UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

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: 001-39460

KYMERA THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-2992166**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
500 North Beacon Street, 4th Floor Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 285-5300

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	KYMR	The Nasdaq Global Market

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

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

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

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

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

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

As of April 26, 2024, the registrant had 61,358,262 shares of common stock, $0.0001 par value per share, outstanding.

SUMMARY OF THE MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

•We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable.

•We have incurred significant operating losses in recent periods and anticipate that we will incur continued losses for the foreseeable future.

•We will need to raise substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or future commercialization efforts.

•We are very early in our development efforts and our IRAK4, STAT3 and MDM2 programs are still in early clinical development. If we are unable to advance them through the clinic for safety or efficacy reasons or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

•We cannot be certain of the timely completion or outcome of our preclinical testing, including our STAT6 and TYK2 programs. In addition, the results of preclinical studies may not be predictive of the results of clinical trials and the results of any early-stage clinical trials we commence may not be predictive of the results of later-stage clinical trials.

•Our approach to the discovery and development of product candidates based on our Pegasus™ platform is novel and unproven, which makes it difficult to predict the time, cost of development, and likelihood of successfully developing any products.

•Business interruptions resulting from any pandemic or similar public health crises could cause a disruption to our supply chain or the development of our product candidates and adversely impact our business.

•We may not be successful in our efforts to identify or discover additional product candidates or 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.

•If we experience delays or difficulties in the initiation or enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

•Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

•Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

•We rely, and expect to continue to rely, on third parties to conduct our ongoing and planned clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.

•If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, express or implied statements about:

- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and future clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to continue to construct Pegasus™, our drug discovery platform, and to enable a rational and effective drug discovery and development engine;
- the timing and the success of preclinical development efforts for STAT6 and TYK2 and clinical studies under our IRAK4, STAT3 and MDM2 programs;
- our plans to submit investigational new drug applications to the U.S. Food and Drug Administration, or FDA for current and future product candidates;
- the subsequent initiation of planned clinical trials;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop product candidates, including by applying learnings from one program to other programs and from one modality to our other modalities;
- our potential ability to manufacture our drug substances, delivery vehicles, and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business, product candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

•our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;

•the success of competing therapies that are or may become available;

•our ability to attract and retain key scientific or management personnel;

•the impact of laws and regulations;

•developments relating to our competitors and our industry;

•the effect of any pandemics, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials; and

•other risks and uncertainties, including those listed under the caption “Risk Factors.”

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

KYMERA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except for share and per share amounts)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 93,510	$ 109,966
Marketable securities (Note 4)	427,034	264,915
Accounts receivable	—	15,000
Contract assets	2,030	3,762
Prepaid expenses and other current assets	14,679	11,674
Total current assets	$ 537,253	$ 405,317
Marketable securities, non-current (Note 4)	224,390	61,434
Property and equipment, net (Note 6)	49,336	48,134
Right-of-use assets, operating leases	49,329	52,945
Other non-current assets	2,118	2,118
Restricted cash	5,825	5,811
Total assets	$ 868,251	$ 575,759
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,812	$ 7,075
Accrued expenses (Note 8)	15,997	33,864
Deferred revenue	22,613	37,883
Operating lease liabilities	8,757	5,068
Finance lease liabilities	1,133	1,277
Other current liabilities	824	524
Total current liabilities	$ 56,136	$ 85,691
Non-current liabilities		
Deferred revenue, net of current portion	23,781	16,768
Operating lease liabilities, net of current portion	75,975	77,028
Finance lease liabilities, net of current portion	1,156	1,301
Total liabilities	$ 157,048	$ 180,788
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 shares authorized at March 31, 2024 and December 31, 2023, 61,353,146 and 55,585,305 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	6	6
Additional paid-in capital	1,292,283	926,269
Accumulated deficit	(579,309)	(530,752)
Accumulated other comprehensive loss	(1,777)	(552)
Total stockholders' equity	711,203	394,971
Total liabilities and stockholders' equity	$ 868,251	$ 575,759

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

KYMERA THERAPEUTICS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Three months ended March 31, 2024 and 2023
(In thousands, except for share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Collaboration Revenue	$ 10,287	$ 9,466
Operating expenses:		
Research and development	$ 48,819	$ 42,227
General and administrative	14,374	12,565
Impairment of long-lived assets	4,925	—
Total operating expenses	68,118	54,792
Loss from operations	(57,831)	(45,326)
Other income (expense):		
Interest and other income	9,343	4,453
Interest and other expense	(69)	(55)
Total other income:	9,274	4,398
Net loss	$ (48,557)	$ (40,928)
Other comprehensive loss:		
Unrealized gain (loss) on marketable securities	(1,225)	1,911
Total comprehensive loss	$ (49,782)	$ (39,017)
Net loss	$ (48,557)	$ (40,928)
Net loss per share, basic and diluted	$ (0.69)	$ (0.70)
Weighted average common stock outstanding, basic and diluted	70,770,320	58,187,038

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

KYMERA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the three months ended March 31, 2024 and 2023
(In thousands, except for share amounts)
(Unaudited)

	Common Stock		Additional Paid in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Capital	Deficit	Gain/(Loss)	Equity
Balance at December 31, 2022	55,039,380	$ 6	$ 878,884	$ (383,790)	$ (4,949)	$ 490,151
Exercise of stock options	208,705	—	1,486	—	—	1,486
Vesting restricted stock	28,141	—	—	—	—	—
Stock-based compensation expense	—	—	9,385	—	—	9,385
Unrealized gain on marketable securities	—	—	—	—	1,911	1,911
Net Loss	—	—	—	(40,928)	—	(40,928)
Balance at March 31, 2023	55,276,226	$ 6	$ 889,755	$ (424,718)	$ (3,038)	$ 462,005
Balance at December 31, 2023	55,585,305	$ 6	$ 926,269	$ (530,752)	$ (552)	$ 394,971
Issuance of common stock and accompanying pre-funded warrants from public offering, net of issuance costs of $14.9 million	3,884,158	—	301,373	—	—	301,373
Issuance of common stock through at-the market sales agreement, net of issuance costs of $1.2 million	1,519,453	—	$ 48,740	—	—	48,740
Exercise of stock options	281,021	—	3,933	—	—	3,933
Vesting restricted stock	83,209	—	—	—	—	—
Stock-based compensation expense	—	—	11,968	—	—	11,968
Unrealized gain on marketable securities	—	—	—	—	(1,225)	(1,225)
Net loss	—	—	—	(48,557)	—	(48,557)
Balance at March 31, 2024	61,353,146	$ 6	$ 1,292,283	$ (579,309)	$ (1,777)	$ 711,203

