biopharmaceutical products.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

Unaudited Interim Financial Information

The accompanying condensed balance sheet as of September 30, 2023, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed statements of stockholders' equity (deficit) as of September 30, 2023 and 2022, the condensed statements of cash flows for the nine months ended September 30, 2023 and 2022, and the financial data and other financial information disclosed in the notes to the condensed financial statements are unaudited. The unaudited interim condensed financial statements have been prepared on a basis consistent with the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2023 and the results of its operations for the three and nine months ended September 30, 2023 and 2022. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the full year ending December 31, 2023, any other interim periods, or any future year or period. These condensed financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 15, 2023 (Annual Report)

Need for Additional Capital

The Company has incurred net losses since its inception of $483.5 million as of September 30, 2023. The Company expects that its cash, cash equivalents and investments as of September 30, 2023 will be sufficient to fund its operations for a period of at least one year from the date of issuance of these condensed financial statements. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital.

The Company intends to raise additional capital through the issuance of equity securities, debt financings or other sources in order to continue its operations. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates.

The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a material adverse effect on its financial condition and ability to pursue business strategies. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. In the event that the Company

requires additional funding, there can be no assurance that it will be successful in obtaining sufficient funding on terms acceptable to the Company to fund its continuing operations, if at all.

2. SIGNIFICANT ACCOUNTING POLICIES, ESTIMATES AND JUDGMENTS

Significant Accounting Policies

In 2023, the Company began to recognize revenue related to research and development services and licenses. Refer below for a description of the revenue recognition policy. There have been no additional changes to the accounting policies during the nine months ended September 30, 2023, as compared to the significant accounting policies described in Note 2 of the “Notes to Financial Statements” of the Company’s audited financial statements included in its Annual Report for the year ended December 31, 2022.

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the condensed financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed financial statements include, but are not limited to, revenue, the accrual of research and development expenses, the fair value of investments, the fair value of the Company’s long-lived assets, income tax uncertainties, the valuation of equity instruments and the incremental borrowing rate for determining the operating lease assets and liabilities. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company’s estimates.

Revenue Recognition

The Company recognizes revenue in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers (“ASC 606”).* The Company recognizes revenue when the Company’s customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses and related transfer of know-how, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain further research and development services and licenses to the Company’s intellectual property. The payment terms of these agreements may include nonrefundable upfront fees, payments for electing the contractual options, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration.

The Company exercises judgment in assessing those promised goods and services that are distinct and thus representative of performance obligations. To the extent the Company identifies multiple performance obligations in a contract, the Company must develop assumptions that require judgment to determine the estimated standalone selling price for each performance obligation in order to allocate the transaction price among the identified performance obligations. The transaction is allocated on a relative standalone selling price basis.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will

not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are reassessed each reporting period as required.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligations and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligations using an input measure. The estimated period of performance and level of effort, including the value of the Company researchers' time and third-party costs, are reviewed quarterly and adjusted, as needed, to reflect the Company's current expectations. The measurement of progress is then used to calculate revenue, including any revenue adjustments as a result of the change in estimate. For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligations to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon the performance of the licensee. Funds received in advance are recorded as deferred revenue and are recognized as the related performance obligations are satisfied.

There are no performance, cancellation, termination, or refund provisions in any of the arrangements that contain material financial consequences to the Company.

Recent Accounting Pronouncements

The Company continues to monitor new accounting pronouncements issued by the Financial Accounting Standards Board and does not believe any accounting pronouncements issued, and not yet adopted, through the date of this report will have a material impact on the Company's consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The Company measures and reports its cash equivalents and investments at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Investments measured at fair value based on inputs other than quoted prices that are derived from observable market data are classified as Level 2.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ 24,864	$ —	$ —	$ 24,864
Certificates of deposit	975	—	—	975
Commercial paper	—	—	—	—
Corporate bonds	—	9,299	—	9,299
U.S. agency securities	—	6,073	—	6,073
U.S. treasury securities	128,239	—	—	128,239
Total financial assets	$ 154,078	$ 15,372	$ —	$ 169,450

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ 49,003	$ —	$ —	$ 49,003
Certificates of deposit	490	—	—	490
Commercial paper	—	1,667	—	1,667
Corporate bonds	—	30,657	—	30,657
U.S. agency securities	—	13,000	—	13,000
U.S. treasury securities	138,734	—	—	138,734
Total financial assets	$ 188,227	$ 45,324	$ —	$ 233,551

The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term maturities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

The Company did not have any financial assets or liabilities as of September 30, 2023 and December 31, 2022 that required Level 3 inputs.

4. INVESTMENTS

The fair value and amortized cost of available-for-sale securities by major security type as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 24,864	$ —	$ —	$ 24,864
Certificates of deposit	980	—	(5)	975
Commercial paper	—	—	—	—
Corporate bonds	9,306	—	(7)	9,299
U.S. agency securities	6,075	1	(3)	6,073
U.S. treasury securities	128,480	2	(243)	128,239
Total cash equivalents and investments	$ 169,705	$ 3	$ (258)	$ 169,450

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 49,003	$ —	$ —	$ 49,003
Certificates of deposit	490	—	—	490
Commercial paper	1,667	—	—	1,667
Corporate bonds	30,683	3	(29)	30,657
U.S. agency securities	13,024	—	(24)	13,000
U.S. treasury securities	139,477	4	(747)	138,734
Total cash equivalents and investments	$ 234,344	$ 7	$ (800)	$ 233,551

These available-for-sale securities were classified on the Company's condensed balance sheets as of September 30, 2023 and December 31, 2022 as (in thousands):

	Fair Value	
	September 30, 2023	December 31, 2022
Cash equivalents	$ 28,666	$ 61,577
Short-term investments	129,114	162,212
Long-term investments	11,670	9,762
Total cash equivalents and investments	$ 169,450	$ 233,551

The fair values of available-for-sale securities by contractual maturity as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023	December 31, 2022
Due in 1 year or less	$ 132,917	$ 174,786
Due in 1 to 2 years	11,670	9,762
Total	$ 144,587	$ 184,548

As of September 30, 2023 and December 31, 2022, the remaining contractual maturities of available-for-sale securities were less than two years, respectively. There have been no significant realized losses on available-for-sale securities for any of the periods presented in the accompanying condensed financial statements. As of September 30, 2023 and December 31, 2022, securities with a fair value of $12.4 million and zero, respectively, were in a continuous net unrealized loss position of $44 thousand and zero, respectively, for more than 12 months. Unrealized losses on available-for-sale securities are not attributed to credit risk for any of the periods presented. The Company believes that it is more likely than not that investments in an unrealized loss position will be held until maturity and all interest and principal will be received. The Company believes that an allowance for credit losses is unnecessary because the unrealized losses on certain of the Company's available-for-sale securities are due to market factors. To date, the Company has not recorded any impairment charges on available-for-sale securities.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Accrued interest on short-term available-for-sale securities	$ 492	$ 572
Prepaid equipment service contracts	281	289
Prepaid external research and development and outside services	2,175	2,276
Prepaid software	1,117	905
Prepaid insurance	111	1,630
Other prepaid expenses	674	434
Total prepaid expenses and other current assets	$ 4,850	$ 6,106

6. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Property and equipment:		
Lab equipment	$ 9,090	$ 8,475
Leasehold improvements	8,703	9,348
Furniture and fixtures	619	619
Computer equipment	71	58
Total property and equipment	18,483	18,500
Less: Accumulated depreciation	(7,173)	(5,515)
Total property and equipment, net	$ 11,310	$ 12,985

Depreciation expense was $0.5 million and $0.6 million for the three months ended September 30, 2023 and 2022, respectively and $1.7 million and $1.7 million for the nine months ended September 30, 2023 and 2022, respectively.

During the nine months ended September 30, 2023, the Company recognized a non-cash impairment charge of $0.6 million to Leasehold improvements. There was no charge in the three months ended September 30, 2023 and three and nine months ended September 30, 2022. Please refer to Note 12, “Leases”, section “Impairment of Operating Lease Right-of-Use Asset and Other Long-Lived Assets” for further details.

7. ACCRUED EXPENSES AND CURRENT PORTION OF OTHER LIABILITIES

Accrued expenses consisted of the following as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Accrued compensation	$ 3,702	$ 4,277
External research and development	4,023	7,694
Accrued outside services	1,055	945
Accrued taxes	—	40
Other accrued expenses	371	7
Total accrued expenses	$ 9,151	$ 12,963

Current portion of other liabilities consist of the following as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Current portion of unvested early exercised share liability	$ 350	$ 891
ESPP withholdings	249	238
Total current portion of other liabilities	$ 599	$ 1,129

8. STOCK-BASED COMPENSATION

2020 Equity Incentive Plan

In October 2020, the Company adopted its 2020 Equity Incentive Plan (the 2020 Plan) which replaced the 2017 Equity Incentive Plan (Prior Plan) upon completion of the IPO. The 2020 Plan provides for the grant of incentive stock options or nonqualified stock options, stock appreciation rights, restricted stock awards ("RSA"), restricted stock units ("RSU"), performance awards and other forms of awards to employees, directors, and consultants of the Company. The number of shares of common stock reserved for issuance under the 2020 Plan will automatically increase each year for a period of ten years, beginning in 2021 and continuing through 2030, in an amount equal to (1) 5.0% of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Board of Directors no later than December 31 of the immediately preceding year. As of September 30, 2023, the maximum number of shares of common stock that may be issued was 20,417,192 shares.

The Company recognizes the impact of forfeitures on stock-based compensation expense as forfeitures occur. The Company applies the straight-line method of expense recognition to all awards with only service-based vesting conditions. Options shall not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date. Vesting periods are determined at the discretion of the Board of Directors. Stock options typically vest over four years. The maximum contractual term is 10 years.

As of September 30, 2023, there were 4,260,124 shares reserved by the Company under the 2020 Plan for the future issuance of equity awards.

Stock Options

Stock option activity under the 2020 Plan as of September 30, 2023 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Balance, December 31, 2022	7,454,665	$ 11.83	7.69	$ 54
Granted	3,200,631	1.99		
Forfeited	(1,471,660)	10.94		
Exercised	(242,379)	3.21		
Balance, September 30, 2023	8,941,257	$ 8.69	8.00	$ 17

The aggregate intrinsic values of options outstanding was calculated as the difference between the exercise price of the options and the closing price of the Company's common stock on the Nasdaq Global Select Market on September 30, 2023. There was no future tax benefit related to options exercised, as the Company had accumulated net operating losses as of September 30, 2023 and December 31, 2022.

The weighted-average grant-date fair value per share of stock options granted, using the Black–Scholes option pricing model, was $1.41 during the nine months ended September 30, 2023.

As of September 30, 2023 and December 31, 2022, there was $20.2 million and $35.4 million of unrecognized stock-based compensation related to stock options, respectively, which is expected to be recognized over a weighted-average period of 1.89 years and 2.25 years, respectively.

Restricted Stock

Restricted stock awards and restricted stock units as of September 30, 2023 are summarized as follows:

	Number of Restricted Stock	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Vesting Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Unvested, December 31, 2022	2,297,745	$ 9.18	1.58	$ 3,722
Granted	1,611,211	1.99		
Vested and converted to shares	(723,876)	8.21		
Forfeited	(652,996)	5.25		
Unvested, September 30, 2023	2,532,084	$ 5.90	1.08	$ 3,292

As of September 30, 2023, there was $6.6 million of unrecognized stock-based compensation related to RSUs, which is expected to be recognized over a weighted average remaining vesting life.

As of September 30, 2023, there was $0.1 million of unrecognized stock-based compensation related to RSAs, which is expected to be recognized over a weighted average remaining vesting life.

2020 Employee Stock Purchase Plan

In October 2020, the Company adopted its 2020 Employee Stock Purchase Plan (ESPP), which initially reserved 688,000 shares of the Company's common stock for employee purchase under terms and provisions established by the Board of Directors. The number of shares of our common stock reserved for issuance under the ESPP automatically increased in 2021 and continues to increase through 2030, by the lesser of (i) 1.0% of the total number of shares of common stock outstanding on December 31 of the immediately preceding year, and (ii) 1,376,000 shares, except before the date of any increase, the Board of Directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). The Company did not issue any shares of common stock during both the three months ended September 30, 2023 and 2022. The Company issued 247,048 shares and 12,539 shares of common stock during the nine months ended September 30, 2023 and 2022, respectively.

Stock-Based Compensation Summary

Total stock-based compensation expense related to stock options, restricted stock units, restricted stock awards and the employee stock purchase plan for the three and nine months ended September 30, 2023 and 2022 is as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development expenses	$ 3,237	$ 3,500	$ 9,472	$ 11,355
General and administrative expenses	3,059	3,961	10,337	12,101
Total stock-based compensation expense	$ 6,296	$ 7,461	$ 19,809	$ 23,456

Early Exercised Options

The Company allows certain of its employees and its consultants to exercise options granted under the Prior Plan prior to vesting. The shares related to early exercised stock options are subject to the Company's lapsing repurchase right upon termination of employment or service on the Board of Directors at the lesser of the original purchase price or fair market value at the time of repurchase. In order to vest, the holders are required to provide continued service to the Company. The early exercise by an employee or consultant of a stock option is not considered to be a substantive exercise for accounting purposes, and therefore the payment received by the employer for the exercise price is recognized as a liability. For accounting purposes, unvested early exercised shares are not considered issued and outstanding and therefore not reflected as issued and outstanding in the accompanying balance sheets or the accompanying statements of stockholders' equity (deficit) until the awards vest.

The deposits received are initially recorded in current portion of other liabilities and other noncurrent liabilities for the noncurrent portion. The liabilities are reclassified to common stock and paid-in capital as the repurchase right lapses. At September 30, 2023 and December 31, 2022, there was $0.4 million and $0.9 million recorded in current portion of other liabilities, respectively. At September 30, 2023 and December 31, 2022, there was zero and $0.2 million recorded in other noncurrent liabilities, respectively, related to shares held by employees and nonemployees that were subject to repurchase.

9. INCOME TAXES

The Company did not record any income tax expense for the three and nine months ended September 30, 2023 and 2022. The Company has incurred net operating losses for all the periods presented and has not reflected any benefit of such net operating loss carryforwards in the accompanying condensed financial statements. The Company has recorded a full valuation allowance against all of its deferred tax assets as it is not more likely than not that such assets will be realized in the near future.

It is the Company's policy to record penalties and interest related to income taxes as a component of income tax expense. The Company has not recorded any interest or penalties related to income taxes during the three and nine months ended September 30, 2023 and 2022. The Company has not identified any new uncertain tax positions as of September 30, 2023. Unrecognized tax benefits are not expected to change during the next 12 months. The reversal of the unrecognized tax benefits would not affect the effective tax rate. The Company is subject to examination by U.S. federal and state tax authorities for all years since its inception.

10. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share of the Company for the three and nine months ended September 30, 2023 and 2022 (in thousands, except share and per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net loss	$ (31,374)	$ (32,256)	$ (87,353)	$ (101,422)
Weighted-average common stock outstanding, basic and diluted	58,146,306	56,318,571	57,567,489	56,093,091
Net loss per share, basic and diluted	$ (0.54)	$ (0.57)	$ (1.52)	$ (1.81)

The Company's potentially dilutive securities, which include options to purchase shares of the Company's common stock and restricted stock subject to future vesting, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share.

The Company excluded the following potential shares of common stock, presented based on amounts outstanding at each stated period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	September 30, 2023	September 30, 2022
Stock options to purchase common stock	8,843,067	7,362,762
Early exercised stock options subject to future vesting	98,190	386,862
Restricted stock awards subject to future vesting	28,577	62,870
Restricted stock units subject to future vesting	2,503,507	2,271,896
Expected shares to be purchased under Employee Stock Purchase Plan	1,502,501	829,820
Total	12,975,842	10,914,210

In addition to the potentially dilutive securities noted above, the Company also has the option under its agreement with Tempus to issue common shares upon the achievement of specified milestones. Please refer to Note 11, “Commitment and Contingencies” for further details. Because the necessary conditions for issuance of the shares had not been met as of September 30, 2023, the Company excluded these shares from the table above.

