

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, 2021

OR

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

For the transition period from _____ to _____

Commission file number: 001-39592

Kronos Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

82-1895605

(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 2, 2021 the registrant had 56,347,286 shares of common stock, \$0.001 par value per share, outstanding.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

KRONOS BIO, INC.
Condensed Balance Sheets
(Unaudited)

(in thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		(1)
Current assets:		
Cash and cash equivalents	\$ 216,993	\$ 248,009
Short-term investments	181,389	165,052
Prepaid expenses and other current assets	4,445	6,741
Total current assets	402,827	419,802
Long-term investments	—	49,001
Property and equipment, net	15,131	13,646
Operating lease right-of-use assets	27,433	27,322
Restricted cash	2,026	2,027
Other noncurrent assets	112	166
Total assets	<u>\$ 447,529</u>	<u>\$ 511,964</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,940	\$ 4,550
Accrued expenses	7,350	4,974
Current portion of operating lease liabilities	1,728	937
Current portion of other liabilities	1,756	2,395
Total current liabilities	14,774	12,856
Noncurrent operating lease liabilities	32,326	31,120
Other noncurrent liabilities	1,406	2,469
Total liabilities	48,506	46,445
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.001 par value, 200,000,000 authorized as of September 30, 2021 and December 31, 2020; 55,217,844 and 54,073,901 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.	55	54
Preferred stock, \$0.001 par value; 10,000,000 authorized; no shares issued and outstanding.	—	—
Additional paid-in capital	599,611	577,390
Accumulated deficit	(200,650)	(111,906)
Accumulated other comprehensive income (loss)	7	(19)
Total stockholders' equity	399,023	465,519
Total liabilities, convertible preferred stock and stockholders' equity	<u>\$ 447,529</u>	<u>\$ 511,964</u>

(1) The balance sheet as of December 31, 2020 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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 24,688	\$ 16,755	\$ 62,084	\$ 30,125
General and administrative	8,985	4,054	26,908	6,831
Total operating expenses	33,673	20,809	88,992	36,956
Loss from operations	(33,673)	(20,809)	(88,992)	(36,956)
Other income (expense), net:				
Change in fair value of convertible notes payable	—	(15,215)	—	(15,215)
Interest expense	—	(3,889)	—	(3,890)
Interest and other income, net	70	200	248	774
Total other income (expense), net	70	(18,904)	248	(18,331)
Net loss	(33,603)	(39,713)	(88,744)	(55,287)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	1	(117)	26	65
Net comprehensive loss	\$ (33,602)	\$ (39,830)	\$ (88,718)	\$ (55,222)
Net loss per share, basic and diluted	\$ (0.61)	\$ (6.48)	\$ (1.63)	\$ (9.39)
Weighted-average shares of common stock, basic and diluted	54,977,085	6,127,146	54,549,747	5,886,191

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

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	\$ —	54,073,901	\$ 54	\$ 577,390	\$ (19)	\$ (111,906)	\$ 465,519
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	312,062	—	590	—	—	590
Stock-based compensation expense	—	—	—	—	5,238	—	—	5,238
Net unrealized gain on available-for-sale securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(26,086)	(26,086)
Balance at March 31, 2021	—	\$ —	54,385,963	\$ 54	\$ 583,218	\$ (23)	\$ (137,992)	\$ 445,257
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	322,812	1	626	—	—	627
Stock-based compensation expense	—	—	—	—	6,432	—	—	6,432
Employee stock purchase plan	—	—	50,569	—	817	—	—	817
Net unrealized gain on available-for-sale securities	—	—	—	—	—	29	—	29
Net loss	—	—	—	—	—	—	(29,055)	(29,055)
Balance at June 30, 2021	—	\$ —	54,759,344	\$ 55	\$ 591,093	\$ 6	\$ (167,047)	\$ 424,107
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	458,500	—	1,381	—	—	1,381
Stock-based compensation expense	—	—	—	—	7,137	—	—	7,137
Net unrealized gain on available-for-sale securities	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(33,603)	(33,603)
Balance at September 30, 2021	—	\$ —	55,217,844	\$ 55	\$ 599,611	\$ 7	\$ (200,650)	\$ 399,023

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)

(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2019	21,504,893	\$ 122,907	5,660,391	\$ 6	\$ 271	\$ (18)	\$ (23,462)	\$ (23,203)
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	119,939	—	20	—	—	20
Stock-based compensation expense	—	—	—	—	188	—	—	188
Net unrealized loss on available-for-sale securities	—	—	—	—	—	158	—	158
Net loss	—	—	—	—	—	—	(6,995)	(6,995)
Balance at March 31, 2020	21,504,893	\$ 122,907	5,780,330	\$ 6	\$ 479	\$ 140	\$ (30,457)	\$ (29,832)
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	171,713	—	113	—	—	113
Stock-based compensation expense	—	—	—	—	293	—	—	293
Net unrealized loss on available-for-sale securities	—	—	—	—	—	24	—	24
Net loss	—	—	—	—	—	—	(8,579)	(8,579)
Balance at June 30, 2020	21,504,893	\$ 122,907	5,952,043	\$ 6	\$ 885	\$ 164	\$ (39,036)	\$ (37,981)
Issuance of common stock upon vesting and exercise of options and vesting of restricted stock	—	—	332,283	—	278	—	—	278
Stock-based compensation expense	—	—	—	—	1,253	—	—	1,253
Net unrealized loss on available-for-sale securities	—	—	—	—	—	(117)	—	(117)
Net loss	—	—	—	—	—	—	(39,713)	(39,713)
Balance at September 30, 2020	21,504,893	\$ 122,907	6,284,326	\$ 6	\$ 2,416	\$ 47	\$ (78,749)	\$ (76,280)

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (88,744)	\$ (55,287)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,431	539
Net amortization/accretion on available-for-sale securities	3,175	105
Change in accrued interest on available-for-sale securities	211	71
Stock-based compensation expense	18,807	1,734
Noncash lease expense	1,487	1,994
Change in fair value of convertible notes payable	—	15,215
Debt issuance costs on convertible notes payable	—	3,889
Acquired in-process research and development	—	3,565
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,843	(493)
Other long-term assets	54	150
Accounts payable	(650)	1,129
Accrued expenses	3,288	879
Right-of-use operating assets and liabilities, net	399	(588)
Other liabilities	(1,703)	4,816
Net cash used in operating activities	(59,402)	(22,282)
Cash flows from investing activities:		
Purchase of property and equipment	(3,782)	(5,886)
Purchase of available-for-sale securities	(163,615)	(41,205)
Maturities of marketable securities	175,340	45,611
Sale of marketable securities	17,032	—
Net cash provided by (used in) investing activities	24,975	(1,480)
Cash flows from financing activities:		
Principal payments on finance lease	(5)	(24)
Proceeds from issuance of common stock upon exercise of stock options	2,598	411
Proceeds from issuance of common stock under the employee stock purchase plan	817	—
Proceeds from issuance of convertible notes, net of issuance costs	—	151,275
Payments of deferred offering costs	—	(2,248)
Net cash provided by financing activities	3,410	149,414
Net increase (decrease) in cash and cash equivalents	(31,017)	125,652
Cash, cash equivalents and restricted cash at beginning of period	250,036	32,570
Cash, cash equivalents and restricted cash at end of period	\$ 219,019	\$ 158,222
Supplemental disclosures of non-cash activities:		
Property and equipment additions included in accounts payable and accrued expenses	\$ 408	\$ 1,325
Reduction of right-of-use asset due to modification	\$ (1,741)	\$ —
Right-of-use asset obtained in exchange for operating lease liability	\$ 3,764	\$ 30,898
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 682
Cash and cash equivalents at end of period	\$ 216,993	\$ 156,196
Restricted cash at end of period	2,026	2,026
Cash, cash equivalents and restricted cash at end of period	\$ 219,019	\$ 158,222

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 a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel cancer therapeutics designed to transform patient outcomes through a precision medicine strategy by targeting dysregulated transcription.

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.

Initial Public Offering

In October 2020, the Company completed an initial public offering (IPO) of its common stock. In connection with its IPO, the Company issued and sold 15,131,579 shares of its common stock, which included 1,973,684 shares of its common stock issued and sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of \$19.00 per share. As a result of the IPO, the Company received 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 payable by the Company. At the closing of the IPO, all then outstanding convertible preferred stock were automatically converted into 22,687,625 shares of common stock, and the then outstanding 2020 Notes were automatically converted into 9,610,713 shares of common stock. At the closing of the IPO, the then outstanding Gilead Note (See Note 11) was also converted into 188,567 shares of common stock. Following the IPO, there were no shares of convertible preferred stock outstanding.

Forward Stock Split

On October 2, 2020, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a forward split of shares of the Company's common stock on a 1.055-for-1 basis (the Forward Stock Split). In connection with the Forward Stock Split, the conversion ratio for the Company's outstanding convertible preferred stock was proportionally adjusted such that the common stock issuable upon conversion of such preferred stock was increased in proportion to the Forward Stock Split. The par value of the common stock was not adjusted as the result of the Forward Stock Split. All references to common stock, options to purchase common stock, early exercised options, share data, per share data, convertible preferred stock (to the extent presented on an as-converted to common stock basis) and related information contained in these condensed financial statements have been retrospectively adjusted to reflect the effect of the Forward Stock Split for all periods presented.