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

KYMERA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
For the three months ended March 31, 2024 and 2023
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating activities		
Net loss	$ (48,557)	$ (40,928)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,968	9,385
Lease Impairment Charge	4,925	—
Depreciation and amortization	1,461	879
Premiums and discounts on available-for-sale marketable securities	(3,072)	(1,326)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,005)	(1,641)
Accounts Receivable	15,000	—
Contract asset	1,732	(783)
Accounts payable	75	2,217
Accrued expenses and other current liabilities	(15,394)	(10,037)
Deferred revenue	(8,257)	(6,145)
Operating lease right-of-use assets	619	1,138
Operating lease liabilities	2,636	2,915
Other assets and liabilities	278	358
Net cash used in operating activities	$ (39,591)	$ (43,968)
Investing activities		
Purchase of property and equipment, net	(7,402)	(4,009)
Purchases of investments	(422,704)	(61,835)
Maturities of investments	99,499	90,428
Net cash provided by investing activities	$ (330,607)	$ 24,584
Financing activities		
Proceeds from issuance of common stock and accompanying pre-funded warrants from public offering, net of underwriting discounts and issuance costs	301,373	—
Proceeds from issuance of common stock through at-the market sales agreement, net of issuance costs	48,740	—
Proceeds from stock option exercises	3,933	1,486
Payments on finance leases	(290)	(327)
Net cash provided by financing activities	$ 353,756	$ 1,159
Net increase in cash, cash equivalents and restricted cash	(16,442)	(18,225)
Cash, cash equivalents and restricted cash at beginning of period	115,777	74,524
Cash, cash equivalents and restricted cash at end of period	$ 99,335	$ 56,299
Supplemental disclosure of cash flow activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ -	$ 48,833
Cash paid for interest	49	52
Supplemental disclosure of noncash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ 1,205	$ 1,100

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of each of the periods shown above:

	March 31,	
	2024	**2023**
Cash and cash equivalents	$ 93,510	$ 50,152
Restricted cash	5,825	6,147
Total cash, cash equivalents, and restricted cash	$ 99,335	$ 56,299

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

1. Organization and Nature of Business

Kymera Therapeutics, Inc., together with its subsidiary Kymera Securities Corporation, is referred to on a consolidated basis as the “Company”. The Company is a biopharmaceutical company focused on discovering and developing small molecule therapeutics that selectively degrade disease-causing proteins by harnessing the body’s own natural cellular process, a method known as targeted protein degradation. The Company has devoted its efforts principally to research and development since formation. The Company has not yet completed product development, filed for or obtained regulatory approvals for any products, nor verified the market acceptance and demand for such products. As a result, the Company is subject to a number of risks common to emerging companies in the biotech industry. Principal among these risks are the uncertainties of the product discovery and development process, dependence on key individuals, development of the same or similar technological innovations by the Company’s competitors, protection of proprietary technology, compliance with government regulations and approval requirements, the Company’s ability to access capital and uncertainty of market acceptance of products.

The Company has historical net losses and anticipates that it will continue to incur losses for the foreseeable future and had an accumulated deficit of $579.3 million as of March 31, 2024. The Company has funded these losses principally through issuance of preferred stock, convertible notes, common stock, including its initial public offering and concurrent private placement completed in August 2020 (“IPO”), follow-on offering and concurrent private placement completed in July 2021 (“2021 Follow-on”) offering, August 2022 Private Investment in Public Equity (“PIPE”) offering, follow-on offering completed in January 2024 ("2024 Follow-on"), sales under our Sales agreement with Cowen, and from cash proceeds received in connection with the Company’s collaboration agreements with Vertex Pharmaceuticals Incorporated (“Vertex”) and Genzyme Corporation (“Sanofi”) (see Note 5). The Company expects to continue to incur operating losses and negative cash flows until such time as it generates a level of revenue that is sufficient to support its cost structure.

As of March 31, 2024, the Company had cash, cash equivalents and marketable securities of $744.9 million. The Company believes these cash, cash equivalents and marketable securities will be sufficient to fund its operations and capital expenditure requirements through at least twelve months from the issuance of these condensed consolidated financial statements.

The Company expects to finance the future research and development costs of its product portfolio with its existing cash, cash equivalents and marketable securities, or through strategic financing opportunities that could include, but are not limited to future offerings of its equity, collaboration agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical studies and clinical trials.

Private Investment in Public Equity “PIPE” offering

On August 18, 2022, the Company and certain accredited investors entered into a securities purchase agreement pursuant to which the Company agreed to sell and issue to such investors in a private placement (i) an aggregate of 2,769,228 shares of the Company’s common stock at a purchase price of $26.00 per share, and (ii) 3,000,000 pre-funded warrants to purchase common stock, at a purchase price of $25.9999 per Pre-Funded Warrant. The Pre-Funded Warrants will have an exercise price of $0.0001 per share of common stock. The offering closed on August 22, 2022, resulting in net proceeds of $149.8 million after offering expenses.

2024 Follow-on Public Offering

On January 9, 2024, the Company completed a follow-on offering of its common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase shares of its common stock. The Company issued and sold 3,884,158 shares of common stock, including full exercise of the underwriters’ over-allotment option to purchase an additional 1,633,663 shares, at a public offering price of $25.25 per share. Additionally, in lieu of common stock to certain investors, the Company issued and sold pre-funded warrants to purchase 8,640,594 shares of its common stock at a public offering price of $25.2499 per pre-funded warrant, which represents the per share public offering price of each share of common stock less the $0.0001 per share exercise price for each pre-funded warrant. The aggregate gross proceeds before deducting underwriting discounts and commissions, and other estimated offering expenses payable by the Company were approximately $316.2 million.

Pre-funded warrants

In connection with certain offerings mentioned above the Company has issued pre-funded warrants to purchase common stock in lieu of common stock. As the pre-funded warrants are indexed to the Company's common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the pre-funded warrants as additional paid-in capital on the Company's consolidated balance sheets. The pre-funded warrants are exercisable at any time. The holders of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to such exercise. The holders of Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

During the three months ended March 31, 2024, no pre-funded warrants were exercised. As of March 31, 2024, there were 11,640,594 pre-funded warrants outstanding.

2. Summary of Significant Accounting Policies

The accompanying condensed consolidated financial statements reflect the application of certain significant accounting policies as described in this note, and elsewhere in the accompanying condensed consolidated financial statements and notes.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary Kymera Securities Corporation. All intercompany transactions and balances have been eliminated in consolidation.

Basis of Presentation

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") as found in the Accounting Standards Codification ("ASC"), Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB") and the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K, filed with the SEC on February 22, 2024.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2023, and, in the opinion of management, reflect all adjustments necessary, all of which were normal and recurring, for the fair statement of the Company's financial position as of March 31, 2024, and the results of operations and cash flows for the three months ended March 31, 2024 and 2023. The results for the three months ended March 31, 2024 are not necessarily indicative of the results for the year ended December 31, 2024 or for any future period.

Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three months ended March 31, 2024 are consistent with those discussed in Note 2 to the consolidated financial statements in the 2023 Annual Report on Form 10-K.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of March 31, 2024 and December 31, 2023 (in thousands):

	Fair Value Measurements at March 31, 2024:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market fund	$ 50,248	$ —	$ —	$ 50,248
US treasuries	19,928	—	—	19,928
Corporate bonds	19,666	—	—	19,666
Marketable securities, current				
US treasuries	167,206	—	—	167,206
US government agencies	—	106,672	—	106,672
Corporate bonds	—	153,157	—	153,157
Marketable securities, non-current				
US treasuries	20,365	—	—	20,365
US government agencies	—	36,278	—	36,278
Corporate bonds	—	167,746	—	167,746
Restricted cash	5,825	—	—	5,825
Total	$ 283,238	$ 463,853	$ —	$ 747,091

	Fair Value Measurements at December 31, 2023:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market fund	$ 78,010	$ —	$ —	$ 78,010
US treasuries	27,985		—	27,985
Commercial Paper	997		—	997
Marketable securities, current				
US treasuries	23,253	—	—	23,253
US government agencies	—	114,384	—	114,384
Corporate bonds	—	127,278	—	127,278
Marketable securities, non-current				
US treasuries	—	—	—	-
US government agencies	—	28,307	—	28,307
Corporate bonds	—	33,127	—	33,127
Restricted cash	5,811	—	—	5,811
Total	$ 136,056	$ 303,096	$ —	$ 439,152

During the three months ended March 31, 2024 and the year ended December 31, 2023, there were no transfers in or out of Level 3.

4. Marketable Securities

The following tables summarize the available-for-sale debt securities held at March 31, 2024 and December 31, 2023 (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2024				
US treasury securities	$ 187,847	$ —	$ (277)	$ 187,570
US government agencies	143,361	12	(423)	142,950
Corporate securities	321,978	10	(1,084)	320,904
Total	$ 653,186	$ 22	$ (1,784)	$ 651,424

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2023				
US treasury securities	$ 23,361	$ 5	$ (113)	$ 23,253
US government agencies	142,948	48	(305)	142,691
Corporate securities	160,598	113	(306)	160,405
Total	$ 326,907	$ 166	$ (724)	$ 326,349

As of March 31, 2024, the Company held 113 securities that had been in an unrealized loss position for less than 12 months with an aggregate fair value of $467.4 million. As of December 31, 2023, the Company held 109 securities that had been in an unrealized loss position for less than 12 months with an aggregate fair value of $229.7 million. As of March 31, 2024, the Company held 39 securities that had been in an unrealized loss position for greater than 12 months with an aggregate fair value of $81.5 million. As of December 31, 2023, the Company held 16 securities that had been in an unrealized loss position for greater than 12 months with an aggregate fair value of $36.6 million.

As of March 31, 2024 the Company had 140 securities with a fair value of $427.0 million with a contractual maturity of less than 12 months and 61 securities with a fair value of $224.4 million with a contractual maturity of greater than 12 months. As of December 31, 2023 the Company had 124 securities with a fair value of $264.9 million with a contractual maturity of less than 12 months and 27 securities with a fair value of $61.4 million with a contractual maturity of greater than 12 months.

The Company is required to determine whether a decline in the fair value below the amortized cost basis of available-for-sale securities is due to credit-related factors. At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

Unrealized losses on available-for-sale securities presented in the previous table have not been recognized in the condensed consolidated statements of operations because the securities are high credit quality, investment grade securities that the Company does not intend to sell and will not be required to sell prior to their anticipated recovery, and the decline in fair value is attributable to factors other than credit losses. Based on its evaluation, the Company determined it does not have any credit losses related to its available-for-sale securities as of March 31, 2024 and December 31, 2023.

5. Collaborations

Sanofi Agreement

Agreement Terms

On July 7, 2020, the Company entered into a collaboration agreement, or the Sanofi Agreement, with Sanofi, to co-develop drug candidates directed to two biological targets. Under the Sanofi Agreement, the Company granted to Sanofi a worldwide exclusive license to develop, manufacture and commercialize certain lead compounds generated during the collaboration directed against IRAK4, or Collaboration Target 1, and one additional undisclosed target in an undisclosed field of use, or Collaboration Target 2. Such license is exercisable on a collaboration target-by-collaboration target basis only after specified milestones. For compounds directed against IRAK4, the field of use includes diagnosis, treatment, cure, mitigation or prevention of any diseases, disorders or conditions, excluding oncology and immuno-oncology.

Pursuant to the Sanofi Agreement, the Company is responsible for discovery and preclinical research and conducting a Phase 1 clinical trial for at least one degrader directed against IRAK4 plus up to three backup degraders. With respect to both targets, Sanofi is responsible for development, manufacturing, and commercialization of product candidates after a specified development milestone occurs with respect to each collaboration candidate.

In addition, pursuant to the Sanofi Agreement, Sanofi will grant to the Company an exclusive option, or Opt-In Right, exercisable on a collaboration target-by-collaboration target basis that will include the right to (i) to fund 50% of the United States development costs for collaboration products directed against such target in the applicable field of use and (ii) share equally in the net profits and net losses of commercializing collaboration products directed against such target in the applicable field of use in the United States. In addition, if the Company exercises the Opt-In Right, Sanofi will grant to the Company an exclusive option, applicable to each collaboration target, which upon exercise will allow the Company to conduct certain co-promotion activities in the field in the United States.

The Sanofi Agreement, unless earlier terminated, will expire on a product-by-product basis on the date of expiration of all payment obligations under the Sanofi Agreement with respect to such product. The Company or Sanofi may terminate the agreement upon the other party's material breach or insolvency or for certain patent challenges. In addition, Sanofi may terminate the Sanofi Agreement for convenience or for a material safety event upon advance prior written notice, and the Company may terminate the Sanofi Agreement with respect to any collaboration candidate if, following Sanofi's assumption of responsibility for the development, commercialization or manufacturing of collaboration candidates with respect to a particular target, Sanofi ceases to exploit any collaboration candidates directed to such target for a specified period.

In consideration for the exclusive licenses granted to Sanofi under the Sanofi Agreement, Sanofi paid to the Company an upfront payment of $150.0 million. The Company will also be reimbursed for certain research activities for a certain backup degrader under the IRAK4 program as well as contract manufacturing costs for the lead KT-474 program, unless certain criteria are not met for an initial IRAK4 degrader. In addition to the upfront payment and the reimbursements, the Company is eligible to receive certain development milestone payments of up to $1.48 billion in the aggregate, of which more than $1.0 billion relates to the IRAK4 program, upon the achievement of certain developmental or regulatory events. The Company will be eligible to receive certain commercial milestone payments up to $700.0 million in the aggregate, of which $400.0 million relates to the IRAK4 program, which are payable upon the achievement of certain net sales thresholds. The Company will be eligible to receive tiered royalties for each program on net sales ranging from the high-single digits to high teens, subject to low-single digits upward adjustments in certain circumstances.

On November 15, 2022, we entered into an Amended and Restated Collaboration and License Agreement with Sanofi, or the Amended Sanofi Agreement, which amended the Original Sanofi Agreement to revise certain research terms and responsibilities set forth under the Original Sanofi Agreement. The Amended Sanofi Agreement also specifies details around the timing and number of Phase 2 trials required under the terms of the collaboration. The Amended Sanofi Agreement became effective on December 5, 2022.