11. COMMITMENTS AND CONTINGENCIES

Amended Research and Development Services Agreement

In October 2021, as subsequently amended in April 2023, the Company entered into an agreement for research and development services (the Amended Tempus Agreement) with Tempus Labs, Inc. (Tempus), pursuant to which Tempus agreed to provide the Company with research and development services for a period of four years. The three primary services are analytical services, data licensing, and organoid services. The Company intends to utilize the services contemplated under the Amended Tempus Agreement to advance the development of KB-0742 and lanraplenib.

In consideration for the access to the services throughout the term of the Amended Tempus Agreement, the Company has agreed to pay an annual minimum commitment of $1.5 million in year one, $2.5 million in year two, $3.0 million in year three and $2.5 million in year four. Payments are made in quarterly installments. As of September 30, 2023, the Company has paid cumulatively $4.0 million under the Amended Tempus Agreement, including $2.9 million paid for the nine months ended September 30, 2023, $1.1 million paid for the year ended December 31, 2022 and null for the year ended December 31, 2021.

In addition, the Company is required to make milestone payments upon successful achievement of certain regulatory milestones for KB-0742, lanraplenib, and other discovery pipeline compounds up to a combined maximum of $22.4 million. For each milestone payment that becomes due, the Company has the right to pay up to 50% of such milestone payment amount in shares of its common stock as long as certain regulatory requirements are met. As of September 30, 2023 and December 31, 2022, the Company determined that achievement of the milestones is not probable and therefore no corresponding liability has been recorded.

Asset Purchase Agreement

In July 2020, the Company entered into an asset purchase agreement (Gilead Asset Purchase Agreement) with Gilead Sciences, Inc. (Gilead), pursuant to which the Company acquired certain assets from Gilead related to entospletinib and lanraplenib, and patents and other intellectual property covering or related to the development, manufacture and commercialization of entospletinib and lanraplenib. Under the agreement, the Company is required to make milestone payments upon successful achievement of certain regulatory and sales milestones for lanraplenib, entospletinib and other SYK inhibitor compounds covered by the patent rights acquired pursuant to the Gilead Asset Purchase Agreement and developed by us as a back-up to entospletinib or lanraplenib (Other Compounds).

Upon successful completion of certain regulatory milestones in the United States, European Union and United Kingdom for lanraplenib, entospletinib and any Other Compounds, across up to two distinct indications, we will be required to pay to Gilead an aggregate total of $51.3 million. Upon achieving certain thresholds for the aggregate annual net sales of lanraplenib, entospletinib, and any Other Compounds combined, we would owe to Gilead potential milestone payments totaling $115.0 million.

Gilead is also eligible to receive (i) tiered marginal royalties ranging from high-single digits to the mid-teens on annual worldwide net sales of lanraplenib, (ii) tiered marginal royalties ranging from the very low-teens to high-teens on annual worldwide net sales of entospletinib, and (iii) tiered marginal royalties ranging from the low single digits to mid-single digits on annual worldwide net sales of any Other Compounds. The royalties in the foregoing clauses are subject to reduction, on a country-by-country basis, for products not covered by certain claims within the assigned patents, for generic entry and, in the case of lanraplenib and entospletinib, for any royalties paid for future licenses of third-party intellectual property required to develop or commercialize lanraplenib or entospletinib. Our royalty obligation with respect to a given product in a given country begins upon the first commercial sale of such product in such country and ends on the latest of (i) expiration of the last claim of a defined set of the assigned patent rights covering such product in such country, (ii) loss of exclusive data or marketing rights to such product in such country or (iii) 10 years from the first commercial sale of such product in such country.

Under the Gilead Asset Purchase Agreement, we are required to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize either lanraplenib or entospletinib.

We are currently unable to estimate the timing or likelihood of achieving remaining milestones or generating future product sales.

Purchase Commitments

In the normal course of business, the Company enters into contracts with contract research organizations (CROs) for preclinical and clinical studies and other vendors for services and products. These agreements generally provide for termination or cancellation, other than for costs already incurred and certain wind down costs that may be associated with the termination of a contract or clinical trial program.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

12. LEASES

In March 2020, the Company entered into an 11-year lease agreement to move its research and development operations from 21 Erie Street, Cambridge, Massachusetts, to a 40,514 square-feet facility at 301 Binney Street, Cambridge, Massachusetts (Cambridge facility). The lease commenced on February 28, 2020 with an initial annual base rent of $4.1 million. The initial rent payment was paid as of September 30, 2020, with rent payments escalating 3.0% annually after the initial 12 payments. The Company executed a letter of credit for $2.0 million in connection with the lease. The lease includes $3.7 million in certain tenant improvement allowances, which the Company included in its calculation of the right-of-use asset in the lease at commencement. As of September 30, 2023, $3.7 million in improvement costs incurred by the Company were reimbursed by the lessor and are now included within the total lease liability. In connection with the lease, the Company recognized an operating lease right-of-use asset of $18.6 million and $21.9 million and an aggregate lease liability of $26.5 million and $28.0 million as of September 30, 2023 and December 31, 2022, respectively. The remaining lease term is 7 years and 5 months, and the estimated incremental borrowing rate is 8.50%.

In February 2021, the Company entered into a new lease agreement for its office space in San Mateo, California totaling 17,340 square-feet. The initial annual base rent for the new space was $1.2 million, and such amount increases by 3% annually on each anniversary of the new premises commencement date. In connection with the larger space leased, the Company made a one-time cash security deposit in the amount of $59,000. The lease commenced in April 2021 and terminates August 31, 2026. In connection with the lease, the Company recognized an operating lease right-of-use asset of $1.9 million and $2.8 million and an aggregate lease liability of $3.1 million and $3.7 million as of September 30, 2023 and December 31, 2022, respectively. The remaining lease term is 2 years and 9 months, and the estimated incremental borrowing rate is 11.18%.

The following table summarizes the presentation of the Company's operating leases in its balance sheets as of September 30, 2023 and December 31, 2022 (in thousands):

Balance Sheet Caption	September 30, 2023	December 31, 2022
Assets:		
Operating lease assets	$ 20,454	$ 24,707
Liabilities:		
Current portion of operating lease liabilities	$ 3,263	$ 2,347
Noncurrent operating lease liabilities	26,279	28,744
Total operating lease liabilities	$ 29,542	$ 31,091

The following table summarizes the effect of operating lease costs in the Company's statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Statement of Operations and Comprehensive Loss Caption	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development	$ 897	$ 767	$ 2,431	$ 2,301
General and administrative	561	511	1,582	1,532
Total operating lease cost	$ 1,458	$ 1,278	$ 4,013	$ 3,833

Under the lease agreements, the Company made cash payments of $1.3 million and $3.7 million during the three and nine months ended September 30, 2023, respectively. The Company made cash payments of $1.9 million and $4.2 million during the three and nine months ended September 30, 2022, respectively.

The undiscounted future non-cancellable lease payments under the Company's operating leases as of September 30, 2023 for the next five years and thereafter is expected to be as follows (in thousands):

	Amount
Remaining three months of 2023	$ 1,440
2024	5,749
2025	5,921
2026	5,405
2027 and thereafter	21,298
Total undiscounted lease payments	39,813
Less: Present value adjustment	(10,271)
Present value of operating lease liabilities	$ 29,542

Impairment of Operating Lease Right-of-Use Asset and Other Long-Lived Assets

The Company evaluates the carrying value of long-lived assets, which include property and equipment and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying

amounts of the asset may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset or asset group and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

As a result of the sustained decline in the Company's stock price, the Company determined an impairment indicator was present. The Company determined all of its long-lived assets represent a single asset group for the purpose of the long-lived asset impairment assessment. The Company concluded that the carrying value of the single asset group was not recoverable as it exceeded the future net undiscounted cash flows that are expected to be generated from the use and eventual disposition of the assets within the asset group. To allocate and recognize the impairment loss, the Company, with the assistance of a third-party valuation firm, determined the fair value of the Company using the adjusted net asset method under the cost approach. The implied allocated impairment loss to any individual asset within the long-lived asset group shall not reduce the carrying amount of that asset below its fair value. To determine the fair value of the individual assets within the asset group, the Company utilized the discounted cash flow method of the income approach and the indirect cost approach.

Based on this analysis, during the nine months ended September 30, 2023, the Company recognized a non-cash impairment charge of $2.9 million, including $2.3 million for the right-of-use assets and $0.6 million for the leasehold improvements (please see Note 6, "Property and Equipment, Net" for further details). The Company recorded $1.9 million in "Research and Development" and $1.0 million in "General and Administration", based on the relative allocation of the operating lease costs and depreciation and amortization expense. No impairment charge was recorded for the three months ended September 30, 2023 and three and nine months ended September 30, 2022.

These represent a Level 3 nonrecurring fair value measurement. Calculating the fair value of the assets involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates and market conditions. Changes in the factors and assumptions used could materially affect the amount of impairment loss recognized in the period the asset was considered impaired.

13. RELATED PARTIES

On December 1, 2017, the Company entered into a services agreement with Two River Consulting, LLC (Two River) to provide various clinical development, operational, managerial, accounting and financial, and administrative services to the Company. Arie Belldegrun, M.D., FACS, the Chairman of the Board of Directors, is the Chairman of Two River. Mr. Joshua Kazam and Mr. David Tanen, each a director of the Company, are each partners of Two River. Mr. Christopher Wilfong, a strategic advisor to the Company, is an Operating Partner of Two River and Mr. Sean Algeo, serving as a financial consultant to the Company, is the Chief Financial Officer of Two River. During the three and nine months ended September 30, 2023, the Company incurred expenses of $24,000 and $72,000, respectively, for these services. During the three and nine months ended September 30, 2022, the Company incurred expenses of $30,000 and $71,000, respectively, for these services.

In 2019, the Company entered into a consulting agreement with Bellco Capital, LLC (Bellco) to provide various executive services to the Company. Arie Belldegrun, M.D., FACS, the Chairman of the Board of Directors, is the Chairman of Bellco. During the three and nine months ended September 30, 2023, the Company incurred expense of $6,300 and $18,900, respectively, for these services. During the three and nine months ended September 30, 2022, the Company incurred expense of $6,300 and $18,900, respectively, for these services.

14. COLLABORATION AND LICENSE AGREEMENT

On January 6, 2023, the Company entered into a Collaboration and License Agreement with Genentech, Inc., a member of the Roche Group ("Genentech"). Pursuant to the agreement, the parties have agreed to initially collaborate on two discovery research programs in oncology, each focused on a designated transcription factor, to discover small-molecule GLP-Tox-ready candidates that modulate transcription factor targets selected by Genentech. Each discovery research program primarily consists of (i) a mapping phase with the goal of identifying the transcription regulatory network for such designated transcription factor, and (ii) a screening phase having the

goal of identifying and characterizing multiple screening hits suitable for nomination as a preclinical development program.

The Company leads discovery and research activities under the discovery research programs and uses its proprietary drug discovery platform, including the small molecule microarray (SMM), for hit finding. Following the completion of initial discovery and research activities, Genentech will have the exclusive right to pursue further preclinical and clinical development and commercialization of compounds identified in the discovery research programs and designated by Genentech (each, a “Hit Program”).

Pursuant to the agreement, the Company received an upfront payment of $20.0 million from Genentech. In addition, the Company is eligible for additional milestone payments upon achievement of certain preclinical, clinical and regulatory (including first-sale) milestones, totaling up to $177 million for the first development candidate per Hit Program, and is eligible to receive net sales milestones of up to $100 million for the first licensed product per Hit Program. The Company is also eligible to receive tiered royalties in the low- to high-single digits on any products that are commercialized by Genentech as a result of the collaboration.

The term of the discovery research programs under the agreement is up to 24 months, which may be extended by six months at the Company’s option subject to satisfying certain conditions.

Unless earlier terminated, the agreement will remain in effect for each product licensed under the agreement until expiration of the royalty term for such licensed product. Genentech has the right to terminate this agreement in its entirety, or with respect to a particular discovery research program or Hit Program, in its sole discretion, at any time by providing 60 days’ advance written notice to the Company. Each party may also terminate the agreement upon the other party’s material breach that remains uncured for 90 days (or 45 days in the event of nonpayment), or in the event of certain insolvency events involving the other party.

The Company evaluated the agreement and determined it was within the scope of ASC 606. The Company determined there were performance obligations to perform research and development services. Each consists of various exclusive and non-exclusive licenses to use the Company’s intellectual property and know-how, initial discovery activities, and substitution of the designated transcription factor. The Company also identified customer options contained within the contract to perform further research and development services and the renewal of the licenses that were deemed a material right as these involved a discount to Genentech that they would not have otherwise received. As a result, the material rights for various options were recognized as separate performance obligations and the transaction price was allocated to the material rights based on the relative standalone selling price, the identified discount and the probability that the customer will exercise the option or the option is cancelled. Amounts allocated to a material right are not recognized as revenue until the option is exercised. The transaction price was determined to consist of the upfront payment of $20.0 million. Potential development and regulatory milestones have been fully constrained. The Company is expected to perform research and development services for each selected target up until a defined point at which time Genentech will decide whether or not to exercise an option to nominate a development candidate and take over future development and commercialization. The Company concluded this is not a material right. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Genentech.

The Company determined that the performance obligations to perform research and development services are satisfied over time, and therefore, the related revenue will be recognized as services are provided. The Company recognized $0.9 million and $4.0 million in revenue during the three and nine months ended September 30, 2023, respectively, using the cost-based input model related to the research and development activities associated with the identified performance obligations. The remaining $16.0 million of the upfront payment is included in short and long-term deferred revenue as of September 30, 2023 and will be recognized as the performance obligations are satisfied.

15. SUBSEQUENT EVENT

On October 30, 2023, the Board of Directors of the Company approved an approximately 19% reduction of its workforce as part of a strategic resource allocation, restructuring and cost containment plan. The workforce reduction was completed on November 2, 2023.

In connection with the reduction in workforce, the Company expects to incur charges of approximately $1.8 million associated with cash severance payments in the fourth quarter of 2023, and up to approximately $0.3 million in charges associated with cash payments for COBRA reimbursement over as much as the next six months.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the condensed financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and related notes as of and for the fiscal year ended December 31, 2022 included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2023.

Forward Looking Statements

This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. In some cases, you could identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will," or the negative of these terms or similar expressions. As a result of many factors, including those factors set forth under "Risk Factors" included in Item 1A of Part II of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 while 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 an exhaustive 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.

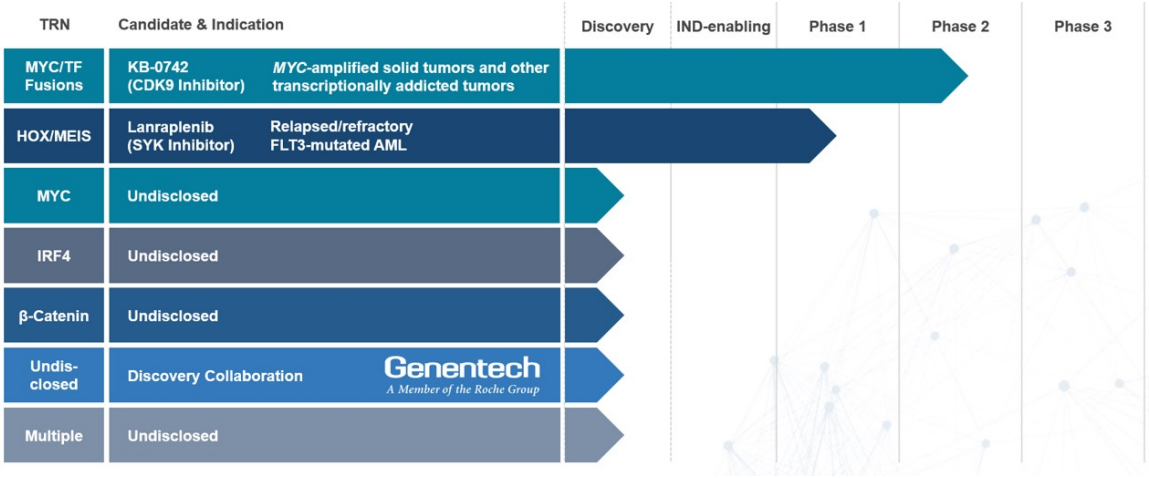
Overview

We are an integrated discovery through clinical development biopharmaceutical company, with a focus on developing therapeutics that target the dysregulated transcription that causes cancer and other serious diseases. We are enrolling patients in clinical trials for two compounds. Our product engine, which includes our proprietary small molecule microarray (SMM) screening platform, provides us with the capability to map and target transcription regulatory networks (TRNs) in a differentiated manner to enable discovery of novel compounds and improve our ability to discover and optimize clinical development candidates. In addition to our own internal preclinical programs, we have entered into a collaboration agreement with Genentech, Inc., a member of the Roche Group (Genentech).