Need for Additional Capital

The Company has incurred net operating losses since its inception of \$200.7 million as of September 30, 2021. The Company expects that its cash, cash equivalents and investments as of September 30, 2021 will enable it to fund its planned operating expenses and capital expenditure requirements for 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 to fully implement its business plan.

The Company intends to raise additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. 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 Company expects that its cash and cash equivalents and investments will be sufficient to fund its operations for a period of at least one year from the date the accompanying financial statements are filed with the Securities and Exchange Commission (SEC).

The Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 pandemic on the financial performance of the Company will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

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

Unaudited Interim Financial Information

The accompanying balance sheet as of September 30, 2021, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the statements of convertible preferred stock and stockholders' equity (deficit) as of September 30, 2021 and 2020, the statements of cash flows for the nine months ended September 30, 2021 and 2020, and the financial data and other financial information disclosed in the notes to the condensed financial statements are unaudited. The unaudited interim 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, 2021 and the results of its operations for the three and nine months ended September 30, 2021 and 2020. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the full year ending December 31, 2021, any other interim periods, or any future year or period. These financial statements should be read in conjunction with the Company's audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 23, 2021.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the 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, the accrual of research and development expenses, the fair value of convertible notes and investments, 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.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 2021, 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.

Recent Accounting Pronouncements Not Yet Adopted

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*, which clarifies and reduces diversity in accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This guidance will be effective for the Company in the first quarter of 2022, and early adoption is permitted. The effect on our consolidated financial statements and related disclosures is not material.

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, investments, and convertible notes 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, 2021 and December 31, 2020 were as follows:

	September 30, 2021			Fair Value
	Level 1	Level 2	Level 3	
	(in thousands)			
Financial Assets:				
Money market funds	\$ 180,352	\$ —	\$ —	\$ 180,352
Corporate bonds	—	79,934	—	79,934
U.S. treasury securities	103,455	—	—	103,455
Total financial assets	<u>\$ 283,807</u>	<u>\$ 79,934</u>	<u>\$ —</u>	<u>\$ 363,741</u>

KRONOS BIO, INC.
Notes to Condensed Financial Statements
(Unaudited)

	December 31, 2020			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds	\$ 114,184	\$ —	\$ —	\$ 114,184
Certificates of deposit	1,229	—	—	1,229
Corporate bonds	—	40,736	—	40,736
U.S. agency securities	—	10,001	—	10,001
U.S. treasury securities	284,721	—	—	284,721
Total financial assets	\$ 400,134	\$ 50,737	\$ —	\$ 450,871

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, 2021 and December 31, 2020 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, 2021 and December 31, 2020 were as follows:

	September 30, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	\$ 180,352	\$ —	\$ —	\$ 180,352
Corporate bonds	79,937	9	(12)	79,934
U.S. treasury securities	103,446	10	(1)	103,455
Total cash equivalents and investments	\$ 363,735	\$ 19	\$ (13)	\$ 363,741

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	\$ 114,184	\$ —	\$ —	\$ 114,184
Certificates of deposit	1,225	4	—	1,229
Corporate bonds	40,743	9	(16)	40,736
U.S. agency securities	9,999	2	—	10,001
U.S. treasury securities	284,739	3	(21)	284,721
Total cash equivalents and investments	\$ 450,890	\$ 18	\$ (37)	\$ 450,871

KRONOS BIO, INC.
Notes to Condensed Financial Statements
(Unaudited)

These available-for-sale securities were classified on the Company's balance sheets as of September 30, 2021 and December 31, 2020 as:

	Fair Value	
	September 30, 2021	December 31, 2020
	(in thousands)	
Cash equivalents	\$ 182,352	\$ 236,818
Short-term investments	181,389	165,052
Long-term investments	—	49,001
Total cash equivalents and investments	<u>\$ 363,741</u>	<u>\$ 450,871</u>

The fair values of available-for-sale securities by contractual maturity as of September 30, 2021 and December 31, 2020 were as follows:

	September 30, 2021	December 31, 2020
		(in thousands)
Due in 1 year or less	\$ 183,389	\$ 287,686
Due in 1 to 2 years	—	49,001
Instruments not due at a single maturity date	180,352	114,184
Total cash equivalents and investments	<u>\$ 363,741</u>	<u>\$ 450,871</u>

As of September 30, 2021 and December 31, 2020, the remaining contractual maturities of available-for-sale securities were less than 2 years. There have been no significant realized losses on available-for-sale securities for any of the periods presented in the accompanying financial statements. Based on the Company's review of its available-for-sale securities, the Company believes that it had no other-than-temporary impairments on these securities as of September 30, 2021 and December 31, 2020 because the Company does not intend to sell these securities nor does it believe that it will be required to sell these securities before the recovery of their amortized cost basis. Gross realized gains and gross realized losses were immaterial for any of the periods presented in the accompanying financial statements.

As of September 30, 2021 and December 31, 2020, unrealized losses on available-for-sale investments are not attributed to credit risk. The Company believes that an allowance for credit losses is unnecessary because the unrealized losses on certain of the Company's marketable securities are due to market factors.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
	(in thousands)	
Accrued interest on short-term available-for-sale securities	\$ 1,048	\$ 612
Prepaid equipment service contracts	392	383
Prepaid external research and development and outside services	1,184	1,889
Prepaid software	583	736
Prepaid insurance	129	2,881
Prepaid rent and other	1,109	240
Total prepaid expenses and other current assets	\$ 4,445	\$ 6,741

6. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
	(in thousands)	
Property and equipment:		
Lab equipment	\$ 7,919	\$ 5,619
Leasehold improvements	9,285	8,957
Furniture and fixtures	596	216
Finance lease on R&D equipment	—	139
Computer equipment	44	—
Total property and equipment	17,844	14,931
Less: Accumulated depreciation and amortization	(2,713)	(1,285)
Total property and equipment, net	\$ 15,131	\$ 13,646

Depreciation and amortization expense was \$0.5 million and \$0.2 million for the three months ended September 30, 2021 and 2020, respectively, and \$1.4 million and \$0.5 million for the nine months ended September 30, 2021 and 2020, respectively. Computer equipment has a useful life of 3 years.

7. ACCRUED EXPENSES AND CURRENT PORTION OF OTHER LIABILITIES

Accrued expenses consisted of the following as of September 30, 2021 and December 31, 2020:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(in thousands)	
Accrued compensation	\$ 2,767	\$ 2,274
Accrued taxes	29	558
External research and development	3,557	1,017
Accrued outside services	927	—
Accrued leasehold improvements	—	927
Other accrued expenses	70	198
Total accrued expenses	\$ 7,350	\$ 4,974

Current portion of other liabilities consist of the following as of September 30, 2021 and December 31, 2020:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(in thousands)	
Current portion of finance lease liability	\$ —	\$ 5
Current portion of unvested early exercised share liability	1,429	2,174
ESPP withholdings	327	216
Total current portion of other liabilities	\$ 1,756	\$ 2,395

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, restricted stock units, 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, 2021, the maximum number of shares of common stock that may be issued was 14,739,827 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. 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, 2021, there were 4,699,032 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, 2021 is summarized as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2020	6,251,159	\$ 8.95		
Granted	1,592,606	26.52		
Forfeited ⁽¹⁾	(120,384)	13.74		
Exercised	(972,660)	2.67		
Balance, September 30, 2021	<u>6,750,721</u>	<u>\$ 13.91</u>	<u>8.83</u>	<u>\$ 67,390</u>

⁽¹⁾ Included in forfeited are 12,748 options that were early exercised, but not yet vested at the time of termination of the grantee, and repurchased by the Company. The weighted-average exercise price of the repurchased options was \$0.61 per share.

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were 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, 2021. There was no future tax benefit related to options exercised, as the Company had accumulated net operating losses as of September 30, 2021 and December 31, 2020.

The weighted-average grant-date fair value per share of stock options granted, using the Black-Scholes option pricing model, was \$18.91 during the nine months ended September 30, 2021.

As of September 30, 2021 and December 31, 2020, there was \$54.0 million and \$36.3 million of unrecognized stock-based compensation related to stock options, respectively, which is expected to be recognized over a weighted-average period of 3.15 and 3.70 years, respectively.

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 increases 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 issued and sold zero and 50,569 shares of common stock during the three and nine months ended September 30, 2021, respectively, under the ESPP. The Company has 1,197,766 shares reserved for future issuance as of September 30, 2021.

Restricted Stock

Restricted stock awards and units as of September 30, 2021 are summarized as follows:

	Number of Restricted Stock	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Vesting Life (in years)	Aggregate Intrinsic Value (in thousands)
Unvested, December 31, 2020	810,197	\$ 22.26		
Granted	347,267	29.14		
Vested and converted to shares	(120,714)	1.41		
Forfeited	(20,476)	29.83		
Unvested, September 30, 2021	<u>1,016,274</u>	<u>\$ 26.93</u>	<u>2.26</u>	<u>\$ 21,301</u>

As of September 30, 2021, there was \$20.3 million of unrecognized stock-based compensation related to RSUs, which is expected to be recognized over a weighted average period of 2.26 years.