Additionally with respect to Sanofi, on December 2, 2022, Sanofi provided the Company with written notice of its intention to advance the collaboration target 1 candidate, KT-474, into Phase 2 clinical trials. In the fourth quarter of 2023, the Company achieved two milestones of $40.0 million and $15.0 million relating to the dosing of the first patient in the Phase 2 clinical trial for the first and second indications, respectively.

In September 2023, the Company and Sanofi mutually agreed to cease activities related to Collaboration Target 2.

Accounting Treatment

The Company analyzed the discovery and pre-clinical research activities as well as the exclusive license grants under the Sanofi Agreement and concluded that the arrangement was indicative of a vendor-customer relationship and would be accounted for under ASC 606.

The Company identified the following material promises under the arrangement: (1) research services for Collaboration Target 1, (2) research license for Collaboration Target 1, (3) exclusive license for Collaboration Target 1, (4) research services for Collaboration Target 2, (5) research license for Collaboration Target 2, (6) exclusive license for Collaboration Target 2, (7) option to extend the research term, and (8) optional research services during the development period.

The Company determined that Collaboration Targets 1 and 2 are distinct from each other. The research associated with degraders directed to each target is at different stages and the licensed field, should development activities be successful, are different from each other. As such, all promises associated with each target are considered distinct from promises associated with the other target.

The research and development services for each collaboration target were determined not to be distinct from the research license and the exclusive license and have been combined into a single performance obligation for each collaboration target. That is, two performance obligations were identified, the combined research services, research license and exclusive license for Collaboration Target 1 and the combined research services, research license and exclusive license for Collaboration Target 2. The exclusive license for each target is not distinct from the pre-clinical and clinical research and development services under the Sanofi Agreement, primarily due to the highly specialized nature of the research and novel technology involved with developing protein degraders – the pre-clinical activities and studies and first phase 1 clinical trial could not be conducted by another party in the manner required.

The option to extend the research term and optional research services during the development period were evaluated as material rights. The fees associated with each option are at or above the standalone selling price. As such, the underlying options are not performance obligations and fees associated with each option are excluded from the transaction price until the underlying option is exercised.

The Company determined the total transaction price to be $150.0 million, which consists solely of the upfront payment. All milestone payments and option payments are constrained as the achievement of such milestones are contingent upon the success of the underlying research and development activities and are generally outside the control of the Company. The reimbursement of costs for the IRAK4 backup degrader is also treated as constrained variable consideration as the criteria for reimbursement may not always be met, under which circumstances the Company would be responsible for the costs related to the backup degrader. Upon becoming unconstrained, the reimbursement consideration will be added to the transaction price and allocated to Collaboration Target 1.

The Company allocated the upfront payment to each performance obligation based on the relative standalone selling price, as follows:

•Collaboration Target 1: $120.0 million

•Collaboration Target 2: $30.0 million

The Company determined the allocation of the $150.0 million transaction price between Collaboration Target 1 and Collaboration Target 2 based on the value of the research and development for the programs from projected research and development costs for each collaboration target plus a developer's profit and the total potential milestones for each collaboration target.

The Company recognizes revenue associated with each performance obligation as the research and development services are provided using an input method, according to costs incurred as related to the research and development activities for each individual program and the costs expected to be incurred in the future to satisfy that individual performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying each performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability on the Company's consolidated balance sheet and will be recognized over the remaining research and development period until the performance obligation is satisfied. Milestone and reimbursement consideration added to the transaction price will be recognized as revenue with a cumulative catch-up upon becoming unconstrained. The performance obligation associated with Collaboration Target 1 has not been fully satisfied as of March 31, 2024. The performance obligation associated with Collaboration Target 2 has been fully satisfied. In the three months ended March 31, 2024, the Company recognized $10.3 million in revenue under the Sanofi Agreement, all of which was associated with Collaboration Target 1. In the three months ended March 31, 2023, the Company recognized $7.7 million in revenue under the Sanofi Agreement, of which $7.1 million was associated with Collaboration Target 1 and $0.6 million was associated with Collaboration Target 2. Of the $10.3 million of revenue recognized in the three months ended March 31, 2024, $8.7 million was recognized from amounts that were recorded in deferred revenue as of December 31, 2023. The aggregate amount of the transaction price allocated to the

Company's unsatisfied performance obligations and recorded in deferred revenue at March 31, 2024 and December 31, 2023 is $46.4 million and $54.7 million, respectively. During the three months ended March 31, 2024, the Company received $3.8 million in cost reimbursement payments, and additionally received a $15.0 million milestone payment from Sanofi for dosing of the first patient in the second indication of the Phase 2 Clinical Trial which had been recorded in accounts receivable as of December 31, 2023. As of March 31, 2024, the Company recorded a contract asset for unbilled accounts receivable of $2.0 million related to reimbursable research and development costs under the Sanofi Agreement for activities performed during the first quarter of 2024 The Company will recognize the deferred revenue related to the performance obligations based on a cost input method, as described, over the remaining research term, which as a result of the amended agreement, is a maximum of approximately 2.8 years as of March 31, 2024.

Any additional consideration related to performance-based milestones will be recognized when the risk of probable reversal is resolved, at which point the Company shall adjust the transaction price determined for the agreement accordingly and recognize revenue on a cumulative-catch up basis, reallocating the revised arrangement consideration to the performance obligations. Any consideration related to sales milestone payments and royalties will be recognized when the related milestone events or sales occur and therefore are recognized at the later of when the related sales occur or the relevant performance obligation is satisfied. As part of its evaluation of constraining the milestones, the Company considered numerous factors, including the fact that the achievement of the research and development milestones are contingent upon the results of the underlying research and development activities and are thus outside of the control of the Company. In the fourth quarter of 2023, the Company achieved two development milestones relating to the dosing of the first patient in the KT-474 Phase 2 clinical trials for the first and second indications, respectively. In connection with these milestones the Company unconstrained $55.0 million of consideration in the fourth quarter of 2023. During the quarter ended March 31, 2024, the Company recognized $2.3 million of revenue from the unconstrained milestones. As of March 31, 2024, $42.6 million of the $55.0 million of consideration has been recorded as revenue, with the remaining $12.4 million recorded as deferred revenue.

Vertex Agreement

On May 9, 2019 (the “Effective Date”), the Company entered into a collaboration agreement (the “Vertex Agreement”) with Vertex to advance small molecule protein degraders against up to six targets. Under the Vertex Agreement, Vertex had the exclusive option to license the rights to the product candidates developed for the designated targets at which point Vertex would control development and commercialization. Pursuant to the Vertex Agreement, the Company was only responsible for discovery and preclinical research on the targets, and Vertex was responsible for development, manufacturing, and commercialization of the product candidates after it exercises its option to license. The initial research term of the collaboration was four (4) years, extendable for an additional one (1) year period upon mutual agreement by the parties and payment by Vertex of certain per-target fees.