We are developing KB-0742, our internally discovered, orally-administered, cyclin dependent kinase 9 (CDK9) inhibitor, for the treatment of MYC-amplified and other transcriptionally addicted solid tumors. We have initiated the Phase 2 portion of our Phase 1/2 clinical trial. KB-0742 was generated from our optimization of a compound that was identified using our SMM platform.

We are also developing lanraplenib, our selective, orally administered spleen tyrosine kinase (SYK) inhibitor, and are in the dose escalation stage of our Phase 1b/2 clinical trial. This clinical trial evaluates lanraplenib in combination with gilteritinib in patients with relapsed or refractory FLT3-mutated acute myeloid leukemia (AML).

The following chart summarizes our pipeline by stage, including development programs, KB-0742 and lanraplenib, and discovery programs.



In our research efforts, we are leveraging our product engine to drive multiple oncology discovery programs targeting dysregulated transcription factors and their associated TRNs. Some of the most powerful oncogenes in all of human cancer encode transcription factors: proteins that bind to specific DNA sequences on the genome and control how sets of genes are turned on and off. Transcription factors historically have been difficult to target in drug development because they are typically intrinsically disordered, adopting a functional structure only when assembled with a complex of cofactors in the nucleus on the genome. Transcription factors with aberrant expression or activity result in dysregulated TRNs, which are frequently responsible for reprogramming healthy cells into cancerous tumor cells. Therapeutically modulating dysregulated transcription factors requires a sophisticated and holistic approach due to their complexity and their regulation of complex TRNs in a context-dependent manner.

In January 2023, we entered into a research collaboration with Genentech, focused on discovering and developing small-molecule drugs that modulate transcription factor targets selected by Genentech. Under the collaboration, we are leveraging our proprietary drug discovery platform, including the small molecule microarray, for hit finding, to build upon research conducted by Genentech.

In November 2023, we announced corporate restructuring plans designed to optimize our resource allocation and contain costs in light of the positive preliminary safety and efficacy clinical data from our Phase 1/2 clinical trial of KB-0742. We believe this plan positions us to optimize the development of KB-0742 while continuing to advance the development of lanraplenib, and also enables us to focus our discovery efforts on maturing projects and our Genentech collaboration activities. We expect that these restructuring efforts, which include a 19% reduction in workforce, will extend our cash runway into 2026. In connection with the reduction in workforce, the Company expects to incur charges of approximately $1.8 million associated with cash severance payments in the fourth quarter of 2023, and up to approximately $0.3 million in charges associated with cash payments for COBRA reimbursement over as much as the next six months.

Since our formation, we have incurred significant operating losses, primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. Our net loss was $31.4 million and $32.3 million for the three months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $483.5 million. As of September 30, 2023, we had $198.4 million of cash, cash equivalents and investments. We expect to continue to incur net losses for the foreseeable future, and we expect to continue to make significant investments in our research and development and general and administrative functions.

Strategic Agreements

Genentech Collaboration Agreement

On January 6, 2023, we entered into a Collaboration and License Agreement with Genentech, a member of the Roche Group. Pursuant to the agreement, the parties have agreed to initially collaborate on two discovery research programs in oncology, each focused on a designated transcription factor, to discover small-molecule GLP-Tox-ready candidates that modulate transcription factor targets selected by Genentech. Each discovery research program primarily consists of (i) a mapping phase with the goal of identifying the transcription regulatory network for such designated transcription factor, and (ii) a screening phase having the goal of identifying and characterizing multiple screening hits suitable for nomination as a preclinical development program.

We lead discovery and research activities under the discovery research programs and use our proprietary drug discovery platform, including our SMM, for hit finding. Following the completion of initial discovery and research activities, Genentech will have the exclusive right to pursue further preclinical and clinical development and commercialization of compounds identified in the discovery research programs and designated by Genentech (each, a Hit Program).

In connection with the agreement, we received an upfront payment of $20.0 million from Genentech. In addition, we are eligible for additional milestone payments upon achievement of certain preclinical, clinical and regulatory (including first-sale) milestones, totaling up to $177.0 million for the first development candidate per Hit Program, and are eligible to receive net sales milestones of up to $100.0 million for the first licensed product per Hit Program. We are also eligible to receive tiered royalties in the low- to high-single digits on any products that are commercialized by Genentech as a result of the collaboration.

The term of the discovery research programs is up to 24 months, which may be extended by six months at our option subject to satisfying certain conditions.

Tempus Research and Development Services Agreement

In October 2021, as subsequently amended in April 2023, we entered into an agreement for research and development services (the Amended Tempus Agreement) with Tempus Labs, Inc. (Tempus), pursuant to which Tempus has agreed to provide us with research and development services for a period of four years. The three primary services are analytical services, data licensing, and organoid services. We intend to utilize the services contemplated under the Amended Tempus Agreement to advance the development of KB-0742 and lanraplenib.

In consideration for the access to the services throughout the term of the Amended Tempus Agreement, we have agreed to pay an annual minimum commitment of $1.5 million in year one, $2.5 million in year two, $3.0 million in year three and $2.5 million in year four. Payments are made in quarterly installments. As of September 30, 2023, we have paid $4.0 million under the Amended Tempus Agreement.

In addition, we are required to make milestone payments upon successful achievement of certain regulatory milestones for KB-0742, lanraplenib, and other discovery pipeline compounds up to a combined maximum of $22.4 million. For each milestone payment that becomes due, we have the right to pay up to 50% of such milestone payment amount in shares of our common stock as long as certain regulatory requirements are met.

Gilead Asset Purchase Agreement

In July 2020, we entered into the Gilead Asset Purchase Agreement, pursuant to which we acquired certain assets from and assumed certain liabilities of Gilead related to lanraplenib or entospletinib, and patents and other intellectual property covering or related to the development, manufacture and commercialization of lanraplenib or entospletinib.

In consideration for such assets, on the date of the Gilead Asset Purchase Agreement, we made a $3.0 million upfront cash payment and issued a $3.0 million principal amount convertible promissory note, which was settled in exchange for 188,567 shares of common stock in connection with the closing of our IPO at a settlement price of $16.15 per share. We also made a $0.7 million payment to reimburse Gilead for certain liabilities we assumed pursuant to the Gilead Asset Purchase Agreement. In addition, we are required to make milestone payments upon successful achievement of certain regulatory and sales milestones for lanraplenib, entospletinib and other SYK inhibitor compounds covered by the patent rights acquired pursuant to the Gilead Asset Purchase

Agreement and developed by us as a back-up to entospletinib or lanraplenib (Other Compounds). Upon successful completion of certain regulatory milestones in the United States, European Union and United Kingdom for lanraplenib, entospletinib and any Other Compounds, across up to two distinct indications, we will be required to pay to Gilead an aggregate total of $51.3 million. Upon achieving certain thresholds for the aggregate annual net sales of lanraplenib, entospletinib, and any Other Compounds combined, we would owe to Gilead potential milestone payments totaling $115.0 million.

Gilead is also eligible to receive (i) tiered marginal royalties ranging from high-single digits to the mid-teens on annual worldwide net sales of lanraplenib, (ii) tiered marginal royalties ranging from the very low-teens to high-teens on annual worldwide net sales of entospletinib, and (iii) tiered marginal royalties ranging from the low single digits to mid-single digits on annual worldwide net sales of any Other Compounds. The royalties in the foregoing clauses are subject to reduction, on a country-by-country basis, for products not covered by certain claims within the assigned patents, for generic entry and, in the case of lanraplenib and entospletinib, for any royalties paid for future licenses of third-party intellectual property required to develop or commercialize lanraplenib or entospletinib. Our royalty obligation with respect to a given product in a given country begins upon the first commercial sale of such product in such country and ends on the latest of (i) expiration of the last claim of a defined set of the assigned patent rights covering such product in such country, (ii) loss of exclusive data or marketing rights to such product in such country or (iii) 10 years from the first commercial sale of such product in such country.

Under the Gilead Asset Purchase Agreement, we are required to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize either lanraplenib or entospletinib.

Components of Our Results of Operations

Revenues

As of September 30, 2023, our revenue has been exclusively generated from our collaboration and license agreement with Genentech. We received a $20.0 million upfront payment from Genentech in February 2023 and are eligible for additional milestone payments upon achievement of certain preclinical, clinical and regulatory (including first-sale) milestones. See Note 14 to our financial statements appearing elsewhere in this Quarterly Report for more information related to our recognition of revenue and the Genentech agreement.

Operating Expenses

Our operating expenses consisted of research and development expenses and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with our therapeutic discovery efforts and the preclinical and clinical development of our product candidates, as well as the development of our product engine.

Direct costs include:

- expenses incurred under agreements with contract research organizations (CROs) and other vendors that conduct our clinical trials and preclinical activities;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of acquiring, developing, and manufacturing clinical trial materials and lab supplies; and
- payments made under third-party strategic agreements.

Indirect costs include:

- personnel costs, which include salaries, benefits, and other employee related costs, including stock-based compensation, for personnel engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- facilities costs, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

We expense research and development costs as the services are performed or the goods are received. We recognize costs for certain development activities based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our internal management. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our condensed financial statements as prepaid or accrued research and development expenses.

Because we are working on multiple research and development programs at any one time, we intend to track our direct costs by the stage of program, clinical or preclinical. However, our internal costs, employees and infrastructure are not directly tied to any one program and are deployed across multiple programs. As such, we do not track indirect costs on a specific program basis.

Our research and development expenses may vary significantly based on a variety of factors, such as:

- the scope, rate of progress, and results of our preclinical development activities;
- per patient trial costs;
- the number of trials required for approval; the number of sites included in the trials;

- the number of patients that participate in the trials;
- the countries in which the trials are conducted;
- uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the safety and efficacy of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- significant and changing government regulation and regulatory guidance;
- potential additional trials requested by regulatory agencies;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the extent to which we establish additional strategic collaborations or other arrangements;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

A change in the outcome of any of these 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.

We expect to continue to make significant investments into research and development for the foreseeable future as we continue to identify and develop additional product candidates and as more of our product candidates move into later stages of clinical development, which typically have higher development costs than those in earlier stages of clinical development due to the increased size and duration of later-stage clinical trials.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' development, which could increase our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, which include salaries, benefits and other employee related costs, such as stock-based compensation, for personnel in our executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; recruiting costs; travel expenses; and facilities-related costs.

We expect to maintain the general and administrative function for the foreseeable future to support personnel in research and development and to support our operations generally as we execute on our research and development activities. We also expect to continue to incur expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Interest and Other Income, Net

Interest and other income, net primarily consists of interest earned on our cash, cash equivalents and investments.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Revenue	$ 917	$ —	$ 917
Operating expenses:			
Research and development	$ 25,344	$ 23,403	$ 1,941
General and administrative	9,398	10,135	(737)
Total operating expenses	34,742	33,538	1,204
Loss from operations	(33,825)	(33,538)	(287)
Other income, net:			
Interest and other income, net	2,451	1,282	1,169
Total other income, net	2,451	1,282	1,169
Net loss	$ (31,374)	$ (32,256)	$ 882

Revenue

Revenue was $0.9 million for the three months ended September 30, 2023 and zero for the three months ended September 30, 2022. The increase of $0.9 million was due to revenue recognized under the Collaboration and License Agreement entered into with Genentech in January 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Direct Costs	$ 14,915	$ 12,894	$ 2,021
Indirect Costs:			
Personnel	8,108	8,445	(337)
Facilities, depreciation and other expenses	2,321	2,064	257
Total research and development expenses	$ 25,344	$ 23,403	$ 1,941

Research and development expenses were $25.3 million for the three months ended September 30, 2023 compared with $23.4 million for the three months ended September 30, 2022. The increase of $1.9 million was due to an increase in consulting and outside services attributable to increased enrollment and site start-up for the KB-0742 study.

General and Administrative Expenses

General and administrative expenses were $9.4 million for the three months ended September 30, 2023 compared with $10.1 million for the three months ended September 30, 2022. The decrease of $0.7 million was primarily due to a decrease in stock-based compensation of $0.9 million and a decrease of $0.4 million in professional fees primarily attributable to insurance and legal services. These decreases were partially offset by an increase of $0.8 million in personnel expenses.

Comparison of Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Revenue	$ 4,002	$ —	$ 4,002
Operating expenses:			
Research and development	$ 67,675	$ 70,547	$ (2,872)
General and administrative	30,813	32,886	(2,073)
Total operating expenses	98,488	103,433	(4,945)
Loss from operations	(94,486)	(103,433)	8,947
Other income, net:			
Interest and other income, net	7,133	2,011	5,122
Total other income, net	7,133	2,011	5,122
Net loss	$ (87,353)	$ (101,422)	$ 14,069

Revenue was $4.0 million for the nine months ended September 30, 2023 and zero for the nine months ended September 30, 2022. The increase was due to the revenue recognized under the Collaboration and License Agreement entered into with Genentech in January 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine months ended September 30,		
	2023	2022	Change
Direct Costs	$ 34,892	$ 37,738	$ (2,846)
Indirect Costs:			
Personnel	24,222	26,876	(2,654)
Facilities, depreciation and other expenses	8,561	5,933	2,628
Total research and development expenses	$ 67,675	$ 70,547	$ (2,872)

Research and development expenses were $67.7 million for the nine months ended September 30, 2023, compared with $70.5 million for the nine months ended September 30, 2022. The decrease of $2.9 million was primarily due to a decrease of $3.1 million in consulting and other outside research expenses related to the discontinuation of our Phase 3 entospletinib trial in the three months ended December 31, 2022, a decrease in stock-based compensation of $1.9 million and a decrease of $0.8 million in personnel costs both primarily attributable to the decreased headcount. These decreases were partially offset by a $2.5 million increase in facilities, depreciation and other expenses, primarily consisting of the non-cash impairment charge of $1.9 million, and an increase in lab costs of $0.4 million. Please refer to Part 1. Financial Information, Note 12, “Leases”, section “Impairment of Operating Lease Right-of-Use Asset and Other Long-Lived Assets” for further details.

General and Administrative Expenses

General and administrative expenses were $30.8 million for the nine months ended September 30, 2023 compared with $32.9 million for the nine months ended September 30, 2022. The decrease of $2.1 million was primarily due to a decrease of $1.9 million in professional fees primarily attributable to insurance and other professional services and a $1.8 million decrease in stock-based compensation primarily attributable to the $1.0 million reversal of expense in connection with equity award forfeitures upon the departure of our Chief Financial Officer in September 2023. These decreases were partially offset by an increase of $0.8 million in facilities, depreciation and other expenses primarily contributed by the non-cash impairment charge of $1.0 million, and an increase of $0.8 million in personnel expenses primarily attributable to increased headcount. Please refer to Part 1. Financial Information, Note 12, “Leases”, section “Impairment of Operating Lease Right-of-Use Asset and Other Long-Lived Assets” for further details.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever. Prior to our IPO, our operations were financed primarily by net proceeds from the sale and issuance of our convertible preferred stock and convertible notes, totaling aggregate gross proceeds of $278.2 million. Upon completion of our IPO on October 14, 2020, we sold an aggregate of 15,131,579 shares of our common stock including 1,973,684 shares of common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares at a price of $19.00 per share and received approximately $263.7 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

As of September 30, 2023, we had cash, cash equivalents and investments of $198.4 million. We expect that our cash, cash equivalents and investments as of September 30, 2023, will enable us to fund our planned operating expenses and capital expenditure requirements into 2026.