As of September 30, 2021, there was \$0.4 million of unrecognized stock-based compensation related to RSAs, which is expected to be recognized over a weighted average period of 2.83 years.

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, 2021 and 2020 as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development expenses	\$ 3,525	\$ 247	\$ 9,553	\$ 541
General and administrative expenses	3,612	1,007	9,254	1,193
Total stock-based compensation expense	\$ 7,137	\$ 1,254	\$ 18,807	\$ 1,734

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 convertible preferred stock and 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, 2021 and December 31, 2020, there was \$1.4 million and \$2.2 million recorded in current portion of other liabilities, and \$1.4 million and \$2.5 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, 2021 and 2020. 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 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, 2021 and 2020. The Company has not identified any new uncertain tax positions as of September 30, 2021. 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, 2021 and 2020:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands, except share and per share amounts)		(in thousands, except share and per share amounts)	
Net loss	\$ (33,603)	\$ (39,713)	\$ (88,744)	\$ (55,287)
Weighted-average common stock outstanding, basic and diluted	54,977,085	6,127,146	54,549,747	5,886,191
Net loss per share, basic and diluted	\$ (0.61)	\$ (6.48)	\$ (1.63)	\$ (9.39)

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. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. 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, 2021	September 30, 2020
Stock options to purchase common stock	5,768,855	3,359,622
Early exercised stock options subject to future vesting	981,866	1,858,264
Restricted stock awards subject to future vesting	124,066	271,683
Restricted stock units subject to future vesting	892,208	—
Convertible preferred stock	—	22,687,625
Expected shares to be purchased under Employee Stock Purchase Plan	122,693	—
2020 Notes	—	10,741,406
Gilead Note	—	210,752
Total	7,889,688	39,129,352

11. COMMITMENTS AND CONTINGENCIES

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 (ENTO) and lanraplenib (LANRA), and patents and other intellectual property covering or related to the development, manufacture and commercialization of ENTO and LANRA.

In consideration for such assets, on the date of the Gilead Asset Purchase Agreement, the Company made a \$3.0 million upfront cash payment and issued a \$3.0 million principal amount convertible promissory note to Gilead (Gilead Note). The Company also made a \$0.7 million payment to reimburse Gilead for certain liabilities assumed by the Company pursuant to the Gilead Asset Purchase Agreement. In addition, the Company is required to make milestone payments upon successful achievement of certain regulatory and sales milestones for ENTO, LANRA and other selective spleen tyrosine kinase inhibitor compounds covered by the patent rights acquired pursuant to the Gilead Asset Purchase Agreement and developed by the Company as a back-up to ENTO or LANRA (Other Compounds). Upon initiation of the Company's planned registrational Phase 3 clinical trial of ENTO in combination with induction chemotherapy in acute myeloid leukemia patients with NPM1 mutations, the Company will be required to pay a milestone to Gilead of \$29.0 million, and upon successful completion of certain other regulatory milestones in the United States, European Union and United Kingdom for ENTO, LANRA and any Other Compounds, across up to two distinct indications, the Company 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 ENTO, LANRA and any Other Compounds combined, the Company would owe to Gilead potential milestone payments totaling \$115.0 million.

Gilead is also eligible to receive (i) tiered marginal royalties ranging from the very low-teens to high-teens on annual worldwide net sales of ENTO, (ii) tiered marginal royalties ranging from high-single digits to the mid-teens on annual worldwide net sales of LANRA and (iii) tiered marginal royalties ranging from 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 ENTO and LANRA, for any royalties paid for future licenses of third party intellectual property required to develop or commercialize ENTO or LANRA. The Company's 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, the Company is required to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize either ENTO or LANRA.

The Gilead Note settled upon the completion of the Company's IPO in October 2020.

Purchase Commitments

In the normal course of business, the Company enters into contracts with CROs for preclinical studies and other vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation, other than for costs already incurred.

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 November 2020, the Company entered into a lease termination for its lab space in Cambridge, Massachusetts to terminate the lease as of January 31, 2021, rather than May 31, 2021. The cost for early termination was a payment of \$0.1 million. The Company accounted for this change in lease term as a modification of the originally amended lease. As a result of the modification, the operating right-of-use asset and lease liability were remeasured as of the modification date. As of September 30, 2021, there was no remaining lease liability or right-of-use asset related to this lease.

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-foot 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. As discussed in Note 2, 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, 2021, \$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 \$24.0 million and \$25.1 million and an aggregate lease liability of \$30.1 million and \$30.1 million on the September 30, 2021 and December 31, 2020 balance sheets, respectively. The remaining lease term is 9 years and 5 months, and the estimated incremental borrowing rate is 8.50%.

In July 2018, the Company entered into a lease agreement for a 4,661 square-foot office space to be used for general and administrative activities in San Mateo, California. The lease commenced on August 1, 2018 and had a 37-month initial term expiring on August 31, 2021. The lease also contained an option for the Company to extend the lease upon its initial expiration. In connection with the lease, the Company made a one-time cash security deposit in the amount of \$28,000. In May 2020, the Company amended its agreement to extend the lease for its office in San Mateo, California through April 2025. The initial annual base rent was \$0.3 million, and such amount was to increase by 3% annually on each anniversary of the commencement date. As of September 30, 2021, there was no remaining lease liability or right-of-use asset related to this lease. The operating lease right-of-use asset and aggregate lease liability for this suite were \$1.1 million and \$1.1 million, respectively, as of December 31, 2020.

In July 2020, the Company expanded to an adjacent suite in the San Mateo, California office space, which was treated as a separate lease for accounting purposes. The additional space was approximately 3,414 square feet and was similarly to be used for general and administrative activities. The lease commenced on July 1, 2020 and had an initial expiration date of April 30, 2025. In connection with the additional space leased, the Company made a one-time additional cash security deposit in the amount of \$25,000. The initial annual base rent for the expansion was \$0.2 million, and such amount will increase by 3% annually on each anniversary of the commencement date. In connection with the lease of the 3,414 square foot suite, as of September 30, 2021, there was no remaining lease liability or right-of-use asset related to this lease. The operating lease right-of-use asset and aggregate lease liability for this suite were \$0.8 million and \$0.8 million, respectively, as of December 31, 2020.

In February 2021, the Company entered into a new lease agreement for its office space in San Mateo, California to move from its current suites, totaling 8,075 square-feet, to a larger suite totaling 17,340 square-feet, and relocated in the third quarter of 2021. The Company accounted for this change in lease term of the original suites as a modification of the originally amended lease. As a result of the modification, the operating right-of-use asset and lease liability were remeasured as of the modification date.

KRONOS BIO, INC.
Notes to Condensed Financial Statements
(Unaudited)

The new 17,340 square foot suite will be treated as a separate lease for accounting purposes. The initial annual base rent for the new space will be \$1.2 million, and such amount will increase by 3% annually on each anniversary of the new premises commencement date. In connection with the larger space leased, the Company has also made an additional one-time cash security deposit in the amount of \$59,000. The new lease commenced in April 2021 and the new lease agreement extends the termination date from April 30, 2025 to August 31, 2026. In connection with the lease, the Company recognized an operating lease right-of-use asset of \$3.5 million and an aggregate lease liability of \$4.0 million as of September 30, 2021. The Company did not recognize any right-of-use asset or aggregate lease liability as of December 31, 2020. The remaining lease term is 5 years, 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, 2021 and December 31, 2020:

Balance Sheet Caption	September 30, 2021	December 31, 2020
	(in thousands)	
Assets:		
Operating lease assets	\$ 27,433	\$ 27,322
Liabilities:		
Current portion of operating lease liabilities	\$ 1,728	\$ 937
Noncurrent operating lease liabilities	32,326	31,120
Total operating lease liabilities	\$ 34,054	\$ 32,057

The following table summarizes the effect of finance lease costs in the Company's statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020:

Statement of Operations and Comprehensive Loss Caption	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development	\$ —	\$ 5	\$ 3	\$ 15
Interest expense, net	—	—	—	1
Total finance lease cost	\$ —	\$ 5	\$ 3	\$ 16

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, 2021 and 2020:

Statement of Operations and Comprehensive Loss Caption	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development	\$ 767	\$ 1,397	\$ 2,542	\$ 2,843
General and administrative	256	388	1,245	890
Total operating lease cost	\$ 1,023	\$ 1,785	\$ 3,787	\$ 3,733

The Company made cash payments of \$1.0 million, \$0.7 million, \$3.3 million and \$1.3 million under the lease agreements during the three and nine months ended September 30, 2021 and 2020, respectively.