The Company was eligible to receive up to $170.0 million in payments per target, including development, regulatory and commercial milestones as well as option exercise payments. In addition, Vertex was obligated to pay the Company tiered royalties on future net sales on any products that may result from the Vertex Agreement. None of the payments under the Vertex Agreement are refundable. The Company may also perform follow-on research for an optioned target upon Vertex’s request and at Vertex’s expense.

The term of the Vertex Agreement began on the Effective Date and expired upon the completion of the initial research term on May 9, 2023.

Vertex provided the Company with a non-refundable upfront payment of $50.0 million and purchased 3,059,695 shares of the Company’s Series B-1 Convertible Preferred Stock (the “Series B-1 Preferred Stock”) at $6.54 a share, pursuant to a separate, but simultaneously executed Share Purchase Agreement. The shares were purchased at a premium of $5.9 million, which was included in the transaction price and will be recognized as revenue over the period of performance. As a result of this purchase, Vertex was considered a related party. Vertex is no longer considered a related party.

Accounting Treatment

The Company analyzed the joint research activities required under the Vertex Agreement and concluded that the arrangement was indicative of a vendor-customer relationship and would be accounted for under ASC 606.

The Company identified the following material promises under the arrangement: (1) the non-exclusive, royalty-free research license; (2) the research and development services to be performed on up to six targets; and (3) the option to license each of the targets for development, manufacturing, and commercialization efforts. The research and development services were determined not to be distinct from the research and development license and have been combined into a single performance obligation. The Company determined that the option to license the targets in the future was not priced at a discount, and that the option exercise fee for each target is at or above the standalone selling price for research at this stage of development; as such, the options and the underlying licenses are excluded from the performance obligation and the option exercise fees are excluded from the transaction price until the underlying option is exercised.

As part of its evaluation of constraining the research and development milestones, the Company considered numerous factors, including the fact that the achievement of the research and development milestones is contingent upon the results of the underlying research and development activities and is thus outside of the control of the Company.

At the commencement of the arrangement, two units of accounting were identified: the issuance of 3,059,695 shares of the Series B-1 Preferred Stock and the research activities the Company will perform over the Research Term. The Company determined the total transaction price to be $55.9 million, which consists of $5.9 million attributed to the premium from the shares of Series B-1 Preferred Stock sold to Vertex and the $50.0 million upfront payment. To determine the fair value of the Series B-1 Preferred Stock issued to Vertex, the Company performed a valuation of the shares of the Company's common and preferred stock, which took into consideration recent financings, and the Company's recent development and future exit strategies, as well as a discount for lack of marketability.

The Company recognizes revenue associated with the performance obligation as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities on each program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The Vertex collaboration agreement expired upon completion of the initial research term in May of 2023. Accordingly, the Company fully satisfied its performance obligation and recognized all remaining deferred revenue associated with the Vertex collaboration in May 2023. No revenue was recognized during the three months ended March 31, 2024, under the Vertex Agreement. During the three months ended March 31, 2023, the Company recognized $1.8 million, under the Vertex Agreement. All $1.8 million of revenue recognized in the three months ended March 31, 2023 was recognized from amounts that were recorded in deferred revenue as of December 31, 2022. There were no unsatisfied performance obligations as of March 31, 2024. The aggregate amount of the transaction price allocated to the Company's unsatisfied performance obligation and recorded in deferred revenue is $0 at both March 31, 2024 and December 31, 2023.

The following table presents the changes in accounts receivable, contract assets and contract liabilities for the three months ended March 31, 2024 (in thousands):

	Balance at December 31, 2023	Additions	Deductions	Balance at March 31, 2024
Accounts receivable and contract assets:				
Billed receivables - Sanofi	$ 15,000	$ 3,762	$ (18,762)	$ —
Unbilled receivables - Sanofi	3,762	2,030	(3,762)	2,030
Total accounts receivable and contract assets	$ 18,762	$ 5,792	$ (22,524)	$ 2,030
Contract liabilities:				
Deferred revenue - Sanofi	$ 54,651	$ 2,030	$ (10,287)	$ 46,394
Total contract liabilities	$ 54,651	$ 2,030	$ (10,287)	$ 46,394

6. Property and Equipment

Property and equipment consisted of the following as of March 31, 2024 and December 31, 2023 (in thousands):

	March 31, 2024	December 31, 2023
Lab and office equipment under finance right-of-use asset	$ 5,749	$ 6,725
Lab equipment	7,441	5,098
Computer equipment	966	582
Furniture & fixtures	3,182	1,064
Leasehold improvements	40,084	7,802
Assets not yet in service	2,450	37,303
Total property and equipment	59,872	58,574
Less accumulated depreciation	(10,536)	(10,440)
Property and equipment, net	$ 49,336	$ 48,134

Depreciation expense for the three months ended March 31, 2024 and 2023 was $1.5 million and $0.9 million, respectively.

Included in property and equipment is lab and office equipment right-of-use assets under finance leases with a cost basis of $5.7 million and $6.7 million and accumulated amortization expense of $3.5 million and $4.1 million as of March 31, 2024 and December 31, 2023, respectively.

Amortization expense related to right-of-use assets during the three months ended March 31, 2024 and 2023 was $0.4 million and $0.4 million, respectively.

7. Leases

In October 2019, the Company entered into a noncancelable facility lease agreement (the “2019 Lease”) for 34,522 square feet of research and development and office space in Watertown, Massachusetts. The term of the 2019 Lease is 120 months and expires on March 31, 2030. The 2019 Lease has an option to be extended for an additional five years. The lease is not reasonably certain to be extended and as such the additional term is not included in the measurement of the lease. The 2019 Lease includes a rent escalation clause, and rent expense is being recorded on a straight-line basis. In accordance with the lease agreement, the Company is required to maintain a security deposit and provided a letter of credit to the landlord, which is recorded in restricted cash as of March 31, 2024 and December 31, 2023. The letter of credit totaled $1.3 million and $1.3 million as of March 31, 2024 and December 31, 2023, respectively.

In December 2021, the Company entered into a noncancelable lease (the “2021 Lease”) for 100,624 square feet of office and laboratory space in Watertown, Massachusetts, which the Company began occupying in February 2024. The 2021 Lease is subject to base rent of $0.8 million per month beginning two months after the commencement date, plus the Company’s ratable share of taxes, maintenance and other operating expenses. Base rent is subject to a 3% annual increase over the lease term of approximately 134 months following the commencement date. The Company also has two consecutive options to extend the term of the lease for five years each at then-market rates. The 2021 Lease also includes a tenant improvement allowance of approximately $20.1 million. In connection with the signing of the 2021 Lease, the Company issued a letter of credit for $4.5 million which is classified as restricted cash as of March 31, 2024 and December 31, 2023.