Material Cash Requirements

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our therapeutic discovery efforts, KB-0742 and lanraplenib, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our product candidates are still in the early stages of clinical and preclinical development, and the outcomes of these efforts are uncertain. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration agreements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise capital when needed, we will need to delay, reduce or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Contractual Obligations and Commitments

In March 2020, we entered into a lease agreement for our research and development operations facility at 301 Binney Street, Cambridge, Massachusetts (Cambridge facility). The initial annual base rent was $4.1 million with rent payments escalating 3.0% annually after the initial 12 payments. We executed a letter of credit for $2.0 million in connection with the lease. The remaining lease term is 7 years and 5 months.

In February 2021, the Company entered into a new lease agreement for its office space in San Mateo, California totaling 17,340 square-feet. The initial annual base rent for the new space was $1.2 million, and such amount increases by 3% annually on each anniversary of the new premises commencement date. In connection with the larger space leased, the Company made a one-time cash security deposit in the amount of $59,000. The lease commenced in April 2021 and terminates August 31, 2026.

Pursuant to the Gilead Asset Purchase Agreement, we are obligated to make milestone payments upon the achievement of specified regulatory and clinical milestones as well as royalty payments. The payment obligations under this agreement are contingent upon future events, such as our achievement of specified milestones or generating product sales. We are currently unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See the subsection titled "—Strategic Agreements—Gilead Asset Purchase Agreement" above.

Pursuant to the Amended Tempus Agreement, we are obligated to make milestone payments upon the achievement of specified regulatory milestones as well as annual minimum commitments in quarterly installments. Some payment obligations under this agreement are contingent upon future events, such as our achievement of specified milestones. We are currently unable to estimate the timing or likelihood of achieving these milestones.

See the subsection titled "—Strategic Agreements—Amended Tempus Research and Development Services Agreement" above.

We enter into contracts in the ordinary course of business with CROs for clinical trials, preclinical and clinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are generally terminable by us upon prior notice. Payments due upon termination generally consist only of payments for services provided and expenses incurred up to the date of termination and certain wind down costs that may be associated with the termination of a contract or clinical trial program.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash used in operating activities	$ (53,558)	$ (68,398)
Cash provided by (used in) investing activities	34,808	(63,958)
Cash provided by financing activities	376	1,567
Net decrease in cash and cash equivalents	$ (18,374)	$ (130,789)

Operating Activities

During the nine months ended September 30, 2023, cash used in operating activities was $53.6 million and consisted of our net loss of $87.4 million, adjusted for non-cash charges of $22.6 million and an increase in operating assets and operating liabilities, net, of $11.2 million. The non-cash charges primarily consisted of $19.8 million in stock-based compensation, impairment of long-lived assets of $2.9 million, depreciation and amortization of $1.7 million, non-cash lease expense of $2.0 million, accrued interest on investment securities of $0.4 million partially offset by a decrease related to net amortization and accretion of investment securities of $4.1 million.

During the nine months ended September 30, 2022, cash used in operating activities was $68.4 million, which was primarily attributable to our net loss of $101.4 million, partially offset by non-cash charges of $27.8 million and changes in operating assets and operating liabilities, net, of $5.2 million. The non-cash charges primarily consisted of $23.5 million in stock-based compensation, depreciation and amortization of $1.7 million, noncash lease expense of $1.6 million, and change in accrued interest on investment securities of $0.9 million.

Investing Activities

During the nine months ended September 30, 2023, cash provided by investing activities was $34.8 million, consisting of $170.8 million in purchases of available-for-sale securities and $0.6 million for the purchase of property and equipment, partially offset by $206.3 million in maturities of marketable securities.

During the nine months ended September 30, 2022, cash used in investing activities was $64.0 million, consisting of $307.2 million in purchases of marketable securities partially offset by $243.2 million in maturities of marketable securities.

Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities was $0.4 million, consisting of proceeds from issuance of common stock under the employee stock purchase plan of $0.3 million and proceeds from issuance of common stock upon exercise of stock options of $28,000.

During the nine months ended September 30, 2022, net cash provided by financing activities was $1.6 million, consisting of proceeds from the exercise of stock options of $1.5 million.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our condensed financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

We consider the assumptions and estimates associated with revenues, accrued research and development expenditures, and stock-based compensation to have the most significant impact on our condensed financial statements and therefore we consider these to be our critical accounting policies and estimates.

Revenue Recognition

We recognize revenue in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers ("ASC 606").* We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

We evaluate the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain further research and development services and licenses to our intellectual property. The payment terms of these agreements may include nonrefundable upfront fees, payments for electing the contractual options, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration.

We exercise judgment in assessing those promised goods and services that are distinct and thus representative of performance obligations. To the extent we identify multiple performance obligations in a contract, the Company must develop assumptions that require judgment to determine the estimated standalone selling price for each performance obligation in order to allocate the transaction price among the identified performance obligations. The transaction price is allocated on a relative standalone selling price basis.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required.

We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. For performance obligations satisfied over time, we estimate the efforts needed to complete the performance obligations and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligations using an input measure. The estimated period of performance and level of effort, including the value of our researchers' time and third-party costs, are reviewed quarterly and adjusted, as needed, to reflect our current expectations. The measurement of progress is then used to calculate revenue, including any revenue adjustments as a result of the change in estimate. For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligations to which some or all of the royalty has been allocated has been

satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon the performance of the licensee. Funds received in advance are recorded as deferred revenue and are recognized as the related performance obligations are satisfied.

There are no performance, cancellation, termination, or refund provisions in any of the arrangements that contain material financial consequences to us.

Accrued Research and Development Expenses

As part of the process of preparing our condensed financial statements, we are required to estimate our accrued research and development and manufacturing expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our condensed financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract, which may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the completion of scientific milestones. In accruing fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees, directors, and non-employees based on their fair value on the date of grant and recognize stock-based compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We recognize the impact of forfeitures on stock-based compensation expense as forfeitures occur. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model. This model requires the use of highly subjective assumptions to determine the fair value of stock-based awards, including:

- *Fair Value of Common Stock*—For grants before the completion of our IPO in October 2020 when we were a privately held company with no public market for our common stock, the fair value of our common stock underlying share-based awards was estimated on each grant date by our Board of Directors. In order to determine the fair value of our common stock underlying option grants, our Board of Directors considered, among other things, valuations of our common stock prepared by an unrelated third-party valuation firm in accordance

with the guidance provided by the American Institute of Certified Public Accounts Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For all grants subsequent to our IPO in October 2020, the fair value of common stock was determined by taking the closing price per share of common stock as reported on the Nasdaq Stock Market.

- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.

- *Expected Volatility*—We use an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends, in addition to some consideration to our own stock price volatility. We continue to utilize comparable public companies as part of this process as we do not have sufficient trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash equivalents and investments as of September 30, 2023 consist of money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A one percent change in the interest rates in effect on September 30, 2023 would not have had a material effect on the fair market value of our cash equivalents and investments.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that permit us to satisfy our payment obligations in U.S. dollars (at prevailing exchange rates) but have underlying payment obligations denominated in foreign currencies, primarily including the Euro and GBP. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our condensed financial statements, and we have not had a formal hedging program with respect to foreign currency. A one percent increase or decrease in exchange rates at September 30, 2023 would not have had a material effect on our condensed financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, has evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter 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 or other legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, as of September 30, 2023, we were not a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material effect on our business.

ITEM 1A. RISK FACTORS

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our common stock.

- We have incurred significant net losses since inception and we expect to incur significant losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We will need substantial additional funding. If we are unable to raise capital when needed, we may be compelled to delay, reduce, or eliminate our product development programs or commercialization efforts.
- We have a limited operating history and face significant challenges and will incur substantial expenses as we build our capabilities.
- Our discovery and development activities are primarily focused on novel cancer therapeutics for patients with genetically-defined cancers and it is difficult to predict the time and cost of developing our product candidates and obtaining regulatory approval.
- We have encountered and may continue to encounter delays and difficulties initiating clinical trial sites and enrolling patients in our clinical trials, and, as a result, our clinical development activities could be delayed or otherwise adversely affected.
- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and further develop our product engine to expand our pipeline of product candidates with commercial value.
- We may attempt to secure approval for our product candidates from the U.S. Food and Drug Administration (FDA) or comparable regulatory authorities through the use of accelerated approval pathways, which is uncertain.
- If the market opportunities for our product candidates are smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, it will adversely affect our revenue potential and ability to achieve profitability.
- Our success depends in part on our ability to protect our intellectual property and our proprietary products and technologies and obtain, maintain and enforce our intellectual property, as well as our ability to operate without infringing the patents and other proprietary rights of third parties.
- We rely, and expect to rely in the future, on third parties, including independent clinical investigators, developers of companion diagnostics, and contract research organizations to conduct certain aspects of our preclinical studies and ongoing and planned clinical trials. We also rely, and expect to rely in the future, on contract manufacturing organizations for the manufacture of our product candidates for preclinical and clinical testing, as well as manufacture of any products that we may commercialize.
- Our success is highly dependent on our ability to attract and retain highly-skilled executive officers and employees.

RISK FACTORS

We have identified the following material factors that make an investment in our common stock speculative or risky. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making investment decisions regarding our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. The risks described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We have marked with an asterisk (*) those risk factors that were not included as separate risk factors in, or reflect changes from the similarly titled risk factors included in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission (SEC) on March 15, 2023.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant net losses since inception, and we expect to incur significant losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.*

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through our IPO and, before that, private placements of our convertible preferred stock and convertible notes.

We have incurred significant net losses in each period since we commenced operations in June 2017. For the three months ended September 30, 2023 and 2022, we reported net losses of $31.4 million and $32.3 million, respectively. As of September 30, 2023, we had an accumulated deficit of $483.5 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct preclinical studies and clinical trials for our current and future product candidates;
- continue our research and development efforts, submit INDs and clinically develop our product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, negative or mixed clinical trial results, safety issues or other regulatory challenges, the risk of which in each case may be exacerbated by a health epidemic or pandemic;
- establish a sales, marketing and distribution infrastructure and establish manufacturing capabilities, whether alone or with third parties, to commercialize product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio; and
- hire additional clinical, regulatory and scientific personnel.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and potentially market our product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability, if ever, to generate revenue from our product candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital.

We have not generated any revenue from our product candidates and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, our product candidates. Lanraplenib and KB-0742 are our only product candidates in the clinical stage of development. In addition, all of our product candidates will require additional clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue from our product candidates depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and ongoing and planned clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete IND-enabling studies and successfully submit and receive authorizations to proceed under INDs or comparable applications;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the potential approval and commercialization of our product candidates or of any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk-benefit profile of our product candidates or any future product candidates and such regulatory authorities' acceptance of our biomarker-driven development strategy (i.e., our pursuit of approval based on a biomarker rather than a specific cancer indication);
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over or to use in combination with alternative or more established therapies, such as intensive chemotherapy and hypomethylating agents (HMAs), to treat AML and MYC-amplified solid tumors and other transcriptionally addicted cancers;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMPs);

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing any of our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.*

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we progress our ongoing clinical trials and commence our planned clinical trials and any other future clinical trials, and continue our discovery and preclinical development activities to identify new product candidates, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, and we may need to raise additional funding sooner than expected if we choose to expand more rapidly than we presently anticipate. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, geopolitical events such as the war between Russia and Ukraine (and responses by the United States and certain other countries, including significant sanctions and trade actions against Russia), the war between Israel and Hamas and risk of larger conflict, inflation, high interest rates, bank failures, or a health epidemic or pandemic, could adversely affect the economy and financial markets in general and our ability to raise additional capital. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our discovery, preclinical and clinical development programs or any future commercialization efforts.

We had cash, cash equivalents, and investments of $198.4 million as of September 30, 2023. We believe that, based upon our current operating plan, our existing capital resources will enable us to fund our planned operating expenses and capital expenditure requirements into 2026. However, we have based this estimate on our current development plans and assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control, including as a result of global supply chain issues, inflation, high interest rates, bank failures, or a health epidemic or pandemic. In any event, our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing Phase 1/2 clinical trial of KB-0742;
- the scope, progress, results and costs of our ongoing Phase 1b/2 clinical trial of lanraplenib;
- the scope, progress, results and costs of discovery, preclinical development and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and any required companion diagnostic;
- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims; and
- to the extent we pursue strategic collaborations, including collaborations to commercialize any of our product candidates or any companion diagnostic collaborations, our ability to establish and maintain collaborations on favorable terms, if at all.

We will require additional capital to complete our clinical development programs for our current product candidates to obtain regulatory approval. Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

Our recently announced corporate restructuring to optimize our resource allocation and contain costs may not have the benefits we expect.*

In November 2023, we announced corporate restructuring plans designed to optimize our resource allocation and contain costs. In connection with the restructuring plans, we reduced our workforce by approximately 19%. The reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended workforce reduction, a decrease in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated, certain functions necessary to our reduced operations will remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover that the reductions in workforce and cost cutting measures will make it difficult for us to pursue new opportunities, hire new employees, complete initiatives and require us to hire qualified replacement personnel, which may result in us incurring additional and unanticipated costs and expenses. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition, results of operations and ability to successfully develop our current and future product candidates.

Risks Related to the Discovery and Development of our Product Candidates

We have a limited operating history and face significant challenges and will incur substantial expenses as we build our capabilities.*

We were incorporated in June 2017 and acquired certain rights to lanraplenib and other orally bioavailable small molecule SYK inhibitors from Gilead in July 2020. We have a limited operating history and are subject to the risks inherent in a growing company, including, among other things, risks that we may not be able to hire sufficient qualified personnel and establish operating controls and procedures. We currently do not have complete in-house resources to enable our operations. As we continue to build our capabilities, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields. If we are unable to continue to build our capabilities, our operating and financial results could differ materially from our expectations, and our business could suffer.

We cannot be certain that the clinical trials of our product candidates, including our ongoing Phase 1/2 clinical trial of KB-0742, our only internally generated product candidate, and our Phase 1b/2 clinical trial of lanraplenib will be completed when we currently expect, or at all.

We may not realize the benefits of our asset acquisition from Gilead or any future acquisitions or strategic transactions.*

In the third quarter of 2020, we completed the transfer from Gilead of a portfolio of selective, orally bioavailable small molecule SYK inhibitors, including entospletinib and lanraplenib. After a review of enrollment, we made the decision to close our Phase 3 trial of entospletinib to further enrollment in the fourth quarter of 2022. In this assessment, we projected significant delays due to several factors, including the operational challenges we faced enrolling a genetically defined subset of patients in the frontline setting, the impacts of COVID-19 on clinical trial site staffing and the loss of access to planned clinical trial sites in Ukraine and Russia. Patients who had already enrolled in the Phase 3 study were able to complete their course of treatment.

In addition, we may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our SYK portfolio acquisition from Gilead, and any future acquisitions or strategic transactions depends on the risks and uncertainties involved including, but not limited to, the following:

- unanticipated liabilities related to acquired assets, companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired assets, businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

Future acquisitions or dispositions could also result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

Our discovery and development activities are focused on novel cancer therapeutics for patients with genetically-defined cancers and it is difficult to predict the time and cost of product candidate development and the likelihood of obtaining regulatory approval.*

The discovery and development of novel cancer therapeutics by targeting dysregulated transcription using a biomarker-driven precision medicine strategy is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, and the data for lanraplenib and entospletinib generated in clinical trials conducted by Gilead, the TRNs targeted by our programs drive oncogenic activity, future clinical results may not confirm this hypothesis or may only confirm it for certain mutations or certain tumor types. The patient populations for our product candidates are limited to those with cancers that exhibit specific target mutations that we believe serve as a genomic biomarker of transcription factor dysregulation, and may not be completely defined but are substantially smaller than the general treated cancer population. We will need to screen and identify those patients who have the targeted mutations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing or otherwise obtaining access to satisfactory companion diagnostics to identify such genetic alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval

for each mutation type and commercialize our products and achieve profitability. In any event, we do not know if our approach of treating patients with genetically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer and you may lose all or part of your investment.