KRONOS BIO, INC.
Notes to Condensed Financial Statements
(Unaudited)

The undiscounted future non-cancellable lease payments under the Company's operating leases as of September 30, 2021 for the next five years and thereafter is expected to be as follows:

Period Ending December 31,	Amount
	(in thousands)
Remaining three months of 2021	\$ 1,044
2022	5,020
2023	5,581
2024	5,749
2025 and thereafter	32,849
Total undiscounted lease payments	50,243
Less: Present value adjustment	(16,189)
Less: Tenant improvement allowance	—
Present value of operating lease liabilities	\$ 34,054

13. RELATED PARTIES

On December 1, 2017, the Company entered into a three-year 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 Beldegrun, 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. Tanen additionally serves as our Corporate Secretary. Mr. Christopher Wilfong, a strategic advisor to the Company, is an Operating Partner of Two River and Mr. Sean Algeo, serving as the Company's Financial Consultant, is the Chief Financial Officer of Two River. During the three and nine months ended September 30, 2021 and 2020, the Company incurred expense of zero, \$0.3 million, \$0.3 million and \$0.8 million respectively, for these services.

Some of the Company's expenses are periodically paid by Two River. The Company reimburses Two River for these expenses and no interest is charged on the outstanding balance. These reimbursable expenses were not material for the three and nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, the Company had no payables to Two River. As of December 31, 2020, the Company had payables to Two River of \$182,000.

In 2019, the Company entered into a consulting agreement with Bellco Capital, LLC (Bellco) to provide various executive services to the Company. Arie Beldegrun, M.D., FACS, the Chairman of the Board of Directors, is the Chairman of Bellco. Rebecka Beldegrun, M.D., who served as a director of the Company through January 25, 2021, is the President and Chief Executive Officer of Bellco. During the three and nine months ended September 30, 2021 and 2020, the Company incurred expense of \$6,300, \$6,300, \$18,900 and \$18,900, respectively, for these services.

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, 2020 included in our Annual Report on Form 10-K, as filed with the SEC on March 23, 2021.

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.

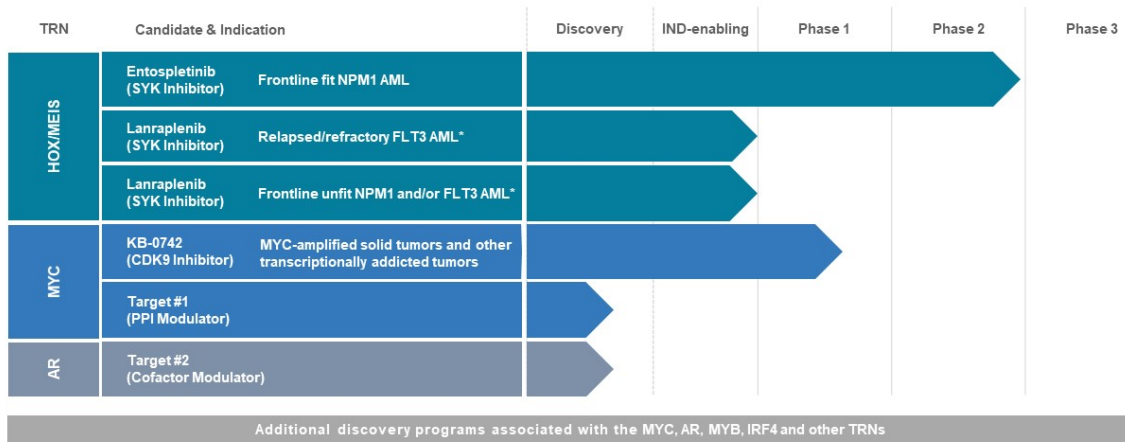
Overview

We are a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel cancer therapeutics designed to transform patient outcomes through a precision medicine strategy by targeting dysregulated transcription. Our proprietary product engine focuses on dysregulated transcription factors and the transcriptional regulatory networks (TRNs) that drive their oncogenic activity.

Our lead product candidate, entospletinib (ENTO), which we acquired from Gilead Sciences (Gilead) in July 2020, is an orally administered, selective SYK inhibitor that has been tested in more than 200 AML patients. Our expertise in TRN biology allowed us to recognize SYK as a critical node in the HOX/MEIS TRN, and this acquisition accelerated our pipeline to late clinical stage. Based on clinical results in a biomarker-defined subset of patients and based on the discussion and guidance from our End-of-Phase 2 meeting with the FDA, we intend to proceed as planned with our registrational Phase 3 clinical trial of ENTO using measurable residual disease (MRD) negative complete response (CR) as the primary endpoint in support of accelerated approval. We plan to initiate our Phase 3 clinical trial in the fourth quarter of 2021, and expect to report results in the second half of 2023. We plan to have similar interactions regarding use of this surrogate primary endpoint with the European Medicines Agency later in 2021. In addition, we are developing KB-0742, which is designed to be an orally bioavailable inhibitor of CDK9 with a differentiated selectivity profile, for the treatment of MYC-amplified solid tumors. The FDA cleared our IND for KB-0742 in December 2020. In February 2021, the first patient was dosed in our Phase 1/2 clinical trial of KB-0742 in patients with advanced solid tumors. We plan to report interim data from the dose escalation stage of this trial in the fourth quarter of 2021, with an initial data read-out from the expansion cohorts of the trial anticipated in 2022. Additionally, we plan to initiate two separate Phase 1/2 clinical trials for lanraplenib (LANRA). We plan to initiate the first of these trials, studying LANRA in combination with gilteritinib in patients with relapsed/refractory FLT3-mutated AML in the first quarter of 2022, with an initial safety and dose selection data readout anticipated in the second half of 2022. We plan to initiate the second of these trials, studying LANRA in combination with venetoclax/azacitidine in patients with newly-diagnosed NPM1-mutated, MLL-r and/or FLT3-mutated AML who are older than 75 years old or are not eligible for intensive induction chemotherapy in the first half of 2022, with an initial data readout anticipated in the first half of 2023. In addition, we are leveraging our product engine to drive multiple oncology discovery programs targeting dysregulated transcription factors and their associated TRNs.

The following chart summarizes the current stages of our development programs including our lead product candidate, ENTO, as well as LANRA and KB-0742, and our next anticipated milestones.

Advancing a robust pipeline of targeted oncology programs



*IND filed

We also are executing on robust discovery programs across multiple TRNs, which focus on cancer types where dysregulated transcription plays a central role, including hematologic malignancies, prostate cancer, and MYC-driven cancers. We have identified two discovery programs to advance in our preclinical pipeline, targeting the MYC and AR TRNs. The MYC program is aimed at modulating a protein-protein interaction in the MYC TRN with the objective of treating additional MYC-dysregulated cancers beyond those targeted by KB-0742. The AR program aims to overcome resistance to current therapies by targeting an AR cofactor that selectively modulates the AR TRN in the context of castration resistant prostate cancer. We anticipate submitting an IND for a drug candidate arising from one of our discovery programs in 2023, although we may not be successful in identifying product candidates that can selectively modulate the specific oncogenic TRNs associated with such programs.

The current COVID-19 pandemic has presented substantial public health and economic challenges around the world. We cannot at this time predict the specific extent, duration or impact that COVID-19 will have on our financial condition and operations, including ongoing research activities, ongoing and planned clinical trials and our financial results. While we are currently continuing to prepare to initiate clinical trials in the fourth quarter of 2021 and in 2022, COVID-19 precautions may directly or indirectly impact their timelines and interrupt clinical enrollment, and our clinical trial partners continue to experience COVID-19-related staffing challenges that may continue to impact our ongoing activities.

Since inception, we have had 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 \$33.6 million and \$39.7 million for the three months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$200.7 million. As of September 30, 2021, we had \$398.4 million of cash, cash equivalents and investments. In October 2020, we completed an initial public offering (IPO) of our common stock. As a result of the IPO, we received approximately \$263.7 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and, to a lesser extent, general and administrative expenditures. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase.

Strategic Agreements

Gilead Asset Purchase Agreement

In July 2020, we entered into an asset purchase agreement with Gilead (Gilead Asset Purchase Agreement), pursuant to which we acquired certain assets from Gilead related to ENTO and LANRA, and patents and other intellectual property covering or related to the development, manufacture and commercialization of ENTO and LANRA.

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 to Gilead (Gilead Note). 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 ENTO, LANRA 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 ENTO or LANRA (Other Compounds). Upon initiation of our planned registrational Phase 3 clinical trial of ENTO in combination with intensive chemotherapy (IC) in AML patients with NPM1 mutations, we will be required to pay a milestone to Gilead of \$29.0 million, and upon successful completion of certain other regulatory milestones in the United States, European Union and United Kingdom for ENTO, LANRA 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 ENTO, LANRA 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 the very low-teens to high-teens on annual worldwide net sales of ENTO, (ii) tiered marginal royalties ranging from high-single digits to the mid-teens on annual worldwide net sales of LANRA 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 ENTO and LANRA, for any royalties paid for future licenses of third party intellectual property required to develop or commercialize ENTO or LANRA. 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 ENTO or LANRA.