The 2021 Lease required the landlord to build-out the base building prior to the construction of the Company’s premises. The Company concluded the accounting commencement date occurred when the landlord completed the build-out of the base building and control passed to the Company, which occurred in early January 2023. The Company assessed the classification of the 2021 Lease at the accounting commencement date and concluded the lease should be accounted for as an operating lease. The Company recorded an operating lease liability of $48.9 million, measured as the present value of the remaining lease payments discounted using the incremental borrowing rate as of the accounting commencement date. The Company recorded an operating lease right-of-use asset of $48.9 million, measured as the present value of the remaining lease payments, net of the tenant incentives.

The Company concluded the improvements paid for by the landlord in connection with the tenant improvement allowance represent lessee assets and therefore recorded $17.6 million of leasehold improvements in property and equipment. The Company recorded an additional $12.1 million of leasehold improvements in excess of the tenant improvement allowance, all of which were placed in service as of March 31, 2024.

Upon occupancy of the 2021 Lease facility in February of 2024, the Company exited the 2019 Lease facility and is actively looking to sublease the entire facility for the remaining noncancellable lease term through March 31, 2030. These actions resulted in an impairment charge of $4.9 million in the three months ended March 31, 2024. The Company continues to evaluate the potential recovery of the ROU asset under sublease scenarios, and thus it is possible that additional impairments could be identified in future periods, and such amounts could be material.

The impairment charge reduces the carrying value of the associated ROU asset, leasehold improvements and certain furniture and fixture assets that remained in the facility to their estimated fair values. The fair values are estimated using a discounted cash flows approach based on forecasted future cash flows expected to be derived from the property based on current sublease market rent, which is considered a level 3 input in the fair value hierarchy, and other key assumptions such as future sublease market conditions and the discount rate.

The Company's finance lease obligations consist of certain property and equipment financed through finance leases.

The components of the lease costs for the three months ended March 31, 2024 and 2023, were as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Operating lease costs	$ 2,489	$ 2,521
Finance lease costs:		
Amortization of right-to-use assets, finance leases	414	369
Interest expense for finance lease liabilities	49	52
Variable lease costs	1,204	220
Total lease costs	$ 4,156	$ 3,162

Supplemental cash flow information relating to the Company's leases for the three months ended March 31, 2024 and 2023, were as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	$ 670	$ 651
Operating cash flows used in finance leases	$ 383	$ 327
Financing cash flows used in finance leases	$ 49	$ 52

Weighted average remaining lease terms and discount rates as of March 31, 2024 and 2023 were as follows:

	Three Months Ended March 31,	
	2024	2023
Remaining lease term:		
Operating lease	10.24 years	10.75 years
Finance lease	2.36 years	2.33 years
Discount Rate:		
Operating lease	8.74%	8.87%
Finance lease	8.17%	8.52%

The undiscounted future lease payments for operating and finance leases as of March 31, 2024, were as follows (in thousands):

Fiscal Year	Operating Leases	Finance Leases
2024 (excluding the first quarter)	$ 6,270	$ 919
2025	12,074	915
2026	12,436	566
2027	12,809	108
2028	13,193	—
Thereafter	74,424	—
Total minimum lease payments	$ 131,206	$ 2,508
Less amounts representing interest or imputed interest	(46,474)	(219)
Present value of lease liabilities	$ 84,732	$ 2,289

The undiscounted future lease payments in 2024 includes approximately $2.6 million of future reimbursements related to landlord funded tenant improvements in connection with the 2021 Lease.

8. Accrued Expenses

Accrued expenses consisted of the following as of March 31, 2024 and December 31, 2023 (in thousands):

	March 31, 2024	December 31, 2023
Research and development expenses	$ 8,021	$ 15,099
Payroll and payroll-related	4,574	11,227
Professional fees	2,271	3,854
Other	1,131	3,684
Accrued expenses	$ 15,997	$ 33,864

9. Other Commitments and Contingencies

Legal Proceedings

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred. The Company is not currently a party to any legal proceedings.

Indemnification Arrangements

As permitted under Delaware law, the Company has agreements whereby it indemnifies its investors, employees, officers, and directors (collectively, the “Indemnified Parties”) for certain events or occurrences while the Indemnified Parties are, or were serving, at its request in such capacity. The term of the indemnification period is for the Indemnified Parties’ lifetime. The Company believes the estimated fair value of these indemnification agreements is minimal. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company’s business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company’s products. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations as of March 31, 2024 or December 31, 2023.

10. Equity-Based Compensation

2018 Stock Option and Grant Plan

In November 2018, the Company adopted, and its stockholders approved, the 2018 Stock Option and Grant Plan (the "2018 Plan"), which provides for the granting of stock options and other equity-based awards at the discretion of the Board of Directors or any subcommittee of the Board of Directors to the Company's employees, officers, directors, and independent contractors. No further grants will be made under the 2018 Plan. However, the 2018 Plan will continue to govern outstanding equity awards granted thereunder. To the extent outstanding options granted under the 2018 Plan are cancelled, forfeited or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2018 Plan, the number of shares underlying such awards will be available for future grant under the 2020 Stock Option and Incentive Plan.

2020 Stock Option and Incentive Plan

In August 2020, the Company and its stockholders approved the 2020 Stock Option and Incentive Plan (the "2020 Plan"), which became effective on August 20, 2020. The 2020 Plan replaced the 2018 Plan as the Company's Board of Directors has determined not to make additional awards under the 2018 Plan following the closing of the Company's IPO. The 2020 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The Company has initially reserved 4,457,370 shares of its common stock for the issuance of awards under the 2020 Plan, which includes the shares of common stock remaining available for issuance under its 2018 Plan as of the business day immediately prior to the effective date of the registration statement. The 2020 Plan provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2021 and each January 1 thereafter, by 4% of the Company's outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation committee. These limits are subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. As of March 31, 2024, there were an aggregate of 3,760,882 shares remaining available for future grants.

2020 Employee Stock Purchase Plan

In August 2020, the Company and its stockholders approved the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective August 20, 2020. The 2020 ESPP initially reserved and authorized the issuance of up to a total of 445,653 shares of common stock to participating employees. The 2020 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2021 and each January 1 thereafter through January 1, 2030, by the lesser of (i) 438,898 shares of common stock, (ii) 1% of the Company's outstanding number of shares of common stock on the immediately preceding December 31 or (iii) such lesser number of shares of common stock as determined by the administrator of the 2020 ESPP. The number of shares reserved under the 2020 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. As of March 31, 2024, there were an aggregate 2,021,393 shares remaining available for future grants.

Stock Options

A summary of stock option activity under the 2020 Plan during the three months ended March 31, 2024 is as follows (in thousands except share and per share data):

	Number of Options Outstanding	Weighted Average Strike Price per Option	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	8,113,164	$ 28.25	7.69	$ 49,622
Granted	2,192,471	42.99		
Exercised	(281,021)	14.00		
Forfeited	(147,900)	30.68		
Outstanding at March 31, 2024	9,876,714	$ 31.90	8.00	$ 109,297
Exercisable at March 31, 2024	5,093,242	$ 26.90	6.87	$ 84,120

The intrinsic value of stock options exercised during the three months ended March 31, 2024 and 2023 was $6.8 million and $5.5 million, respectively.