In addition, in some of our development programs, we are pursuing a biomarker-driven development strategy (i.e., pursuing regulatory approval based on efficacy of our product candidates in a biomarker-defined subset of patients with a specific cancer indication, rather than all such patients who suffer from a specific cancer indication). There are currently a limited number of approved biomarker-specific therapies. We may not receive approval for a biomarker-specific indication or may be delayed in receiving biomarker-specific approval.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.*

We are unable to predict when or if our products candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards (IRBs)/ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts with prospective trial sites;
- clinical trials for our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay clinical trials or abandon product development programs;
- the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- third-party collaborators may undergo a change of control, thus delaying progression of a clinical trial;
- we or potential future third-party collaborators may fail to obtain the clearance or approval of any required companion diagnostic on a timely basis, or at all;
- our third-party contractors, including those developing companion diagnostic tests, may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- our product candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials for our product candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- we or potential future third-party collaborators may fail to receive regulatory approval of a companion diagnostic for one or more of our product candidates, or for use with a marketed product.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. The FDA has substantial discretion in the approval process and may decide that our data is insufficient for approval or insufficient to proceed to a pivotal clinical trial, and the FDA may require additional preclinical, clinical or other studies. Furthermore, we may encounter delays or rejections based upon changes in policy, which could cause delays in the clinical development of our product candidates. For example, the FDA launched Project Optimus as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development. Project Optimus was driven by the FDA's concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies or may request other data or studies pre- or post-approval. If the FDA does not believe we have sufficiently demonstrated that the selected doses for our product candidates maximize, not only the efficacy of the product candidate, but the safety and tolerability as well, our ability to complete existing trials or initiate new trials may be delayed. Even if we conduct any additional studies or generate any additional information requested by the FDA, the FDA could disagree that we have satisfied their requirements, all of which could cause significant delays and expense to our programs.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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

Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA along with other information, including information about the product candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission under which we must receive authorization to proceed with clinical development.

Before obtaining marketing approval from the FDA of any product candidate in any indication, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. We are required to submit an IND to the FDA, which must be cleared prior to initiating any clinical trials in the United States, for our preclinical product candidates.

The FDA may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs.

Any delays in the commencement or completion of our planned or future clinical trials could significantly affect our product development costs. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining FDA or foreign regulatory authority authorization to commence a clinical trial or reaching a consensus with the FDA or a foreign regulatory authority on clinical trial design;
- failing to obtain regulatory clearance or approval of companion diagnostics we may use to identify patients for enrollment in or test the possible effects of our product candidates in patients enrolled in our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs/ECs;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failing to manufacture or obtain sufficient quantities of product candidate or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up, including patients failing to remain in our trials due to movement restrictions, health reasons or contraction of or concerns associated with an infectious disease;
- patients choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or companion diagnostics or any of their components being ordered by the FDA or applicable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- interruptions to operations of clinical sites, manufacturers, suppliers, or other vendors from geopolitical events, such as the war between Russia and Ukraine, or from the war between Israel and Hamas and risk of a larger conflict.
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- us, or our third-party contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need

to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or

- disruptions caused by health epidemics or pandemics, which may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting or completing our ongoing or planned clinical trials.

In addition, our proposal for new or emerging biomarker surrogate endpoints may result in data that is not accepted by certain regulatory bodies or industry professionals, or if such endpoints are later found to be insufficient to establish clinical efficacy, may require us to change the design of our clinical trials. Moreover, we may fail to adequately explore and identify optimal doses for later stage trials and thereby add time and expense to development programs or lead to unnecessary conclusions of lack of effect for a product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 or foreign 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 pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs/ECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

We may also experience delays if our current or planned clinical trials are impacted by geopolitical, economic or military instability. For example, we had anticipated utilizing clinical trial sites in Ukraine and Russia for our Phase 3 clinical trial of entospletinib in combination with intensive chemotherapy in AML patients with NPM1 mutations. However, due to the war in the region, we revised our plans to open clinical trial sites in the region and were planning to utilize clinical trial sites in other countries. The failure to identify and operationalize alternative clinical sites contributed to delays in enrollment for this trial.

Certain of our current or future scientific advisors or consultants who receive compensation from us may become investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we expect any such relationships to be within the FDA's guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, regulatory approval could be delayed or we could fail to obtain regulatory approval.*

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same or a similar patient population as we plan to treat with our product candidates in clinical trials, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

We are conducting a Phase 1/2 clinical trial of KB-0742 in patients with cancer to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of the compound across multiple dose levels. Patients with

these tumor types are relatively rare, and we may be unable to enroll or maintain a sufficient number of these patients in any such cohort, which could adversely affect our development and registration strategy for KB-0742.

Our Phase 3 trial of entospletinib in NPM1-mutated AML patients was discontinued in part due to the difficulties in identifying the small number of patients with this mutation, including the time required for screening diagnostics when physicians and patients have an urgency to begin treatment for their AML. We may encounter similar risks in future trials of our product candidates, which may result in delays and potentially the discontinuation of such trials.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- invasive procedures required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- proximity and availability of clinical trial sites for prospective patients; and
- our ability to timely activate clinical trial sites and other delays and complications resulting from a health epidemic or pandemic.

Enrollment in our trials was adversely impacted by COVID-19 as healthcare facilities and patients experienced periodic delays in visits, scheduling and staffing that adversely impacted enrollment. As a result of ongoing global challenges in clinical trial enrollment for our Phase 3 AGILITY clinical trial of entospletinib in combination with intensive chemotherapy in patients with newly diagnosed NPM1-mutated AML, we closed enrollment in the fourth quarter of 2022 and have discontinued Kronos Bio-led clinical development of entospletinib. Our inability to enroll the required number of patients for our other ongoing and planned clinical trials would 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, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If adverse side effects or unexpected characteristics are identified during the development of our product candidates, we may need to abandon or limit the development of a product candidate.*

Results of our ongoing or planned clinical trials, including those for lanraplenib and KB-0742, could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us or the FDA or foreign regulatory authorities for a number of reasons. Additionally, due to the high mortality rates of

the cancers for which we are initially pursuing development of lanraplenib and KB-0742, a significant percentage of patients in these clinical trials may die during a trial, which could impact development of these product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of our product candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

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

- regulatory authorities may withdraw or limit their approval of the product;
- we may be required to recall a product or we may voluntarily remove it from the marketplace;
- we may be required to change the way the product is administered to patients or conduct additional clinical trials;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- the drug could become less competitive; and
- our reputation may suffer.

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

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.*

From time to time in the future, we may publicly disclose preliminary, interim or topline data from our ongoing or planned clinical trials. These updates are typically based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial or following the completion of such clinical trial or stage of such clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we may report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim, topline or preliminary data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we are unable to successfully develop companion diagnostic tests for our product candidates that require such tests, experience significant delays in doing so, or are unable to obtain any necessary FDA approvals of such tests, we may not be able to obtain approval for our product candidates, may be delayed in doing so, or may not realize the full commercial potential of these product candidates.*

In developing a product candidate for certain indications, we may decide to use a biomarker-based test to identify patients for enrollment or monitor patients in clinical trials. For example, we are used a biomarker-based test to identify patients for enrollment in our discontinued registrational Phase 3 clinical trial of entospletinib in combination with intensive chemotherapy for the treatment of AML patients with NPM1 mutations, and would plan to use a biomarker-based test to identify patients for enrollment if lanraplenib moves into a registrational Phase 3 trial. If the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. The FDA generally requires contemporaneous approvals of a new companion diagnostic with the proposed therapeutic. To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. As such, if a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval or clearance requirements.

We plan to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications, which will include lanraplenib for the treatment of AML patients with FLT3 mutations. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are regulated as medical devices, and we have no prior experience with medical device or diagnostic test development. If we choose to or are required to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may

rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these product candidates may be adversely affected, these product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these products that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and further develop our product engine to expand our pipeline of product candidates with commercial value.

A key element of our strategy is to use our product engine to further develop our pipeline of product candidates and progress these product candidates through clinical development and ultimately achieve approval for the treatment of various cancers by focusing on dysregulated transcription factors and the TRNs through which they drive oncogenic activity. The discovery and development activities that we are conducting may not be successful in developing product candidates that are useful in treating cancer or other diseases.

With respect to internally developed product candidates, our research and development efforts to date have resulted in our discovery and preclinical development of KB-0742 as well as several early-stage discovery programs. KB-0742 may not be safe or effective as a cancer treatment and, with respect to our early-stage discovery programs, we may not identify suitable product candidates for preclinical or clinical development. Our product engine may not be successful in generating additional contributions to our pipeline of product candidates. For example, we may not be successful in identifying novel product candidates that can selectively modulate oncogenic TRNs. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

As a company, we have not completed any clinical trials to date.*

We have not as a company completed any clinical trials to date. We therefore cannot be certain that our ongoing Phase 1/2 clinical trial of KB-0742 or our ongoing Phase 1b/2 trial of lanraplenib will be completed on time, if at all.

In addition, clinical trials require significant financial and management resources and reliance on third-party clinical investigators, CROs, CMOs and consultants. Relying on third-party clinical investigators, CROs, CMOs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs, CMOs and consultants on a timely basis, or at all.

Because of the relatively small number of patients that are being or are planned to be dosed in our Phase 1/2 trials of KB-0742 and lanraplenib, the results from such clinical trials, if completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to further develop and obtain regulatory approval for these product candidates.*

In our Phase 1/2 clinical trial of KB-0742, we are evaluating the safety, PK and PD profile of KB-0742 in patients with advanced solid tumors, and are continuing to dose escalate and enrolling expansion cohorts in specific tumor types. In our Phase 1b/2 clinical trial of lanraplenib, we are evaluating the safety, PK and PD profile of lanraplenib in combination with gilteritinib in patients with FLT3-positive relapsed/refractory AML, and we plan to define an optimal dose and schedule. Though enrollment is still ongoing in both trials, the total number of patients we expect to enroll in these clinical trials will be significantly smaller than the number of patients that would need to be enrolled in a registrational or other late-stage clinical trial. The results of clinical trials with smaller sample sizes, such as our ongoing Phase 1/2 clinical trial of KB-0742 and our ongoing Phase 1b/2 trial of lanraplenib, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of KB-0742 or lanraplenib, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial Phase 1/2 clinical trial.

Risks Related to the Commercialization of Our Product Candidates

If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, it will adversely affect our revenue potential and ability to achieve profitability.*

The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the final label for each product candidate, acceptance by the medical community and patient access, drug and any related companion diagnostic pricing and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be amenable to treatment with our products, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business.

The market opportunities for certain of our product candidates may be relatively small as they may be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.*

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more or different chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. In some instances we may initially seek approval of our product candidates as a second- or third-line therapy. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a second or third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

Even if any of our product candidates are approved, they may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.*

The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments, as well as other perceived advantages and disadvantages;
- the approval, availability, market acceptance, and reimbursement of any companion diagnostic;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the ability to offer the product candidate for sale at competitive prices;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- acceptance by hospital pharmacy and therapeutics committees in the U.S., E.U., and other geographies;
- the availability of the approved product candidate for use as a combination therapy, where applicable;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

We currently have no marketing and sales organization and have no experience as a company in marketing products. If we are unable to establish and maintain marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.*

We currently have no sales, marketing, or distribution capabilities and have no experience as a company in marketing products. We would need to build a commercial infrastructure to support sales of our product candidates if we were to commercialize them independently. We would expect to manage sales, marketing, market access and distribution through internal resources and third-party relationships. We would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing, market access and sales personnel. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities in the United States, or any other geographic regions, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement policies, third-party reimbursement practices, or health care reform initiatives, which could harm our business.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If coverage is not available, or is available only to limited indications or strict coverage criteria, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS) responsible for administering the Medicare program, determines whether and to what extent a new product will be covered and reimbursed under Medicare. One third-party payor's determination to provide coverage for a drug product, however, does not assure that other payors will also provide coverage for the product. As a result, the coverage determination process is often time-consuming and costly. This process may require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.*

The development and commercialization of pharmaceutical products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. 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.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. We operate in the segments of the pharmaceutical, biotechnology and other related markets that address inhibition of kinases and targeting transcriptional regulation in cancer. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages we hope to exploit, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and ultimately commercialize will compete with existing products and new products that may become available in the future.

In the case of lanraplenib, there are product candidates that are currently in clinical development which, if approved, could compete with lanraplenib if we are successful in developing and receiving approval, including: (i) HMPL-523, a SYK inhibitor being developed by Hutchison Medipharma Ltd. that is in Phase 1 evaluation in hematologic malignancies; (ii) product candidates in early clinical development that target the interaction between MLL and MENIN in MLL-r and AML patients with NPM1 mutations, including (a) DS-1594, being developed by Daiichi Sankyo Company in a Phase 1 clinical trial with or without azacitidine/venetoclax in relapsed/refractory AML; (b) JNJ-75276617, being developed by Janssen Research & Development, LLC in a Phase 1 clinical trial in acute leukemias; (c) KO-539, being developed by Kura Oncology, Inc. in a Phase 2 clinical trial as monotherapy in relapsed or refractory AML; and (d) SNDX-5613, being developed by Syndax Pharmaceuticals, Inc. in a Phase 1 clinical trial as monotherapy in relapsed or refractory AML in patients with MLL-r/KMT2A gene rearrangement or NPM1 mutations; and (iii) product candidates that address the subset of AML patients with FLT3 mutations and

are currently in development in combination with FLT3 inhibitors, including (a) venetoclax, a BCL-2 inhibitor being developed by Abbvie; (b) CC-90009, a A Cereblon E3 ligase modulating drug that promotes selective degradation of GSPT1, in Phase 1b, being developed by Bristol-Myers Squibb; (c) CPX-351, a liposomal formulation of daunorubicin and cytarabine being developed by Jazz Pharmaceuticals; and (d) ladademstat, an LSD1 inhibitor in Phase 1 dose escalation being developed by Oryzon.

If we are successful in developing and receiving approval for KB-0742, we expect it would compete against various multi-CDK inhibitors that are currently in early-stage clinical development if they are ultimately approved, including: (a) fadraciclib (CYC-065), being developed by Cyclacel Pharmaceuticals; (b) voruciclib, being developed by MEI Pharma; (c) dinaciclib, being developed by Merck & Co.; (d) zotiraciclib, being developed by the National Cancer Institute; and (e) TP-1287 (alvocidib), being developed by Tolero Pharmaceuticals. We also expect it would compete against (a) GFH009, a CDK9 inhibitor in Phase 1 dose escalation, being developed by Genfleet Therapeutics; (b) PRT2527, a CDK9 inhibitor in Phase 1 dose escalation by Prelude Therapeutics; and (c) VIP152, a PTEFb/CDK9 inhibitor in early-stage clinical development by Vincerx Pharma, Inc.

We also expect that our product candidates, if approved, will compete against more established therapies, such as intensive chemotherapy and HMAs to treat AML and other agents to treat MYC-amplified solid tumors and other transcriptionally addicted cancers.

Many of the companies against which we may ultimately compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our potential competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination in our commercial opportunity if other companies develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than any of our product candidates. These companies also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in their establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are currently on the market for some of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek marketing approvals of our product candidates outside of the United States and, accordingly, we may be subject to additional risks related to operating in foreign countries if we obtain the necessary foreign marketing approvals, including:

- differing regulatory requirements in foreign countries, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States;
- differing intellectual property and regulatory laws in foreign countries, including the availability of obtaining patent term extensions, orphan disease status, or data exclusivity in those countries with respect to the patents covering our products;

- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- differing pricing, payment and reimbursement regimes;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.

Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

As a company, we have not completed any clinical trials of any product candidates, nor have we managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often changes during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients

to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

We are currently conducting, and may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.*

We are currently conducting, and may in the future choose to conduct clinical trials outside the United States, or include study sites outside the United States, including in Europe or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. 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 sole basis of foreign data unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Otherwise, for studies that are conducted at sites outside of the United States and not subject to an IND and which are intended to support a marketing application, the FDA requires the clinical trial to have been conducted in accordance with good clinical practice (GCP) requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities 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 or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval 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. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction could delay the regulatory approval process in others. 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 as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining 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 future collaborator 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 our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Following any regulatory approvals, our products will be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we might become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription pharmaceutical products, such as our product candidates. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label based on the physician's independent medical judgment. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates if at all. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated therapeutic product candidate and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating

insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

Disruptions at the FDA, the SEC or other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.*

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign and domestic manufacturing facilities and products from May 2020 to July 2020, and thereafter resumed on-site inspections of manufacturing facilities subject to a risk-based prioritization system. Regulatory authorities outside the United States adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact their ability to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may attempt to use accelerated approval pathways, and if we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our trials required as a condition to such accelerated approval do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may withdraw approval.*

We may in the future seek an accelerated approval for one or more of our product candidates. The FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint, such as MRD-negative CR, or intermediate clinical endpoint that it determines is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. If granted, accelerated approval is usually contingent, or conditioned on the sponsor's agreement to conduct additional post-approval confirmatory studies or extend one or more ongoing trials to capture additional endpoints to verify and describe the drug's clinical benefit, and to report regularly to the FDA on the progress of such studies. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so.

We may face difficulties from changes to current regulations and future legislation.*

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the Inflation Reduction Act) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The Inflation Reduction Act also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and litigation, 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. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2032 unless additional congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 for drug products.

For example, 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 President 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. Further, the Inflation Reduction Act, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the Inflation Reduction Act will be implemented but it is likely to have a significant effect on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. In addition, Congress is considering other health reform measures. 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, the Inflation Reduction Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and government price reporting, which could expose us to, among other things, criminal sanctions, administrative and civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct our research as well as market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, 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;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- some state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and certain state and local laws that require the registration of pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including, without limitation, our consulting agreements with certain physicians, who may be in a position to order and/or influence the purchase of our product candidates, if approved, and are compensated in the form of stock or stock options for services provided to us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, policies, and other obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); fines and penalties; a disruption of our business operations; reputational hard; and other adverse business impacts.*

In the ordinary course of business, we and the third parties upon whom we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) a large quantity of personal data and sensitive data, including proprietary and confidential business data, trade secret, sensitive third-party data, and patient health data in connection with our preclinical studies, clinical trials and our employees, and are subject to data privacy and information security laws and regulations that apply to the collection, transmission, storage and use of personal data, which among other things, impose certain requirements relating to the privacy, security and transmission of personal data. We are also subject to obligations, such as various laws, regulations, guidance, industry standards, external and internal

privacy and security policies, and contractual requirements, that apply to our processing of sensitive information or processing of sensitive information on our behalf. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us.

In the United States, there are numerous federal, state and local privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal data, including federal and state health information privacy laws, federal and state security breach notification laws, and federal, state and local consumer protection laws (such as Section 5 of the Federal Trade Commission Act) and other similar laws (such as wiretapping laws), to which we are or may become subject. In particular, regulations promulgated pursuant to HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), establish privacy and security standards that limit the use and disclosure of certain individually identifiable health data, or protected health data, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health data and ensure the confidentiality, integrity and availability of electronic protected health data. Determining whether protected health data has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. Further, if we fail to comply or are perceived to have not fully complied with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition, the California Consumer Privacy Act of 2018 as amended by the California Privacy Rights Act of 2020 (CPRA), (collectively, CCPA) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA allows for administrative fines for noncompliance up to $7500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data maintained about California residents. In addition, the CPRA expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new agency to implement and enforce the CCPA. Other states, such as Colorado, Utah and Connecticut, have enacted data privacy laws and similar laws are also being considered in several other states, as well as at the federal and local levels. While these laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and may increase legal risk and compliance costs for us, the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR) impose strict requirements for the processing of personal data of individuals located, respectively, within the European Economic Area (EEA) and the United Kingdom (UK). For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or in each case 4% of the annual global revenue of the company, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Our employees and personnel may use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Certain jurisdictions, such as the EU, Switzerland and the UK, have enacted cross-border personal data transfer laws regulating personal data flows to third countries. In particular, the EEA and UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. The European Commission released a set of "EU Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these EU Standard Contractual clauses are a valid mechanism to transfer personal data outside of the EEA. The EU Standard Contractual Clauses, however, are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. In addition, the EU Standard Contractual Clauses require parties that rely upon that legal mechanism to comply with additional obligations such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. On July 10, 2023, the European Commission adopted its adequacy decision for the successor to the previously invalidated Privacy Shield Framework, the E.U.-U.S. Data Privacy Framework. The adequacy decision on the E.U.-U.S. Data Privacy Framework covers personal information transfers from any public or private entity in the EEA to U.S. companies participating in the E.U.-U.S. Data Privacy Framework. However, it remains to be seen whether the new adequacy decision will withstand scrutiny by the Court of Justice of the European Union if the adequacy decision's validity is challenged. In addition, laws in Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States of America that do not provide an adequate level of personal data protection, with the UK adopting its own data transfer clauses (the International Data Transfer Agreement) and an addendum to the EU Standard Contractual Clauses for transfers from the UK to third countries.

In addition to European restrictions on cross-border personal data transfers, other jurisdictions have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border personal data transfers, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

Our obligations related to data privacy and security (and consumers' data privacy expectations) are quickly becoming increasingly stringent and creating regulatory uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent among jurisdictions or in conflict. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources).

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA require our partners to impose specific contractual restrictions on their own service providers. We publish privacy policies and notices and other statements regarding data privacy and security. If these policies, notices or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

These obligations may necessitate changes to our information technologies, systems, and practices and those of any third parties that process personal data on our behalf. In addition, these obligations may even require us to change our business model. We, or the third parties on which we rely, may at times fail (or be perceived to have failed) to do so. If we, or third parties on which we rely, fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting

requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA requirements, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development

or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

We may be subject to U.S. and foreign anti-bribery and anti-corruption laws with respect to our operations, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Non-compliance with these laws can subject us to criminal or civil liability and harm our business.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. 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. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of 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, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, 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, disgorgement, and other sanctions and remedial measures, 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 international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses, as well as our ability to operate without infringing the proprietary rights of others. If we or our licensors are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims read on the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents, if issued, will not be infringed, designed around, invalidated or rendered unenforceable by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and such protection may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although we have issued patents in the United States and foreign countries, we cannot be certain that the claims in our other pending U.S. patent applications, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our licensors or any of our potential future collaborators will be successful in protecting our technologies and product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we or our licensors have and many of which have made significant investments in competing technologies, may seek or may have already obtained patents that could or will limit, interfere with or block our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensors may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control, or are subject to certain obligations with respect to, the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license or acquire, including those from our licensors and from third parties. We also may require the cooperation of our licensors, whether current or future, in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. Furthermore, the terms of the license agreements with some of our licensors may be non-exclusive, such that we would have no rights to enforce the licensed intellectual property against a competitor.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensors, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

If we fail to comply with our obligations in the agreements under which we license or otherwise acquire intellectual property rights from our licensors and third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business or our business may otherwise be materially harmed.*

In July 2020, we acquired a portfolio of selective, orally bioavailable small molecule SYK inhibitors from Gilead, including lanraplenib, pursuant to the Gilead Asset Purchase Agreement. This agreement imposes on us, and we expect that any future license or other agreements where we in-license or acquire intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations.

We may need to obtain licenses or acquired intellectual property from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates in the absence of such a license or acquisition. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing and acquisitions of intellectual property involve complex legal, business and scientific issues. Disputes may arise between us and our existing or future licensors and other third parties regarding intellectual property subject to a license or purchase agreement, including:

- the scope of rights granted under the license or purchase agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor or other third party that is not subject to the license or purchase agreement;
- our right to sublicense patents and other rights to third parties;

- our diligence obligations with respect to the use of the licensed or acquired technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the effects of termination;
- our right to transfer or assign the license or purchase agreement; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and their affiliates and sublicensees and by us and our partners and sublicensees.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement. And if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities.

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

The patent position of biopharmaceutical 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 existence, 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 product candidates or that effectively prevent others from commercializing competitive product candidates.

Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent issue, and claim scope can be reinterpreted after issuance. Even if patent applications we currently have issue as patents in the future, 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 that we have may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates 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 and 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 not cover our product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review (PGR), and inter partes review (IPR), or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we or third parties from whom we acquired our patents, their counsel, and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is not prior art of which we or third parties from whom we acquired patents and patent applications are aware, but which we or the third parties do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. 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 product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or patent claims being narrowed, invalidated or held unenforceable 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 product candidates. 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, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The patent protection and patent prosecution for some of our product candidates may be dependent on our licensors and third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our owned or in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our owned or in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee of third parties, whether currently or in the future, we rely and may rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under in-license agreements. We have not had, do not have, and may not have in the future, primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, whether current or future, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents, and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. Furthermore, the terms of the license agreements with some of our licensors may be non-exclusive, such that we would have no rights to enforce the licensed intellectual property against a competitor. In such cases, the licensors to our non-exclusive licenses may offer licenses to our competitors.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties, including our licensors, whether currently or in the future, may be subject to retained rights. Our licensors, whether current or future, may often retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidate.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not within the scope of the claims of the patents that we own or license;
- we, third parties from whom we acquired intellectual property, or our licensors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we, third parties from whom we acquired intellectual property, or our licensors might not have been the first to file patent applications directed to certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, inter partes review proceedings and post-grant review proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by development or commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. As such, we may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;

- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this filing, others may hold proprietary rights that could prevent our product candidates from being marketed or could require us to pay significant royalties or other damages. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license, if available, to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time-consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product or service. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is not infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable.

In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, third parties from whom we acquired patents and patent applications and their patent counsel, our licensors, our patent counsel, patent counsel for licensors or third parties, and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we, our licensors, or third parties from whom we acquired patents and patent applications are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before the date of filing of our patents 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. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. 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 or the third parties from which we acquired our patents were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on legislation and decisions made by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We, Gilead, or our licensors, may be subject to claims by third parties asserting that our, Gilead's, or our licensor's, employees or consultants or we, Gilead, or our licensors, have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Some of our employees and consultants, or employees or consultants of Gilead or our licensors, are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, or may have previously provided or may be currently providing consulting services to other biopharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we, and likely Gilead and our licensors, try to ensure that our and their employees and consultants do not use the proprietary information or know-how of others in their work for us or them, we or they may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties or former employers or former or current clients, or claims that we, Gilead, or our licensors have wrongfully hired an employee from a competitor. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, consultants 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, which may result in claims by or against us related to the ownership of such intellectual property. Likewise, Gilead and our licensors may have been or may be unsuccessful in executing such an agreement with each party who conceived or developed intellectual property that we purchased or licensed, which may result in additional such claims by or against us. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we, Gilead, or our licensors may fail or may have failed to obtain such assignments. In addition, such agreements may be breached. Accordingly, we, Gilead, or our licensors may be forced to bring claims against third parties, or defend claims that they may bring against us, Gilead, or our licensors to determine the ownership of what we regard as our owned or licensed intellectual property. If we, Gilead, or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. In addition, the term of a patent may be reduced if a terminal disclaimer is or was filed in that patent, limiting the term of the patent to that of one or more other patents referenced in the terminal disclaimer. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized, and patent term extensions or other means of obtaining market exclusivity, such as data exclusivity, may not be available or adequately protective in countries where we market our products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we or our licensors do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates, but may not be available in other countries. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we own or have acquired or in-licensed issued patents and have pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our technology in all countries outside the United States or from selling or importing products made using our technology 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 or our licensors have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our or our licensors 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our licensors' efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 patents. If we or our licensors 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, documentary, fee payment and other requirements imposed by regulations and governmental 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 governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, licensors and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary information will be effective. 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.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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.

Our registered or unregistered trademarks or trade names 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 collaborators or customers in our markets of interest. At times, competitors 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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 may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, 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.

Risks Related to Our Reliance on Third Parties

We rely on third parties, including independent clinical investigators, developers of companion diagnostics, and CROs, to conduct certain aspects of our preclinical studies and ongoing and planned clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to rely in the future upon third parties, including independent clinical investigators, developers of companion diagnostics, and CROs, to conduct certain aspects of our preclinical studies and ongoing and planned clinical trials and to monitor and manage data for our ongoing preclinical and planned clinical programs.

We rely or will rely on these parties for execution of our preclinical studies and ongoing and planned clinical trials, and may not control, or will only control certain aspects of, their activities. Nevertheless, we are or will be responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Additionally, they may undergo a change in control, which could extend, delay or terminate our clinical trials. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

We have CROs located in China and India. International tension or conflict with these countries could result in a material disruption in our contractual relationship with the CROs, which could delay or otherwise negatively impact progress in our preclinical programs. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach, upon clinical trial subject safety concerns, or upon our insolvency.

The effects of the COVID-19 pandemic and government measures taken in response previously had a significant impact on our CROs, and they have in the past faced disruptions and in the future may face further disruption as a result of a health epidemic or pandemic which may affect our ability to initiate and complete our preclinical studies and ongoing and planned clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If our collaboration with Genentech does not result in the successful discovery, development, and commercialization of product candidates or if it were to be terminated, our business could be adversely affected.*

In January 2023, we entered into a Collaboration and License Agreement with Genentech to collaborate on two discovery research programs in oncology. We lead discovery and research activities under the discovery research programs and use our proprietary drug discovery platform, including our SMM screening platform, for hit finding. Following the completion of initial discovery and research activities, Genentech will have the exclusive right to pursue further preclinical and clinical development and commercialization of compounds identified in the discovery research programs and designated by Genentech (each, a Hit Program).

Under the agreement, we are eligible for milestone payments upon achievement of certain preclinical, clinical and regulatory (including first-sale) milestones, totaling up to $177.0 million for the first development candidate per Hit Program to achieve such milestone event, and are eligible to receive net sales milestones of up to an aggregate of $100.0 million for the first licensed product per Hit Program to achieve such milestone event. We are also eligible to receive tiered royalties in the low- to high-single digits on any products arising under the collaboration that are commercialized by Genentech.

Genentech has the right to terminate the agreement in its entirety, or with respect to a particular discovery research program or Hit Program, in its sole discretion, at any time by providing 60 days' advance written notice to us.

If the discovery and research activities led by us for either discovery program do not produce any compounds that Genentech finds attractive, or if Genentech otherwise elects not to pursue further research or development of any compounds identified from such activities, we may have incurred significant research expenses for such program, depending on the point at which it was terminated, but will not be eligible to receive milestone or royalty payments related to such program. Additionally, if Genentech elects not to pursue development one or more Hit Programs, although we have certain rights in certain circumstances to progress such programs ourselves, with appropriate license grants from Genentech, we may not be able to negotiate suitable terms of such reversion, and therefore we may not be able to progress such programs ourselves. In addition, the perception of our drug discovery platform and our business could be materially and adversely affected, which in turn may make it difficult for us to attract new collaborators for such programs or additional programs based on our platform.

If Genentech elects to pursue further development of a compound in a Hit Program, we will be reliant on Genentech to successfully advance the compound into and through clinical development, and to obtain regulatory approval of and successfully commercialize the product, any of which may not occur for a multitude of reasons, and because Genentech will have exclusive rights to the compound and any related product, our ability to generate revenue from these compounds and any related products will depend in large part on Genentech. Genentech's decisions or objectives in connection with the collaboration, including any commercialization activities, may not be consistent with our best interests. It is possible that Genentech could take actions that may be adverse to us, or it could halt, slow, or deprioritize its development and commercialization efforts under the collaboration. In any such instances, our business, financial condition, results of operations and prospects could be materially harmed.