Harvard License Agreement

In January 2018, we entered into a license agreement with President and Fellows of Harvard College (Harvard), pursuant to which Harvard granted us a non-exclusive, worldwide, royalty-free license to certain intellectual property for the purpose of commercializing products relating to our SMM platform. We paid a one-time license fee in the amount of \$10,000 on the date of the agreement and an annual license maintenance fee of \$20,000 on each of the first two anniversaries. We are required to pay \$25,000 on each subsequent anniversary until the last to expire of any valid claim included in the licensed patents.

Components of Our Results of Operations

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 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, expense 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, particularly in light of the current COVID-19 pandemic environment;
- 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, particularly in light of the current COVID-19 pandemic environment;
- the expense of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights; 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 that our research and development expenses will continue to increase substantially 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 that our general and administrative expenses will continue to increase substantially for the foreseeable future as we continue to increase our general and administrative personnel headcount to support personnel in research and development, and to support our operations generally as we increase our research and development activities and activities related to the potential commercialization of our product candidates. We also expect to continue to incur significant 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, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Change
	2021	2020	
	(in thousands)		
Operating expenses:			
Research and development	\$ 24,688	\$ 16,755	\$ 7,933
General and administrative	8,985	4,054	4,931
Total operating expenses	33,673	20,809	12,864
Loss from operations	(33,673)	(20,809)	(12,864)
Other income (expense), net:			
Change in fair value on convertible notes payable	—	(15,215)	15,215
Interest expense	—	(3,889)	3,889
Interest and other income, net	70	200	(130)
Total other income (expense), net	70	(18,904)	18,974
Net loss	\$ (33,603)	\$ (39,713)	\$ 6,110

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Change
	2021	2020	
	(in thousands)		
Direct Costs	\$ 12,196	\$ 12,292	\$ (96)
Indirect Costs:			
Personnel	8,229	2,592	5,637
Facilities, depreciation and other expenses	4,263	1,871	2,392
Total research and development expenses	\$ 24,688	\$ 16,755	\$ 7,933

Research and development expenses were \$24.7 million for the three months ended September 30, 2021, compared to \$16.8 million for the three months ended September 30, 2020. The increase of \$7.9 million was primarily due to an increase of \$5.6 million in personnel costs primarily attributable to increased research and development personnel headcount, including an increase in stock-based compensation of \$3.3 million. Also contributing to this increase in research and development expenses is an increase of \$2.4 million in facilities, depreciation and other expenses primarily attributable to our Cambridge facility lease, and an increase of \$0.3 million in lab supplies related to increased development activity in connection with our preclinical product candidates. These increases were partially offset by a decrease of \$0.3 million in outside and consulting research expenses.

General and Administrative Expenses

General and administrative expenses were \$9.0 million for the three months ended September 30, 2021 compared to \$4.1 million for the three months ended September 30, 2020. The increase of \$4.9 million was primarily due to an increase in stock-based compensation of \$2.6 million and an increase of \$0.7 million in personnel costs, primarily attributable to increased general and administrative personnel headcount to support the growth of our research and development organization. Also contributing to this increase in general and administrative expenses is an increase of \$1.5 million in professional fees primarily attributable to insurance and other professional services.

Interest and Other Income, Net

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

Comparison of nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Change
	2021	2020	
	(in thousands)		
Operating expenses:			
Research and development	\$ 62,084	\$ 30,125	\$ 31,959
General and administrative	26,908	6,831	20,077
Total operating expenses	88,992	36,956	52,036
Loss from operations	(88,992)	(36,956)	(52,036)
Other income (expense), net:			
Interest expense	—	(3,890)	3,890
Interest and other income, net	248	774	(526)
Total other income (expense), net	248	(18,331)	18,579
Net loss	\$ (88,744)	\$ (55,287)	\$ (33,457)

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Change
	2021	2020	
	(in thousands)		
Direct Costs	\$ 30,403	\$ 18,498	\$ 11,905
Indirect Costs:			
Personnel	22,105	6,726	15,379
Facilities, depreciation and other expenses	9,575	4,901	4,674
Total research and development expenses	\$ 62,084	\$ 30,125	\$ 31,959

Research and development expenses were \$62.1 million for the nine months ended September 30, 2021, compared to \$30.1 million for the nine months ended September 30, 2020. The increase of \$32.0 million was primarily due to an increase of \$6.4 million in personnel costs and an increase in stock-based compensation of \$9.0 million, both of which are primarily attributable to increased research and development personnel headcount. Also contributing to this increase in research and development expenses is an increase of \$10.9 million in outside and consulting research expenses, an increase of \$4.7 million in facilities, depreciation and other expenses primarily attributable to the commencement of the lease for our new Cambridge facility in March 2020, and an increase of \$1.0 million in lab supplies related to increased development activity in connection with our preclinical product candidates.

General and Administrative Expenses

General and administrative expenses were \$26.9 million for the nine months ended September 30, 2021 compared to \$6.8 million for the nine months ended September 30, 2020. The increase of \$20.1 million was primarily due to an increase in stock-based compensation of \$8.1 million and an increase of \$3.3 million in personnel costs, primarily attributable to increased general and administrative personnel headcount to support the growth of our research and development organization. Also contributing to this increase in general and administrative expenses is an increase of \$6.5 million in professional fees, primarily attributable to legal and outside consultant costs, an increase of \$1.2 million in facilities, depreciation and other expenses primarily attributable to the San Mateo facility, and an increase of \$1.0 million in other expenses primarily attributable to increases in taxes and filing fees, facility costs, and information technology related services.

Interest and Other Income, Net

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

Liquidity, Capital Resources and Plan of Operations

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, 2021, we had cash, cash equivalents and investments of \$398.4 million. We expect that our cash, cash equivalents and investments as of September 30, 2021, will enable us to fund our planned operating expenses and capital expenditure requirements for at least one year from the date of this report.

Future Funding Requirements

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to ENTO, LANRA and KB-0742, and our other research efforts, 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.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
	(unaudited)	
	(in thousands)	
Cash used in operating activities	\$ (59,402)	\$ (22,282)
Cash used in (provided by) investing activities	24,975	(1,480)
Cash provided by financing activities	3,410	149,414
Net decrease in cash and cash equivalents	\$ (31,017)	\$ 125,652

Operating Activities

During the nine months ended September 30, 2021, cash used in operating activities was \$59.4 million, which was primarily attributable to our net loss of \$88.7 million, partially offset by non-cash charges of \$25.1 million. The non-cash charges primarily consisted of \$18.8 million in stock-based compensation, net amortization and accretion of investment securities of \$3.2 million, noncash lease expense of \$1.5 million, and depreciation and amortization of \$1.4 million.

During the nine months ended September 30, 2020, cash used in operating activities was \$22.3 million, which was primarily attributable to our net loss of \$55.3 million, partially offset by non-cash charges of \$27.1 million and cash provided by changes in our operating assets and liabilities of \$5.9 million. Net cash provided by changes in our operating assets and liabilities of \$5.9 million during the nine months ended September 30, 2020 consisted of a net increase of \$6.2 million in operating liabilities, offset by a \$0.3 million increase in operating assets.

Investing Activities

During the nine months ended September 30, 2021, cash provided by investing activities was \$25.0 million, consisting of \$175.3 million in maturities of marketable securities and \$17.0 million in sales of marketable securities partially offset by \$163.6 million in purchases of marketable securities and \$3.8 million for the purchase of property and equipment.

During the nine months ended September 30, 2020, cash used in investing activities was \$1.5 million, consisting of \$45.6 million in investment maturities, partially offset by \$41.2 million of net investment purchases and \$5.9 million for the purchase of property and equipment.

Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was \$3.4 million, consisting primarily of proceeds from the exercise of stock options and issuance of common stock under the employee stock purchase plan of \$2.6 million and \$0.8 million, respectively.

Net cash provided by financing activities during the nine months ended September 30, 2020 was \$149.4 million, consisting primarily of \$151.3 million of proceeds from the issuance of convertible notes, net of issuance costs, partially offset by \$2.2 million of payments of deferred offering costs.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2020:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations ⁽¹⁾	\$ 50,401	\$ 4,764	\$ 9,722	\$ 9,885	\$ 26,030
Finance lease obligations	6	6	—	—	—
Total	\$ 50,407	\$ 4,770	\$ 9,722	\$ 9,885	\$ 26,030

(1) Represents payments due for our lease of office space in San Mateo, California and Cambridge, Massachusetts, as of December 31, 2020.

In February 2021, we entered into a new lease agreement for our office space in San Mateo, California, in order to move from our former suites, totaling 8,075 square-feet, to a single, larger suite totaling 17,340 square-feet, and relocated in the third quarter of 2021. We accounted for this change in lease term of the original suites as a modification of the originally amended lease. Refer to Note 12 for further discussion on the accounting implications of the lease substitution.

The initial annual base rent for the new suite is \$1.2 million, and such amount will increase by 3% annually on each anniversary of the new premises commencement date. In connection with the larger space leased, we have also made an additional one-time cash security deposit in the amount of \$59,000. The new lease commenced in April 2021 while tenant improvements were being made and the new lease agreement extends the termination date from April 30, 2025 to 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. We have not included future payments under this agreement in the table above since 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.