The weighted-average fair value of options granted during the three months ended March 31, 2024 and 2023 was $26.53 and $18.67, respectively.

As of March 31, 2024, the total unrecognized stock-based compensation expense for unvested stock options was $101.0 million, with a weighted average recognition period of 2.4 years.

The following table outlines our equity-based compensation expense for stock options for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 5,040	$ 4,184
General and administrative	5,322	4,349
Total equity-based compensation	$ 10,362	$ 8,533

The weighted-average assumptions that the Company used in the Black-Scholes option pricing model to determine the grant date fair value of stock options granted to employees and non-employees for the three months ended March 31, 2024 and 2023 were as follows:

	Three Months Ended March 31,	
	2024	2023
Expected term (in years)	5.79	5.82
Volatility	65%	62%
Risk-free interest rate	4.13%	4.14%
Dividend yield	0.00%	0.00%

Restricted Stock Units

The Company has granted shares of restricted stock units with service-based and performance-based vesting conditions. A summary of restricted stock activity during the three months ended March 31, 2024 is as follows:

	Number of Units Outstanding	Grant Date Fair Value per Share
Unvested at December 31, 2023	593,140	$ 25.36
Granted	231,834	43.31
Vested	(83,209)	33.08
Forfeited	(16,327)	21.93
Unvested at March 31, 2024	725,438	$ 30.29

During the three months ended March 31, 2024 and 2023, the Company granted 231,834 and 216,289 restricted stock units, respectively. As of March 31, 2024, the total unrecognized stock-based compensation expense for unvested restricted stock was $19.5 million with a weighted average recognition period of 2.5 years.

During the three months ended March 31, 2024 the Company recognized approximately $1.4 million of expense for restricted stock of which $0.9 million and $0.5 million was recorded in research and development and general and administrative expense, respectively. During the three months ended March 31, 2023 the Company recognized approximately $0.6 million of expense for restricted stock of which $0.4 million and $0.2 million was recorded in research and development and general and administrative expense, respectively.

Equity-Based Compensation Expense

Total equity-based compensation expense recorded as research and development and general and administrative expenses for employees, directors, and non-employees during the three months ended March 31, 2024 and 2023 is as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 6,083	$ 4,729
General and administrative	5,885	4,656
Total equity-based compensation	$ 11,968	$ 9,385

11. Related-Party Transactions

Other than the collaborations discussed in Note 5, the Company had no related party transactions for the periods presented in the accompanying condensed consolidated financial statements, which have not otherwise been discussed in these notes to the condensed consolidated financial statements.

12. Income Taxes

Income taxes for the three months ended March 31, 2024 and 2023 have been calculated based on an estimated annual effective tax rate and certain discrete items. The company recorded immaterial income tax expense related to investment income for the three months ended March 31, 2024 and 2023.

The Company has never been examined by the Internal Revenue Service or any other jurisdiction for any tax years and, as such, all years within the applicable statutes of limitations are potentially subject to audit.

13. Net Loss per Share

Net Loss per Share

Basic and diluted loss per share is computed by dividing net loss by the weighted-average common shares outstanding for the period, including the pre-funded warrants given their nominal exercise price (in thousands, except for share and per share data):

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	$ (48,557)	$ (40,928)
Denominator:		
Weighted average common shares outstanding, basic and diluted	70,770,320	58,187,038
Net loss per share, basic and diluted	$ (0.69)	$ (0.70)

The Company's potentially dilutive securities, which include restricted stock and stock options, 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 common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at March 31, 2024 and 2023 because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2024	2023
Unvested restricted stock	725,438	452,721
Options to purchase common stock	9,876,714	8,291,731
Total	10,602,152	8,744,452

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

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, the Quarterly Report. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as express or implied statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics that selectively degrade disease-causing proteins by harnessing the body's own natural protein degradation system. Our proprietary targeted protein degradation, or TPD, platform, which we refer to as Pegasus™, allows us to discover highly selective small molecule protein degraders with activity against disease-causing proteins throughout the body. We believe that our small molecule protein degraders have unique advantages over existing therapies and allow us to address a large portion of the human genome that was previously intractable with traditional modalities. We focus on biological pathways that have been clinically validated but where key biological nodes/proteins have not been drugged or are inadequately drugged. To date, we have utilized our Pegasus™ platform to design novel protein degraders focused in the areas of immunology-inflammation and oncology, and we continue to apply our platform's capabilities to additional therapeutic areas. We have a mission to drug all target classes in human cells using TPD.

Our current clinical stage programs are IRAK4, STAT3, and MDM2, which each address high impact targets within biologically-proven pathways, providing the opportunity to treat a broad range of immuno-inflammatory diseases, hematologic malignancies, and/or solid tumors. Our programs exemplify our focus on addressing high impact targets that have been elusive to conventional modalities and that drive the pathogenesis of multiple serious diseases with significant unmet medical needs. Our disclosed preclinical programs target STAT6 and TYK2, two proteins in well-validated pathways where we believe our degrader technology has the potential to offer unique advantages as compared to competing therapies. Both programs are currently in IND-enabling studies.

With respect to our IRAK4 program, we are collaborating with Sanofi S.A, or Sanofi, on the development of drug candidates targeting IRAK4 outside the oncology and immuno-oncology fields. We are developing KT-474, a highly active and selective, orally bioavailable IRAK4 degrader, for the treatment of interleukin-1 receptor/toll-like receptor or IL-1R/TLR-driven immunology-inflammation conditions and diseases with high unmet medical need, including hidradenitis suppurativa, or HS, an inflammatory skin disease, as well as atopic dermatitis, or AD, and potentially other indications. We have completed our Phase 1 trial of KT-474, which included cohorts of healthy volunteers, as well as patients with HS and AD. Phase 2 clinical trials of KT-474, conducted by Sanofi, are initially investigating its potential in HS and AD. The clinical trials for both indications have been initiated, and patient dosing is ongoing.

With respect to our clinical oncology programs, we are evaluating KT-333, a STAT3 degrader, in a Phase 1 clinical trial. The study is evaluating the safety, tolerability, pharmacokinetics (PK)/pharmacodynamics (PD), and clinical activity of KT-333 dosed weekly in adult patients with relapsed and/or refractory lymphomas, leukemias and solid tumors. Patient enrollment and dosing are ongoing in the Phase 1a portion of the trial, and we expect to present additional clinical data in 2024. In September 2023, we announced that the FDA, granted KT-333 Fast Track Designation for the treatment of relapsed/refractory peripheral T cell lymphoma, an indication for which we have previously received Orphan Drug Designation.