We may form or seek collaborations or strategic alliances or enter into additional strategic arrangements in the future, which involve risks, and we may not realize the benefits of such collaborations, alliances or strategic arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional strategic arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval. 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, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any 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.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause 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;
- 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; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. If we are unable to obtain exclusive licenses to any such co-owner’s interest in such

intellectual property, such co-owner may be able to license their rights to third parties, including our competitors, and our competitors could market competing products and technology.

As a result, if we enter into collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We will rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if approved.*

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely for the foreseeable future, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize. In this regard, while we have purchased initial inventory of active pharmaceutical ingredients (APIs) and product candidates for lanraplenib from Gilead under the Gilead Asset Purchase Agreement, we will need to obtain further supplies of APIs and clinical drug supply for lanraplenib, and KB-0742, from third-party manufacturers. We do not currently have arrangements in place for redundant supply for APIs or our clinical product candidates.

We will need to negotiate and maintain contractual arrangements with outside vendors for the supply of our future product candidates and we may not be able to do so on favorable terms. In addition, these third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs. We expect to initially obtain our supplies from manufacturers on a purchase order basis without long-term supply arrangements in place We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate, or may be unable to do so on acceptable terms.

Reliance on third-party manufacturers entails risks, including reliance on single sources for product components and lack of qualified backup suppliers for those components purchased from a sole or single source supplier. We cannot be sure that single source suppliers for our product components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these components for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Manufacturing our product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing our product candidates is complex and highly regulated.

We expect to rely on third parties for the manufacture of our product candidates. These third-party manufacturers may incorporate their own proprietary processes into our product candidate manufacturing processes. We will have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates.

As our product candidates progress through preclinical studies and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates and additional bridging studies or trials may be required.

In addition, in order to conduct clinical trials of our product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If the third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Managing Our Growth, Employee Matters and Other Risks

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.*

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future

have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Our workforce reduction announced in November 2023 may make it more difficult to retain and motivate remaining employees and attract and hire qualified employees in the future.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

In order to achieve our research, development and commercialization goals, we will need to grow the size of our organization and expand our capabilities, and we may experience difficulties in managing this growth.*

As of September 30, 2023, we had 99 full-time employees. In November 2023, we reduced our workforce by approximately 19% as part of our corporate restructuring plans intended to optimize our resource allocation and contain costs. However, we may need to hire additional personnel in the future in order to achieve our goals, particularly in the areas of clinical development, research science, clinical operations, manufacturing and regulatory affairs. In addition, we have relied and continue to rely on a third-party accounting consulting firm to augment our internal accounting and finance function. We will need to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel.

We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel when needed. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

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

If we are not able to effectively manage growth and expand our organization when needed, we may not be able to successfully implement the tasks necessary to achieve our research, development and commercialization goals.

Our information technology systems, or those used by our third-party CROs or other contractors or consultants, may fail, be disrupted or suffer security breaches, which could result in a material disruption of our discovery and development programs or otherwise materially and adversely affect our business.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. If such an event occurs and causes interruptions in our operations, it could result in a material disruption of our discovery and development programs and our business operations. For example, the loss of data from completed or future preclinical studies and 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 parties for the manufacture of our product candidates and will rely on third parties to conduct our clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

If our information technology systems or data, or those of the third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, and a loss of future customers or sales and other adverse consequences.*

In the ordinary course of business, we, or the third parties upon which we rely, may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data (including but not limited to intellectual property, proprietary business information, clinical trial information, and personal data). We have also outsourced elements of our operations to third parties, and as a result we rely on a number of third-party contractors who have access to our proprietary, confidential, and sensitive data, including health-related data. We may share or receive sensitive data with or from third parties. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place.

Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent, continue to rise, increasingly difficult to detect, and come from a variety of sources. In addition to traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel misconduct or error (such as theft or misuse), sophisticated nation-state and nation-state supported actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to conduct clinical trials. We, and the third parties on which we rely, may be subject to a variety of evolving threats, including but not limited to social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fire, flood, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our (and third parties upon whom we rely) ability to operate our business or conduct clinical trials. Certain of our vendors have previously experienced specific instances of cyber events, including email compromise and wire fraud targeting payments to be made by us.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against a security incident, there can be no assurance that these measures will be

effective. We also take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate any vulnerabilities in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. High risk or critical vulnerabilities pose significant risks to our business.

Applicable data privacy and security obligations and public company disclosure obligations may require us to notify relevant stakeholders of certain security incidents, including affected individuals, regulators and investors. Such disclosures are costly, and the disclosures or the failure to comply with such requirements, could lead to adverse impacts. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may impact our ability to conduct clinical trials or bring any approved products to market, and negatively impact our ability to grow and operate our business. There can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of investor or partner confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies.

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

Our operations, and those of our CROs, contract manufacturing organizations (CMOs) and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, epidemics and pandemics, bank failures, wars and other geopolitical conflicts (such as the Russia-Ukraine war and the war between Israel and Hamas) and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. As a result of our private placements and other transactions that have occurred within the three years prior to and including our IPO, which we completed in October 2020, we may have experienced, an "ownership change." We may also experience ownership changes in the future as a result of subsequent issuances of our common stock or other shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, 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. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that our board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then-outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chair of our board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (Exchange Act), or any other claim for which the federal courts have exclusive jurisdiction; and provided that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (Securities Act).

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

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

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company.

Our amended and restated certificate of incorporation provides 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 amended and restated certificate of incorporation provides that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court

of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America 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.

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 amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the degree of success of competitive products or technologies;
- the commencement, enrollment or results of clinical trials and preclinical studies of our product candidates or those of our competitors;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- regulatory or legal developments in the United States and other countries;

- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- receipt of, or failure to obtain, regulatory approvals;
- changes in the structure of healthcare payment systems;
- lower than expected market acceptance of our product candidates following approval, if any, for commercialization;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop, acquire or in-license additional technologies or product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- variations in our financial results or those of companies that are perceived to be similar to us;
- rumors or announcements regarding transactions involving our company or product candidates;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- market conditions or trends in the pharmaceutical and biotechnology sectors;
- the societal and economic impact of public health epidemics;
- general economic, industry and market conditions; and
- the other events or factors, including those described in this "Risk Factors" section.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by

collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We are a non-accelerated filer. For so long as we remain a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements we may enter into may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not control these analysts or the content and opinions or financial models included in their reports. If additional securities analysts do not provide research coverage of our company, or if analysts cease coverage of us, the trading price for our common stock could be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

General Risk Factors

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the Nasdaq Global Select Market, an active trading market for our shares may not be sustained. If an active market for our stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or to sell their shares at all. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

We incur substantial costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.*

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increase in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, bank failures, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms, or the inability to access our existing capital in the event of a failure in the U.S. banking system, could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia started a war against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. Additionally, in October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters.*

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. For instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs. In addition, we currently do not report our environmental emissions, and lack of reporting or future reporting could result in certain investors declining to invest in our common stock.

We have recorded, and may be required to record in the future, significant charges if our long-lived assets become impaired.*

We test long-lived assets for impairment if changes in circumstances or the occurrence of events suggest impairment exists. Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value may give rise to impairment in the period that indicators are present. For example, as a result of the sustained decline in our stock price and related market capitalization and a general decline in equity values in the biotechnology industry, we performed an impairment assessment of long-lived assets in connection with the preparation of the condensed financial statements included in our Quarterly Report

on Form 10-Q for the quarter ending June 30, 2023. Based on that assessment, we recognized a non-cash long-lived asset impairment charge of $2.9 million during the three months ended June 30, 2023. See also Part I Financial Information, Note 12 “Leases”, section “Impairment of Operating Lease Right-of-Use Asset and Other Long-Lived Assets” for additional factors and assumptions that can result in impairment charges on our long-lived assets.

It is possible that changes in circumstances, many of which are outside of our control, or in the numerous variables associated with the assumptions and estimates used in assessing the appropriate valuation of our long-lived assets, could in the future result in an impairment to our long-lived assets, requiring us to record impairment charges, which would adversely affect our results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Use of Proceeds from our Initial Public Offering of Common Stock

In October 2020, we completed our initial public offering, pursuant to which we sold 15,131,579 shares of our common stock at a price to the public of $19.00 per share, including 1,973,684 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The shares were registered pursuant to a registration statement on Form S-1 (File No. 333-248925) that was declared effective on October 8, 2020. As a result of our IPO, we raised a total of approximately $263.7 million in net proceeds after deducting underwriting discounts and commissions of $20.1 million and offering expenses of approximately $3.7 million. Goldman Sachs & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. acted as joint book-running managers for our IPO.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and investments. As of September 30, 2023, we have used $68.6 million of the net proceeds from our IPO for working capital purposes.

We expect to use the net proceeds from our IPO as described under "Use of Proceeds" in the final prospectus for the IPO, as filed with the SEC on October 9, 2020, except funds that would have been directed to our registrational clinical trial of entospletinib are now expected to be directed to development activities related to lanraplenib and KB-0742, to discovery and preclinical development of additional product candidates, and to headcount costs, working capital and other general corporate purposes. We cannot predict with certainty all of the particular uses for the net proceeds from our IPO, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to access additional financing, the relative success and cost of our research, preclinical and clinical development programs and whether we are able to enter into future licensing arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from our IPO.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description Of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K, filed with the SEC on October 14, 2020).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K, filed with the SEC on October 14, 2020).
4.1	Form of Common Stock Certificate of the registrant (incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 (File No. 333-248925), as amended, filed with the SEC on October 5, 2020).
4.2	Amended and Restated Investors' Rights Agreement, by and among the registrant and certain of its stockholders, dated July 1, 2019, as amended on August 20, 2020 (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 (File No. 333-248925), as amended, filed with the SEC on September 18, 2020).
10.1 +	Consulting Agreement by and between the Company and FLG Partners, LLC, dated September 8, 2023.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1#	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 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 (this 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 and contained in Exhibit 101).

+ Indicates management contract or compensatory plan.

The information in Exhibit 32.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KRONOS BIO, INC.

Date: November 13, 2023

By: /s/ Norbert Bischofberger

Norbert Bischofberger, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2023

By: /s/ Sandra A. Gardiner

Sandra A. Gardiner
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

FLG PARTNERS
CFO excellence - when experience counts

CONFIDENTIAL CONSULTING AGREEMENT

This Confidential Consulting Agreement (the "Agreement") is executed as of the date shown on the signature page (the "Effective Date"), by and between FLG Partners, LLC, a California limited liability company ("FLG"), and the entity identified on the signature page ("Client").

RECITALS

WHEREAS, FLG is in the business of providing certain financial services;

WHEREAS, Client wishes to retain FLG to provide and FLG wishes to provide such services to Client on the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, the parties hereto agree as follows:

1. Services.

   A. Commencing on the Effective Date, FLG will perform those services (the "Services") described in one or more exhibits attached hereto. Such services shall be performed by the member or members of FLG identified in Exhibit A (collectively, the "FLG Member").

   B. Client acknowledges and agrees that FLG's success in performing the Services hereunder will depend upon the participation, cooperation and support of Client's most senior management.

   C. Notwithstanding anything in Exhibit A or elsewhere in this Agreement to the contrary, neither FLG nor any of its members shall serve as an employee, an appointed officer, or an elected director of Client. Consistent with the preceding: (i) Client shall not appoint FLG Member as a corporate officer in Client's corporate minutes; (ii) Client shall not elect FLG Member to its board of directors or equivalent governing body; and (iii) the FLG Member shall have no authority to sign any documents on behalf of Client, including, but not limited to, federal or state securities filings, tax filings, or representations and warranties on behalf of Client except as pursuant to a specific resolution(s) of Client's board of directors or equivalent governing body granting such authority to FLG Member as a non-employee consultant to Client.

   D. The Services provided by FLG and FLG Member hereunder shall not constitute an audit, attestation, review, compilation, or any other type of financial statement reporting engagement (historical or prospective) that is subject to the rules of the California Board of Accountancy, the AICPA, or other similar state or national licensing or professional bodies. Client agrees that any such services, if required, will be performed separately by its independent public accountants or other qualified consultants.

   E. During the term of this Agreement, Client shall not hire or retain the FLG Member as an employee, consultant or independent contractor except pursuant to this Agreement.

2. Compensation; Payment; Deposit; Expenses.

   A. As compensation for Services rendered by FLG hereunder, Client shall pay FLG the amounts set forth in Exhibit A for Services performed by FLG hereunder (the "Fees"). The Fees shall be net of any and all taxes, withholdings, duties, customs, bank fees, social contributions or other reductions imposed by any and all authorities which are required to be withheld or collected by Client or FLG, including ad valorem, sales, gross receipts or similar taxes, but excluding US income taxes based upon FLG's or FLG Member's net taxable income.

   B. Consistent with common practice in professional services, FLG reserves the right to increase the Fee set forth in Exhibit A no more frequently than annual anniversary of the Effective Date, and no sooner than at least six (6) months from the Effective Date. Notice of any such increase will be made no less than thirty (30) days in advance of such of Fee increase.

   C. As additional compensation to FLG, Client will pay FLG the incentive bonus or warrants or options, if any, set forth in Exhibit A.

   D. Client shall pay FLG all amounts owed to FLG under this Agreement upon Client's receipt of invoice, with no purchase order required. Any invoices more than thirty (30) days overdue will accrue a late payment fee at the rate of one and 50/100 percent (1.5%) per month. FLG shall be entitled to recover all costs and expenses (including, without limitation, attorneys' fees) incurred by it in collecting any amounts overdue under this Agreement.

   E. Client hereby agrees to pay FLG a deposit as set forth on Exhibit A (the "Deposit") to be held in its entirety as security for Client's future payment obligations to FLG under this Agreement. Upon termination of this Agreement, all amounts then owing to FLG under this Agreement shall be charged against the Deposit and the balance thereof, if any, shall be refunded to Client.

   F. Within ten (10) days of Client's receipt of an expense report from FLG Member performing Services hereunder, Client shall immediately reimburse FLG Member directly for reasonable travel and out-of-pocket business expenses detailed in such expense report. Any required air travel, overnight accommodation and resulting per diem expenses shall be consistent with Client's travel & expense policies for Client's employed executive staff.

3. Relationship of the Parties.

   A. FLG's relationship with Client will be that of an independent contractor and nothing in this Agreement shall be construed to create a partnership, joint venture, or employer-employee relationship. FLG is not the agent of Client and is not authorized to make any presentation, contract, or commitment on behalf of Client unless specifically requested or authorized to do so by Client in writing. FLG agrees that all taxes payable as a result of compensation payable to FLG hereunder shall be FLG's sole liability. FLG shall defend, indemnify and hold harmless Client, Client's officers, directors, employees and agents, and the administrators of Client's benefit plans from and against any claims, liabilities or expenses relating to such taxes or compensation.

4. Term and Termination.

   A. The term of this Agreement shall be for the period set forth in Exhibit A.

   B. Either party may terminate this Agreement upon thirty (30) calendar days advance written notice to the other party.

   C. Either party may terminate this Agreement immediately upon a material breach of this Agreement by the other party and a failure by the other party to cure such breach within ten (10) days of written notice thereof by the non-breaching party to the breaching party.

   D. FLG shall have the right to terminate this Agreement immediately without advance written notice (i) if Client is engaged in, or

CONFIDENTIAL CONSULTING AGREEMENT

requests that FLG or the FLG Member undertake or ignore any illegal or unethical activity, or (ii) upon the death or disability of the FLG Member.

E. This Agreement shall be deemed terminated if during any six (6) month period no billable hours occur, with the termination date effective on the date of the last billable hour therein.

F. If at any time during this engagement there is a conversion of the FLG Member from 1099 to W2 with Client, then a placement fee shall be immediately payable to FLG. In addition, to the extent within one (1) year of the end of this engagement Client directly hires, employs or retains the FLG Member or any FLG Member either via 1099 or W2, then Client will also immediately pay to FLG a placement fee. The placement fee paid by Client to FLG will be equal to thirty percent (30%) of FLG Member's annual base salary including bonus that is agreed to by Client and the FLG Member. Client will not withhold any taxes from any placement fee paid to FLG.