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 and, as a result, are not included in the table of contractual obligations above. Payments due upon termination generally consist only of payments for services provided and expenses incurred up to the date of termination.

Critical Accounting Policies and Use of Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our unaudited condensed financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited 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 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results could differ from our estimates.

We believe that there have been no significant changes in our critical accounting policies and estimates from those described under the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2020.

JOBS Act Accounting Election

We are an “emerging growth company” as defined in the JOBS Act, and we will remain an emerging growth company until December 31, 2021. We will cease to be an “emerging growth company” effective December 31, 2021, because the aggregate market value of our common stock held by non-affiliates exceeded \$700 million as of June 30, 2021.

Under the JOBS Act, emerging growth companies can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is provided in Note 2 to our condensed financial statements included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risk related to changes in interest rates of our investment portfolio of cash equivalents, short-term investments, and long-term investments. As of September 30, 2021, our cash equivalents and short-term investments consisted of money market funds, certificates of deposit, corporate bonds, and U.S. Treasury securities. As of December 31, 2020, our cash equivalents and short-term investments consisted of money market funds, certificates of deposit, corporate bonds, U.S. Treasury securities, and U.S. Agency securities that have contractual maturities of less than one year. As of September 30, 2021, our long-term investments consisted of investments in U.S. Treasury securities and corporate bonds that have contractual maturities of greater than one year. As of December 31, 2020, our long-term investments consisted of investments in U.S. Treasury securities, U.S. agency securities, and corporate bonds that have contractual maturities of greater than one year. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates, including changes resulting from the impact of the COVID-19 pandemic. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. If a 100 basis point increase or decrease in interest rates were to have occurred on September 30, 2021, this change would not have had a material impact on our condensed financial statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

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. 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 financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 100 basis point increase or decrease in exchange rates at September 30, 2021 would not have had a material effect on our condensed financial statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our condensed financial statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

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, 2021, 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, we expect to incur significant losses over the next several years, and we will need substantial additional funding, before we achieve profitability, if at all.
- 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 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 likelihood of obtaining regulatory approval.
- Drug development involves a lengthy and expensive process with uncertain outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results.
- We may be required by the FDA or corresponding 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.
- We plan to attempt to secure approval for ENTO and possibly other of our product candidates from FDA or comparable regulatory authorities through the use of accelerated approval pathways, which is uncertain, and which, if granted, could require us to conduct additional, potentially lengthy and expensive, clinical trials, which, if not successful, could potentially result in our loss of marketing approval.
- The COVID-19 pandemic could adversely impact our business, including our ongoing and planned clinical trials.
- 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 improve upon our product engine to expand our pipeline of product candidates with commercial value.
- If the market opportunities for our product candidates are smaller than we estimate or if any regulatory approval we obtain is based on a narrower definition of the patient population than what we had sought to treat, or if patient access to the approved therapy is limited, our revenue potential and ability to achieve profitability will be adversely affected.
- 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 and contract research organizations to conduct certain aspects of our preclinical studies and ongoing and planned clinical trials.
- 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 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, 2020, as filed with the Commission on March 23, 2021.*

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 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 and nine months ended September 30, 2021 and 2020, we reported net losses of \$33.6 million, \$39.7 million, \$88.7 million and \$55.3 million, respectively. As of September 30, 2021, we had an accumulated deficit of \$200.7 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 the ongoing COVID-19 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;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

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 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. ENTO and LANRA, which we acquired from Gilead in July 2020, 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 IC and 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 (cGMP);

- 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 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, the duration and severity of the COVID-19 pandemic and its impact on the economy and financial markets in general could adversely affect 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 and preclinical development programs or any future commercialization efforts.

We had cash, cash equivalents, and investments of \$398.4 million as of September 30, 2021. We believe that, based upon our current operating plan, our existing capital resources will be sufficient to fund our anticipated operations into 2024, including through the readout of the primary endpoint of our planned registrational Phase 3 clinical trial of ENTO in combination with IC in AML patients with NPM1 mutations and the completion of our Phase 1/2 clinical trial of KB-0742 for the treatment of advanced solid tumors, and the completion of our two planned Phase 1/2 clinical trials of LANRA in genetically-defined subsets of AML patients. 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 the COVID-19 pandemic. In any event, our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our planned registrational Phase 3 clinical trial of ENTO in combination with IC for the treatment of AML patients with NPM1 mutations;
- the scope, progress, results and costs of our Phase 1/2 clinical trial of KB-0742;
- the scope, progress, results and costs of our two planned Phase 1/2 clinical trials of LANRA;
- 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 planned 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.

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 ENTO and LANRA 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, including the risks and uncertainties related to the evolving effects of the COVID-19 pandemic and those described herein. 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 our ongoing or planned clinical trials of our product candidates, including our ongoing Phase 1/2 clinical trial of KB-0742, our only internally generated product candidate, or our planned registrational Phase 3 clinical trial of ENTO or our two planned Phase 1/2 clinical trials of LANRA will begin or 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 ENTO and LANRA, that we acquired from Gilead in July 2020, and it is possible that we will encounter challenges with integrating the data and technology, along with the related regulatory materials, related to these acquired product candidates into our business. In such event, our clinical development plans related to the acquired SYK product candidates, including our planned registrational Phase 3 clinical trial of ENTO in combination with IC in AML patients with NPM1 mutations, our two planned Phase 1/2 clinical trials of LANRA in genetically-defined subsets of AML patients, or the associated or subsequent regulatory filings, could be delayed or otherwise adversely affected.

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 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 ENTO and LANRA 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, and 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, 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 is 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 ENTO or our other 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. In addition, there can be no assurance that the encouraging safety and efficacy data observed in the Phase 1b/2 clinical trial of ENTO in 148 AML patients, which was conducted by Gilead, will be indicative of the safety or efficacy results that we will observe in our planned registrational Phase 3 clinical trial of ENTO in combination with IC in AML patients with NPM1 mutations.

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 made 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.

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 ENTO or of any other 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 become effective 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 otherwise resulting from the evolving effects of the COVID-19 pandemic;
- 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 a health epidemic or pandemic, such as the COVID-19 pandemic;
- 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 the COVID-19 pandemic, 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. With respect to our planned registrational trial of ENTO in patients with NPM1 mutated AML, following our discussions with FDA as part of our End-of-Phase 2 meeting, we plan to use measurable residual disease (MRD) negative CR as the primary endpoint in support of accelerated approval. MRD has only recently emerged as a surrogate endpoint for progression free survival in hematological malignancies, and while regulatory approvals on the basis of MRD status have been granted in acute lymphocytic leukemia and chronic lymphocytic leukemia (CLL), to date there have not been any regulatory approvals on the basis of MRD status in AML. We are proceeding with our randomized, double-blinded, placebo-controlled registrational Phase 3 clinical trial of ENTO in combination with intensive chemotherapy (IC) in approximately 180 newly diagnosed NPM1-mutated AML patients. We intend to complete the validation of the assay necessary to meet regulatory requirements for a companion diagnostic in parallel with the conduct of the clinical trial. Patients will be randomized to receive standard of care IC in combination with twice-daily ENTO or a placebo. MRD will be assessed in patients who achieve a complete response (CR) after two cycles of chemotherapy. Patients who achieve CR, CR with partial hematological recovery (CRh) or CR without count recovery (CRi) may go on to receive consolidation therapy and undergo follow-up assessment for event-free, relapse-free and overall survival. MRD negative CR in the intent-to-treat population is the proposed primary endpoint for accelerated approval. This planned trial may not enable an expeditious path to regulatory approval in newly diagnosed AML patients with NPM1 mutations and may not be accepted by the FDA or otherwise be sufficient to obtain regulatory approval, which could result in a longer time to potential commercialization of ENTO in the United States, if approved and commercialized at all, and could increase the costs of development and could harm our competitive position in the marketplace. In addition, even if we proceed with our planned Phase 3 clinical trial using MRD negative CR as a surrogate endpoint and were to obtain accelerated approval, failure of the industry to adopt MRD negative CR rate as a valid or meaningful endpoint for an AML therapeutic may adversely impact our commercial prospects as a result of our clinical trial results being discounted or disregarded by industry professionals.

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.

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 ENTO or our other 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 prevented.*

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 have initiated a Phase 1/2 clinical trial of KB-0742 in cancer patients to evaluate its safety, PK and PD across multiple dose levels and dosing schedules. Following identification of a recommended Phase 2 clinical trial dose and schedule, we intend to enroll expansion cohorts in one or more biomarker-defined patient populations with transcriptionally addicted cancers, beginning with MYC-amplified solid tumors independent of histology. However, if the safety, PK or PD data from the first stage of the clinical trial suggest our initial doses are suboptimal, this could delay or preclude initiation of the expansion cohorts. We may also seek to enroll an additional cohort of soft tissue sarcoma patients with transcription factor fusions and patients with chordoma, an incurable solid tumor addicted to the brachyury transcription factor, in order to further demonstrate proof of concept for KB-0742. While we believe it is feasible to enroll such patients at major academic centers, 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 additional cohort, which could adversely affect our development and registration strategy for KB-0742.

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 during the ongoing COVID-19 pandemic and other delays and complications resulting from the evolving effects of the COVID-19 pandemic.

Our inability to enroll the required number of patients for our 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.*

As is the case with pharmaceuticals generally, side effects and adverse events (AEs) associated with ENTO have been observed. In ENTO's first clinical trial in healthy volunteers and subjects with rheumatoid arthritis (RA), the most frequently reported AEs were headache, nausea and constipation without any clear relationship to dose level. Mildly increased liver enzymes were observed in some healthy subjects and patients with RA. In a clinical trial of ENTO in more than 700 patients with hematologic malignancies, predominantly with B cell malignancies such as CLL, the most frequently reported treatment-related AEs, with an incidence greater than 10% in CLL patients, were fatigue, nausea, diarrhea, headache, decreased appetite and fever. AEs of Grade 3 or greater in at least 5% of patients included neutropenia, elevated liver enzymes and electrolyte abnormalities. ENTO has also been tested in a Phase 1b/2 clinical trial in 148 AML patients. Early ENTO safety studies were conducted in relapsed patients as monotherapy and in combination with IC and in newly diagnosed elderly patients in combination with HMAs such as azacytidine or decitabine. Aside from the AEs typical of the disease and IC, such as cytopenias and fever, the main AEs attributable to ENTO included diarrhea, nausea, and febrile neutropenia. Results of our ongoing or planned clinical trials, including those for ENTO, LANRA 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 ENTO, LANRA 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, ENTO or any other 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 and, or, monitor patients in clinical trials. For example, we plan to use a biomarker-based test to identify patients for enrollment in our planned registrational Phase 3 clinical trial of ENTO in combination with IC for the treatment of AML patients with NPM1 mutations. 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 ENTO for the treatment of AML patients with NPM1 mutations and LANRA for the treatment of AML patients with NPM1 and/or 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.

The COVID-19 pandemic could adversely impact our business, including our ongoing or planned clinical trials.*

The COVID-19 pandemic in the United States and in other countries in which we have ongoing and planned clinical trials and where our current or future third party manufacturers or supply chain vendors operate, could cause significant disruptions that could severely impact our business and our planned clinical trials, including:

- delays or difficulties in screening and enrolling patients in our ongoing and planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- inability or unwillingness of subjects to travel to the clinical trial sites;
- delays or difficulties in data collection and analysis and other related activities;
- decreased implementation of protocol-required clinical trial activities and quality of source data verification at clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials and our other research and development activities, including because of sickness of employees or their families or mitigation measures such as lock-downs and social distancing;

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, delays, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA or foreign regulatory authorities to accept data from clinical trials in affected geographies; and
- adverse impacts on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise additional capital when needed.

Such disruptions could impede, delay, limit or prevent completion of our preclinical studies or commencement or the continuation of planned or other future clinical trials and ultimately lead to the delay or denial of regulatory approval of our product candidates, which would seriously harm our operations and financial condition and increase our costs and expenses. In addition, we also experienced delays in our discovery and development activities as a result of the COVID-19 pandemic, primarily due to temporary and partial shutdowns at certain of our CROs that have since resumed normal operations, and due to the previous California and Massachusetts stay-at-home orders where our operations are located. Future or revised stay-at-home orders could result in additional delays or otherwise negatively impact our discovery and development activities. The COVID-19 pandemic could also affect the business of the FDA or other health authorities which could result in delays in meetings related to our ongoing and planned clinical trials and ultimately of reviews and approvals of our product candidates. Moreover, to the extent the evolving effects of the COVID-19 pandemic adversely affect our business and financial condition, they may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic may impact our business, preclinical development activities and ongoing and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 an 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.*

Other than our ongoing Phase 1/2 clinical trial of KB-0742, which we initiated in January of 2021, 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 planned clinical trials will begin or be completed on time, or at all. In addition, the ongoing COVID-19 pandemic may create additional challenges in initiating, enrolling or conducting such clinical trials. Moreover, we currently do not have complete in-house resources to enable our operations, including our planned clinical trials, and we may not be able to hire sufficient qualified personnel to support our planned clinical trials.

In addition, large-scale clinical trials require significant financial and management resources and reliance on third-party clinical investigators, CROs and consultants. Relying on third-party clinical investigators, CROs 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 and consultants on a timely basis, or at all.

Because of the relatively small patient population that is planned to be dosed in our Phase 1/2 trial of KB-0742, the results from such clinical trial, 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 this product candidate.

In our Phase 1/2 clinical trial of KB-0742, we plan to evaluate the safety, PK and PD profile of KB-0742 in patients with advanced solid tumors, and define an optimal dose and schedule for expansion cohorts in cancer patients with MYC-amplified solid tumors and other transcriptionally addicted cancers. The number of patients we expect to enroll in this clinical trial is to 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, 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, 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 ENTO and our other 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. Although we are proceeding with our randomized, double-blinded, placebo-controlled registrational Phase 3 clinical trial of ENTO in combination with IC in approximately 180 newly diagnosed NPM1-mutated AML patients, 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, market access or distribution capabilities and have no experience as a company in marketing products. We currently intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing 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, 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. 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.

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.

There are a large number of pharmaceutical and biotechnology companies developing or marketing targeted treatments for cancer that would be competitive with the product candidates we are developing, if our product candidates are approved. Many of these companies are developing cancer therapeutics that are also kinase inhibitors.

If we are successful in developing ENTO, our lead product candidate, or LANRA, our next-generation SYK inhibitor, they may compete against product candidates that are currently in clinical development to the extent any such candidates are approved, 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, which, if approved, could compete with ENTO or LANRA, including (a) 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; (b) KO-539, being developed by Kura Oncology, Inc. in a Phase 1 clinical trial as monotherapy in relapsed or refractory AML, (c) DS-1594, being developed by Daiichi Sankyo Company in a Phase 1 clinical trial with or without azacitidine/venetoclax in relapsed/refractory AML, and (d) JNJ-75276617, being developed by Janssen Research & Development, LLC in a Phase 1 clinical trial in acute leukemias; and (iii) product candidates that may compete with ENTO or LANRA by addressing 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) CPX-351, a liposomal formulation of daunorubicin and cytarabine being developed by Jazz Pharmaceuticals, and (c) CC-90009, a cereblon E3 ligase modulator being developed by Bristol-Myers Squibb.

If we are successful in developing KB-0742, it may compete against various multi-CDK inhibitors that are currently in early-stage clinical development, including: AZD4573, being developed by AstraZeneca; TP-1287 (Alvociclib), being developed by Tolero Pharmaceuticals; fadraciclib (CYC-065), being developed by Cyclacel Pharmaceuticals; Zotiraciclib, being developed by the National Cancer Institute; Dinaciclib, being developed by Merck & Co.; and Voruciclib, being developed by MEI Pharma. We also expect it to compete against VIP152, a PTEFb/CDK9 inhibitor in early-stage clinical development by Vincerx Pharma, Inc., and PRT2527, a CDK9 inhibitor in preclinical development by Prelude Therapeutics.

We also expect that our product candidates, if approved, will compete with more established therapies, such as IC 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 are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing and selling approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors 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 any competitive generic products. The key competitive factors affecting the success of ENTO are likely to be its efficacy, safety, scope and limitations of marketing approval, and availability of reimbursement.

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 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 may in the future choose to conduct one or more 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 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, in March 2020 the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities and products and in July 2020 resumed certain on-site inspections of manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA 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 plan to attempt to secure approval for ENTO and possibly other of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways, which is uncertain. 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 plan to seek accelerated approval for ENTO and may in the future seek an accelerated approval for one or more of our other product candidates. Under the accelerated approval program, 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 existing trials to capture additional endpoints to verify and describe the drug's clinical benefit. 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. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how 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 through 2030 unless additional congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration’s proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021.

As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation interim final rule. In July 2021, the Biden administration release 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 release a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in 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. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives. 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 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; fines and penalties; a disruption of our business operations; reputational harm; and other adverse business impacts.*

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of sensitive information, including confidential business, personal and patient health information 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 information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. We are also subject to internal and external privacy

and security policies, contracts and other obligations 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. Failure, or perceived failure, by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws, regulations or other obligations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws, to which we are or may become subject. Each of these laws is subject to varying interpretations and the legislative landscape is constantly evolving. 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 information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information 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 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. The HHS has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. 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.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect. For example, in June 2018 the State of California enacted the California Consumer Privacy Act of 2018 (CCPA), which went into effect on January 1, 2020 and requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, and allow consumers to opt out of certain data sharing with third parties. The CCPA also provides for civil penalties for violations (up to \$7,500 per violation), as well as a private right of action for certain data breaches that is expected to increase data breach litigation. Moreover, although the CCPA includes limited exceptions from its prescriptions, including exceptions for personal health information collected by covered entities or business associates subject to HIPAA, among others, the CCPA may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. Additionally, a new ballot initiative, the California Privacy Rights Act or, the CPRA, passed in November 2020 in California. The CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, and opt outs for certain uses of sensitive data. It creates a new California data protection agency to enforce the law, and require certain businesses with higher risk privacy and security practices to submit annual audits to the agency on a regular basis. The CPRA may result in broader increased regulatory scrutiny of California for businesses' privacy and security practices, and could lead to a further rise in data protection litigation. The majority of CPRA provisions go into effect in January 2023, and may require additional compliance investment and potential business process changes in the meantime.

Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S. Indeed, other states have enacted or proposed data privacy laws, which could require us to expend significant resources or change our business practices in an effort to comply, increase our potential liability or otherwise adversely affect our business. For example, Virginia recently passed its Consumer Data Protection Act and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and will go into effect on January 1, 2023 and July 1, 2023, respectively. Additionally, Massachusetts and Nevada

have adopted laws requiring the implementation of certain security measures to protect personal information, and all 50 states and the District of Columbia, Puerto Rico, the U.S. Virgin Islands and Guam have adopted breach notification laws. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy, security and data use issues in the U.S. continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to products and services could intensify.

In addition, in May 2018, the General Data Protection Regulation (GDPR), took effect in the European Economic Area (EEA). The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons, replacing data protection laws issued by each European Union (EU) member state based on the Directive 95/46/EC (Directive). Unlike the Directive, which needed to be transposed at a national level, the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. Among other things, the GDPR sets out extensive compliance requirements, including providing detailed disclosures about how personal data is collected and processed, demonstrating that an appropriate legal basis is in place or otherwise exists to justify data processing activities; granting new rights for data subjects in regard to their personal data, as well as enhancing pre-existing rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; complying with the principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit; and expanding the definition of personal data to include coded data and requiring changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators.

In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. Notably, these requirements will regulate the transfer of personal data from our clinical trial sites located in the EEA to jurisdictions outside of the EEA. One of the primary safeguards enabling U.S. companies to import personal information from Europe had been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, in July 2020, the Court of Justice of the EU, or the CJEU, invalidated the EU-U.S. Privacy shield. While the CJEU upheld the adequacy of the Standard Contractual Clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. Additionally, the European Commission issued new SCCs in June 2021 that repeal and replace the previous SCCs adopted under the Data Protection Directive. If we elect to rely on the new SCCs, we may be required to expend significant resources to update our contractual arrangements and to comply with such obligations. If we are unable to implement a valid compliance mechanism for cross-border personal information transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal information from Europe, which could limit our ability to conduct clinical trial activities in Europe. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom.

Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant

costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face regulatory investigations, private litigation, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations. Any inability to adequately address data privacy or information security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and information security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers, interrupt or stop our clinical trials, or otherwise have a material and adverse impact on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

The withdrawal of the United Kingdom from the European Union, commonly referred to as “Brexit,” may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period that ended December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact on the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, and a separate marketing authorization will be required to market our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency, or MHRA, in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive.

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

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 wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. 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 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 ENTO and LANRA, pursuant to the Gilead Asset Purchase Agreement. We also have a non-exclusive worldwide right to certain patents under a license agreement with Harvard University that provides us with rights to use the SMM screen, which is a key component of our product engine. These agreements impose 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. 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 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 and third-party 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. Pursuant to the Gilead Asset Purchase Agreement, Gilead is responsible for certain ongoing clinical trials of ENTO.

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 have also had a significant impact on our CROs, and they have in the past faced disruptions and in the future may face further disruption 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.

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 ENTO and LANRA from Gilead under the Gilead Asset Purchase Agreement, we will need to obtain further supplies of APIs and clinical drug supply for ENTO, KB-0742 and LANRA, from third-party manufacturers. We do not currently have arrangements in place for redundant supply for APIs or our clinical product candidates. In addition, in the third quarter of 2020 we completed the transfer of the SYK technology we acquired from Gilead in July 2020, but we have not yet transferred the manufacturing technology for ENTO or LANRA to a third-party manufacturer. We will need to arrange for the manufacture of these product candidates for use in clinical trials.

We will need to negotiate and maintain contractual arrangements with outside vendors for the supply of our 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.

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.

We have grown rapidly and will need to continue to grow the size of our organization and expand our capabilities, and we may experience difficulties in managing this growth.*

As of September 30, 2021, we had 95 full-time employees. As of January 1, 2019, we had nine full-time employees and since then, we have expanded our executive and leadership team with the additions of our Chief Medical Officer and Executive Vice President, Clinical Development, our Chief Scientific Officer, our Chief Operating Officer and General Counsel, our Chief Financial Officer, our Senior Vice President, Pharmaceutical Development and Manufacturing and our Senior Vice President, Corporate Communications and Investor Relations. We expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, research science, clinical operations, manufacturing, regulatory affairs, and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, we are building a self-sufficient accounting and finance group within our company, and have relied and continue to rely on a third-party accounting consulting firm to augment our internal accounting and finance function. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel.

Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with building clinical development, manufacturing and internal accounting and finance infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. 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, we may not be able to successfully implement the tasks necessary to further develop and commercialize ENTO, LANRA, KB-0742, our other pipeline product candidates or any future product candidates and, accordingly, may not 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 is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, 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 customers or sales.*

We rely on information technology systems that we or our third-party vendors operate to process, transmit and store electronic information in our day-to-day operations. In addition, the affects of the COVID-19 pandemic have intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely and our increased reliance on personnel working from home could increase our cybersecurity risk. In connection with our discovery and development efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. While we have not, to our knowledge, experienced any significant system failure, accident, vulnerability, or security breach to date, a successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer “hackers,” threat actors, personnel misconduct or error (such as theft or misuse), sophisticated nation-state and nation-state-supported actors now engage in attacks. We may be subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), ransomware attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, 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. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure, or perceived failure, to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients’ personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct our ongoing and planned clinical trials and potentially disrupt our business. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

In addition, the information technology systems of various third parties on which we rely, including our CROs and other contractors, vendors, consultants and legal and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. 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. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

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 such as the COVID-19 pandemic, 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 legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief and Economic Security Act (CARES Act), 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. 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 over the past three years, 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. 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.

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

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, most recently due to the COVID-19 pandemic, including severely diminished liquidity and credit availability, 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, whether due to the evolving effects of the COVID-19 pandemic or otherwise, will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our 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 these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

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 pharmaceutical 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, such as the ongoing COVID-19 pandemic;
- 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.

We and our officers, directors, and holders of substantially all of our capital stock, stock options and other securities convertible into, exercisable or exchangeable for our capital stock outstanding immediately prior to the closing of our IPO previously agreed with the underwriters for our IPO, subject to certain exceptions, not to dispose of or hedge any of common stock or securities convertible into or exchangeable for shares of common stock for a period of 180 days following the date of the final prospectus for our IPO, except with the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Piper Sandler & Co. on behalf of the underwriters. We refer to such period as the lock-up period. When the lock-up period expired on April 7, 2021, we and our securityholders subject to a lock-up agreement or market stand-off agreement became able to sell our shares in the public market. Sales of a substantial number of such shares or the perception that such sales may occur could cause our market price to fall.

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. In addition, we have not yet completed the implementation of a risk management program and processes or procedures for identifying and addressing risks to our business in other areas.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.*

We are an “emerging growth company,” as defined in the JOBS Act, and will remain an emerging growth company until December 31, 2021. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We will cease to be an “emerging growth company” effective December 31, 2021, because the aggregate market value of our common stock held by non-affiliates exceeded \$700 million as of June 30, 2021.

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 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. We currently have four securities analysts and may never obtain additional research coverage by other securities and industry analysts. 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, and particularly after we are no longer an emerging growth 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.

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, 2021, we have not used any of the net proceeds from our IPO.

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. 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 6. EXHIBITS

Exhibit Number	Description Of Document
<u>3.1</u>	<u>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).</u>
<u>3.2</u>	<u>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).</u>
<u>4.1</u>	<u>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).</u>
<u>4.2</u>	<u>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).</u>
<u>31.1</u>	<u>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.</u>
<u>31.2</u>	<u>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.</u>
<u>32.1#</u>	<u>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.</u>
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).

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 9, 2021

By: /s/ Norbert Bischofberger

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

Date: November 9, 2021

By: /s/ Yasir Al-Wakeel

Yasir Al-Wakeel, BM BCh
Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)

**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)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

By: /s/ Norbert Bischofberger

Norbert Bischofberger, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

**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, Yasir Al-Wakeel, BM BCh, 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)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2021

By: /s/ Yasir Al-Wakeel

Yasir Al-Wakeel, BM BCh
Chief Financial Officer and Head of Corporate Development
(Principal Financial Officer and Principal Accounting Officer)

**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, 2021, 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, Yasir Al-Wakeel, BM BCh, 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 9, 2021

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

Date: November 9, 2021

By: /s/ Yasir Al-Wakeel
Yasir Al-Wakeel, BM BCh
Chief Financial Officer and Head of Corporate Development
(Principal Financial Officer and Principal Accounting Officer)