5. Disclosures

A. IRS Circular 230. To ensure compliance with requirements imposed by the IRS effective June 20, 2005, FLG hereby informs Client that any tax advice offered during the course of providing, or arising out of, the Services rendered pursuant to this Agreement, unless expressly stated otherwise, is not intended or written to be used, and cannot be used, for the purpose of: (i) avoiding tax- related penalties under the Internal Revenue Code, or (ii) promoting, marketing or recommending to another party any tax- related matter(s) said tax advice address(es).

B. Attorney-Client Privilege. Privileged communication disclosed to FLG or FLG Member may waive the privilege through no fault of FLG. FLG strongly recommends that Client consult with legal counsel before disclosing privileged information to FLG or FLG Member. Pursuant to Paragraph 6, neither FLG nor FLG Member will be responsible for damages caused through Client's waiver of privilege, whether deliberate or inadvertent, by disclosing such information to FLG or FLG Member.

6. **DISCLAIMERS AND LIMITATION OF LIABILITY.**

EXCEPT AS EXPRESSLY SET FORTH HEREIN, ALL SERVICES TO BE PROVIDED BY FLG AND FLG MEMBER (FOR PURPOSES OF THIS PARAGRAPH 6, COLLECTIVELY "FLG") HEREUNDER ARE PROVIDED "AS IS" WITHOUT ANY WARRANTY WHATSOEVER. CLIENT RECOGNIZES THAT THE "AS IS" CLAUSE OF THIS AGREEMENT IS AN IMPORTANT PART OF THE BASIS OF THIS AGREEMENT, WITHOUT WHICH FLG WOULD NOT HAVE AGREED TO ENTER INTO THIS AGREEMENT. FLG EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, TERMS OR CONDITIONS, WHETHER EXPRESS, IMPLIED, OR STATUTORY, REGARDING THE PROFESSIONAL SERVICES, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, TITLE, FITNESS FOR A PARTICULAR PURPOSE AND INFRINGEMENT. NO REPRESENTATION OR OTHER AFFIRMATION OF FACT REGARDING THE SERVICES PROVIDED HEREUNDER SHALL BE DEEMED A WARRANTY FOR ANY PURPOSE OR GIVE RISE TO ANY LIABILITY OF FLG WHATSOEVER.

IN NO EVENT SHALL FLG BE LIABLE FOR ANY INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, UNDER ANY CIRCUMSTANCES, INCLUDING, BUT NOT LIMITED TO: LOST PROFITS; REVENUE OR SAVINGS; WAIVER BY CLIENT, WHETHER INADVERTENT OR INTENTIONAL, OF CLIENT'S ATTORNEY-CLIENT PRIVILEGE THROUGH CLIENT'S DISCLOSURE OF LEGALLY PRIVILEGED INFORMATION TO FLG; OR THE LOSS, THEFT, TRANSMISSION OR USE, AUTHORIZED OR OTHERWISE, OF ANY DATA, EVEN IF CLIENT OR FLG HAVE BEEN ADVISED OF, KNEW, OR SHOULD HAVE KNOWN, OF THE POSSIBILITY THEREOF. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, FLG'S AGGREGATE CUMULATIVE LIABILITY HEREUNDER, WHETHER IN CONTRACT, TORT, NEGLIGENCE, MISREPRESENTATION, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED AN AMOUNT EQUAL TO THE LAST SIX (6) MONTHS OF FEES PAYABLE BY CLIENT UNDER PARAGRAPH 2(A) OF THIS AGREEMENT. CLIENT ACKNOWLEDGES THAT THE COMPENSATION PAID BY IT UNDER THIS AGREEMENT REFLECTS THE ALLOCATION OF RISK SET FORTH IN THIS AGREEMENT AND THAT FLG WOULD NOT ENTER INTO THIS AGREEMENT WITHOUT THESE LIMITATIONS ON ITS LIABILITY. THIS PARAGRAPH SHALL NOT APPLY TO EITHER PARTY WITH RESPECT TO A BREACH OF ITS CONFIDENTIALITY OBLIGATIONS.

A. As a condition for recovery of any amount by Client against FLG, Client shall give FLG written notice of the alleged basis for liability within ninety (90) days of discovering the circumstances giving rise thereto, in order that FLG will have the opportunity to investigate in a timely manner and, where possible, correct or rectify the alleged basis for liability; provided that the failure of Client to give such notice will only affect the rights of Client to the extent that FLG is actually prejudiced by such failure. Notwithstanding anything herein to the contrary, Client must assert any claim against FLG by the sooner of: (i) ninety (90) days after discovery; (ii) ninety (90) days after the termination of this Agreement; (iii) ninety (90) days after the last date on which the Services were performed; or, (iv) sixty (60) days after completion of a financial or accounting audit for the period(s) to which a claim pertains.

7. Indemnification.

A. FLG and FLG Member acting in relation to any of the affairs of Client shall, to the fullest extent permitted by law, as now or hereafter in effect, be indemnified and held harmless, and such right to indemnification shall continue to apply to FLG and FLG Member following the term of this Agreement out of the assets and profits of the Client from and against all actions, costs, charges, losses, damages, liabilities and expenses which FLG or FLG Member, or FLG's or FLG Member's heirs, executors or administrators, shall or may incur or sustain by or by reason for any act done, concurred in or omitted in or about the execution of FLG's or FLG Member's duty or Services performed on behalf of Client; and Client shall advance the reasonable attorney's fees, costs and expenses incurred by FLG or FLG's Member in connection with litigation related to the foregoing on the same basis as such advancement would be available to the Client's officers and directors, PROVIDED THAT Client shall not be obligated to indemnify, hold harmless or make payments to or on behalf of any person (i) in connection with services provided by such person outside the scope of Services contemplated by this Agreement, and not authorized or consented to by Client's CEO or Board of Directors, or (ii) in respect of any (a) gross negligence or willful misconduct of such person, or (b) negligence of such person, but only to the extent that FLG's errors and omissions liability insurance would cover such person for such negligence without regard to Client's obligation to indemnify FLG hereunder.

B. FLG and FLG Member shall have no liability to Client relating to the performance of its duties under this Agreement except in the event of FLG's or FLG Member's gross negligence or willful misconduct.

CONFIDENTIAL CONSULTING AGREEMENT

C. FLG and FLG Member agree to waive any claim or right of action FLG or FLG Member might have whether individually or by or in the right of Client, against any director, secretary and other officers of Client and the liquidator or trustees (if any) acting in relation to any of the affairs of Client and every one of them on account of any action taken by such director, officer, liquidator or trustee or the failure of such director, officer, liquidator or trustee to take any action in the performance of his duties with or for Client; PROVIDED THAT such waiver shall not extend to any matter in respect of any gross negligence or willful misconduct which may attach to any such persons.

8. Representations and Warranties.

A. Each party represents and warrants to the other that it is authorized to enter into this Agreement and can fulfill all of its obligations hereunder.

B. FLG and FLG Member warrant that they shall perform the Services diligently, with due care, and in accordance with prevailing industry standards for comparable engagements and the requirements of this Agreement. FLG and FLG Member warrant that FLG Member has sufficient professional experience to perform the Services in a timely and competent manner. While at Client's premises, FLG Member will remain in areas designated by Client and will comply with all Client policies and procedures, including without limitation badge and pass requirements, standard operating procedures, record keeping policies, and security policies.

C. Each party represents and warrants that it has and will maintain a policy or policies of insurance with reputable insurance companies providing the members, officers and directors, as the case may be, of itself with coverage for losses from wrongful acts. FLG covenants that it has an error and omissions insurance policy in place in the form provided to Client prior to or contemporaneously with the date of execution of this Agreement and will continue to maintain such policy or equivalent policy provided that such policy or equivalent policy shall be available at commercially reasonable rates.

9. Work Product License.

The parties do not anticipate that FLG or FLG Member will create any intellectual property for Client in performing the Services pursuant to this Agreement. However, FLG and FLG Member grant to Client a world- wide, perpetual, exclusive, royalty-free, irrevocable license to use and create derivative works from all tangible and electronic documents, spreadsheets, and financial models (collectively, "Work Product") produced or authored by FLG Member in the course of performing the Services pursuant to this Agreement. Any patent rights arising out of the Services will be assigned to and owned by Client and not FLG or FLG Member. All other rights, including, but not limited to, the residual memory of any methods, discoveries, developments, improvements, know-how, ideas, insights, analytical concepts and skills directly inherent to, or reasonably required for, the competent execution of FLG Member's profession as a chief financial officer are reserved in their entirety by FLG and FLG Member.

10. Miscellaneous.

A. Any notice required or permitted to be given by either party hereto under this Agreement shall be in writing and shall be personally delivered or sent by a reputable courier mail service (e.g., Federal Express) or by facsimile or email transmission confirmed by reputable courier mail service, to the other party as set forth in this Paragraph 10(A). Notices will be deemed effective two (2) days after deposit with a reputable courier service or upon confirmation of receipt by the recipient from such courier service or the same day if sent by facsimile or email transmission and confirmed as set forth above.

If to FLG:
U. Heather Ogan
FLG Partners, LLC
228 Hamilton Ave., 3rd Floor, Palo Alto, CA 94301
PO BOX 192304
San Francisco, CA 94119 Tel: 415-508-4048, ext 201
Fax: 415-508-6896
E-mail: accounting@flgpartners.com

If to Client: the address, telephone numbers and email address shown below Client's signature on the signature page.

B. This Agreement will be governed by and construed in accordance with the laws of California without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

C. Any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement (including any other agreement(s) contemplated hereunder), including, without limitation, any action or claim based on tort, contract, or statute (including any claims of breach or violation of statutory or common law protections from discrimination, harassment and hostile working environment), or concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement ("Claim"), shall be resolved by final and binding arbitration before a single arbitrator ("Arbitrator") selected from and administered by the San Francisco office of JAMS (the "Administrator") in accordance with its then existing commercial arbitration rules and procedures. The arbitration shall be held in San Francisco, California. The Arbitrator shall, within fifteen (15) calendar days after the conclusion of the Arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The Arbitrator also shall be authorized to grant any temporary, preliminary or permanent equitable remedy or relief he or she deems just and equitable and within the scope of this Agreement, including, without limitation, an injunction or order for specific performance. Each party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Administrator and the Arbitrator; provided, however, the Arbitrator shall be authorized to determine whether a party is the prevailing party, and if so, to award to that prevailing party reimbursement for its reasonable attorneys' fees, costs and disbursements, and/or the fees and costs of the Administrator and the Arbitrator. The Arbitrator's award may be enforced in any court of competent jurisdiction. Notwithstanding the foregoing, nothing in this Paragraph 10(C) will restrict either party from applying to any court of competent jurisdiction for injunctive relief.

D. Neither party may assign its rights or delegate its obligations hereunder, either in whole or in part, whether by operation of law or otherwise, without the prior written consent of the other party; provided, however, that FLG may assign its rights and delegate its obligations hereunder to any affiliate of FLG. The rights and liabilities of the parties under this Agreement will bind and inure to the benefit of the parties' respective successors and permitted assigns.

E. If any provision of this Agreement, or the application thereof, shall for any reason and to any extent be invalid or unenforceable, the remainder of this Agreement and application of such provision to other persons or circumstances shall be interpreted so as best to reasonably effect the intent of the parties. The parties further agree to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that will achieve, to the

extent possible, the economic, business and other purposes of the void or unenforceable provision.

F. This Agreement, the Exhibits, and any executed Non-Disclosure Agreements specified herein and thus incorporated by reference constitute the entire understanding and agreement of the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous agreements or understandings, express or implied, written or oral, between the parties with respect hereto. The express terms hereof control and supersede any course of performance or usage of the trade inconsistent with any of the terms hereof.

G. Any term or provision of this Agreement may be amended, and the observance of any term of this Agreement may be waived, only by a writing signed by the parties. The waiver by a party of any breach hereof for default in payment of any amount due hereunder or default in the performance hereof shall not be deemed to constitute a waiver of any other default or succeeding breach or default.

H. Upon completion of the engagement hereunder, upon the written consent of Client, FLG may place customary "tombstone" advertisements using Client's logo and name in publications of FLG's choice at its own expense, and/or cite the engagement in similar fashion on FLG's website.

I. If Client discloses FLG Member's name on Client's website (such as in an executive biography, for example), press releases, SEC filings and other public documents and media, then Client shall include in the description of FLG Member a sentence substantially the same as "[FLG Member] is also a partner at FLG Partners, a leading CFO services firm in Silicon Valley."

J. If and to the extent that a party's performance of any of its obligations pursuant to this Agreement is prevented, hindered or delayed by fire, flood, earthquake, elements of nature or acts of God, acts of war, terrorism, riots, civil disorders, rebellions or revolutions, or any other similar cause beyond the reasonable control of such party (each, a "Force Majeure Event"), and such non-performance, hindrance or delay could not have been prevented by reasonable precautions of the non-performing party, then the non-performing, hindered or delayed party shall be excused for such non-performance, hindrance or delay, as applicable, of those obligations affected by the Force Majeure Event for as long as such Force Majeure Event continues and such party continues to use its best efforts to recommence performance whenever and to whatever extent possible without delay, including through the use of alternate sources, workaround plans or other means.

K. This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which when executed and delivered shall constitute an original, but all the counterparts together constitute one and the same instrument.

L. This Agreement may be executed by facsimile signatures (including electronic versions of this document in Adobe Acrobat Portable Document Format form which contain scanned or secure, digitally signed signatures) by any party hereto and such signatures shall be deemed binding for all purposes hereof, without delivery of an original signature being thereafter required.

M. Survivability. The following Paragraphs shall survive the termination of this Agreement: 6 ("Disclaimers and Limitation of Liability"); 7 ("Indemnification"); 8 ("Representations and Warranties"); 9 ("Work Product License"); and 10 ("Miscellaneous").

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

CLIENT:

Kronos Bio, Inc.,

a Delaware corporation.

By: Allison Frisbee

Signed: /s/ Allison Frisbee Title: Senior Vice President and General Counsel Address: 1300 So. El Camino Real, Suite 400
San Mateo, CA 94402

Email:

FLG:

FLG Partners, LLC,

a California limited liability company. By: U. Heather Ogan

Signed: /s/ U. Heather Ogan Title: Administrative Partner
Effective Date: September 8, 2023.

REMAINDER OF THIS PAGE LEFT BLANK

FLG PARTNERS
CFO excellence - when experience counts

CONFIDENTIAL CONSULTING AGREEMENT

EXHIBIT A

1. Description of Services: CFO level services typical for a publicly held corporation.

2. FLG Member: Sandy Gardiner.

3. Fees: $650 per hour, subject to any hourly maximums that Client may establish from time to time. Invoices shall be sent to invoice@kronosbio.com and shall include the name of the payee and address to which payment shall be sent or the appropriate ACH information.

4. Additional Compensation: None.

5. Deposit: $25,000.

6. Term: Indefinite, and terminable pursuant to Paragraph 4 of the Agreement.

7. Non-Disclosure Agreement: FLG-Client Mutual Non-Disclosure Agreement dated September 8, 2023 (the "NDA"). FLG hereby expressly consents to the public disclosure of the existence of FLG's relationship with Client, by Client, provided that the terms and conditions herein shall remain confidential pursuant to the terms of the NDA.

REMAINDER OF THIS PAGE LEFT BLANK

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Norbert Bischofberger, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kronos Bio, 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 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 13, 2023

By: */s/ Norbert Bischofberger*

Norbert Bischofberger, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sandra A. Gardiner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kronos Bio, 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 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 13, 2023

By: */s/ Sandra A. Gardiner*

Sandra A. Gardiner
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 on Form 10-Q of Kronos Bio, Inc. (the "Company") for the fiscal quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Norbert Bischofberger, Ph.D., the Chief Executive Officer of the Company, and I, Sandra A. Gardiner, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2023

By: */s/ Norbert Bischofberger*
Norbert Bischofberger, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2023

By: */s/ Sandra A. Gardiner*
Sandra A. Gardiner
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)