Our Phase 1 clinical trial of KT-253, a MDM2 degrader is evaluating the safety, tolerability, PK/PD, and clinical activity of ascending doses of KT-253 in adult patients with relapsed or refractory high grade myeloid malignancies, acute lymphocytic leukemia, or ALL, lymphomas, and solid tumors. Patient enrollment and dosing are ongoing in the Phase 1a portion of the trial, and we expect to present additional clinical data in 2024. In November, 2023 we provided initial safety, proof-of-mechanism and proof-of-concept data . In June 2023, KT-253 was granted orphan drug designation by the FDA for the treatment of acute myeloid leukemia.

Since our inception in 2015, we have devoted substantially all our efforts to organizing and staffing our company, research and development activities, business planning, raising capital, building our intellectual property portfolio and providing general and administrative support for these operations. To date, we have received gross proceeds of $1.45 billion from sales of our convertible preferred stock, the sale of common stock including our August 2020 initial public offering, or IPO, and concurrent private placement, our July 2021 follow-on offering and concurrent private placement, our August 2022 private investment in public equity offering, or PIPE, our January 2024 follow-on offering, our sales agreement with Cowen and Company, LLC., and through our corporate collaborations.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current product candidates or any future product candidates. Our net losses were $147.0 million and $154.8 million for the years ended December 31, 2023 and 2022, respectively. We reported net losses of $48.6 million and $40.9 million for the three months ended March 31, 2024 and 2023, respectively. In addition, as of March 31, 2024 and December 31, 2023 we had an accumulated deficit of $579.3 million and $530.8 million, respectively. We expect that our expense and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- initiate and complete preclinical studies and clinical trials for current or future product candidates;
- prepare and submit Investigational New Drug applications, or INDs, with the U.S. Food and Drug Administration, or FDA, for current and future product candidates;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;
- secure facilities to support continued growth in our research, development and commercialization efforts;
- advance research and development related activities to expand our product pipeline;
- expand and improve the capabilities of our Pegasus™ platform;
- seek regulatory approval for our product candidates that successfully complete clinical development;
- contract to manufacture our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel; and
- incur additional costs associated with continuing to operate as a public company.

In addition, if we obtain marketing approval for any of our lead product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain marketing approval for our drug candidates. The lengthy process of securing marketing approvals for new drugs requires the expenditure of substantial resources. Any delay or failure to obtain regulatory approvals would materially adversely affect our product candidate development efforts and our business overall. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2024, we had cash, cash equivalents and marketable securities of $744.9 million. We believe the existing cash, cash equivalents and marketable securities on hand will be sufficient to fund our operations into the first half of 2027, which is expected to take us beyond the Phase 2 data for KT-474, as well as additional proof-of-concept data for KT-253 and KT-333, and several clinical inflection points for our STAT6 and TYK2 programs. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and capital resources.”

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. Our only revenues have been derived from research collaboration arrangements with Vertex and Sanofi. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreements and any additional collaborations that we may enter into in the future. To date, we have not received any royalties under any of the collaboration agreements.

Vertex Collaboration Agreement

On May 9, 2019, we entered into a collaboration agreement, or the Vertex Agreement, with Vertex, to advance small molecule protein degradation against up to six targets. Under the Vertex Agreement, Vertex was granted the exclusive option to license the rights to the product candidates developed through the collaboration at which point Vertex would control development and commercialization. Pursuant to the Vertex Agreement, we were responsible for discovery and preclinical research on the targets, and Vertex was responsible for development, manufacturing, and commercialization of the product candidates after it exercises its option to license. Vertex provided us with a non-refundable upfront payment of $50.0 million and purchased 3,059,695 shares of our Series B-1 Convertible Preferred Stock at $6.54 a share, pursuant to a separate, but simultaneously executed Share Purchase Agreement.

The Vertex Agreement expired upon the completion of the initial research term on May 9, 2023.

Sanofi Agreement

On July 7, 2020, we entered into a collaboration agreement, or the Sanofi Agreement, with Sanofi to co-develop drug candidates directed to two biological targets. Under the Sanofi Agreement, we granted to Sanofi a worldwide exclusive license to develop, manufacture and commercialize certain lead compounds generated during the collaboration directed against IRAK4 and one additional undisclosed target in an undisclosed field of use. Such license is exercisable on a collaboration target-by-collaboration target basis only after a specified milestone. For compounds directed against IRAK4, the field of use includes diagnosis, treatment, cure, mitigation or prevention of any diseases, disorders or conditions, excluding oncology and immunooncology. We are responsible for discovery and preclinical research and conducting a phase 1 clinical trial for at least one degrader directed against IRAK4 plus up to three backup degraders. With respect to both targets, Sanofi is responsible for development, manufacturing, and commercialization of product candidates after a specified development milestone occurs with respect to each collaboration candidate.

We have an exclusive option, or Opt-In Right, exercisable on a collaboration target-by-collaboration target basis that will include the right to (i) to fund 50% of the United States development costs for collaboration products directed against such target in the applicable field of use and (ii) share equally in the net profits and net losses of commercializing collaboration products directed against such target in the applicable field of use in the United States. In addition, if we exercise the Opt-In Right, Sanofi will grant us an exclusive option, applicable to each collaboration target, which upon exercise will allow us to conduct certain co-promotion activities in the field in the United States.

The Sanofi Agreement, unless earlier terminated, will expire on a product-by-product basis on the date of expiration of all payment obligations under the Sanofi Agreement with respect to such product. We or Sanofi may terminate the agreement upon the other party's material breach or insolvency or for certain patent challenges. In addition, Sanofi may terminate the agreement for convenience or for a material safety event upon advance prior written notice, and we may terminate the agreement with respect to any collaboration candidate if, following Sanofi's assumption of responsibility for the development, commercialization or manufacturing of collaboration candidates with respect to a particular target, Sanofi ceases to exploit any collaboration candidates directed to such target for a specified period.

In consideration for the exclusive licenses granted to Sanofi under the Sanofi Agreement, Sanofi made an upfront payment of $150.0 million. In addition to the upfront payment, we are eligible to receive certain development milestone payments of up to $1.48 billion in the aggregate, of which more than $1.0 billion relates to the IRAK4 program, upon the achievement of certain developmental or regulatory events. We will be eligible to receive certain commercial milestone payments up to $700.0 million in the aggregate, of which $400.0 million relates to the IRAK4 program, which are payable upon the achievement of certain net sales thresholds. We will be eligible to receive tiered royalties for each program on net sales ranging from the high single digits to high teens, subject to low-single digits upward adjustments in certain circumstances. As of March 31, 2024, we have achieved $55.0 million of milestones to date under the Sanofi Agreement related to certain IRAK4 clinical milestones.

On November 15, 2022, we entered into an Amended and Restated Collaboration and License Agreement with Sanofi, or the Amended Sanofi Agreement, which amended the Original Sanofi Agreement to revise certain research terms and responsibilities set forth under the Original Sanofi Agreement. The Amended Sanofi Agreement also specifies details around the timing and number of Phase 2 trials required under the terms of the collaboration. The Amended Sanofi Agreement became effective on December 5, 2022.

Additionally with respect to Sanofi, on December 2, 2022, Sanofi provided the Company with written notice of its intention to advance the collaboration target 1 candidate, KT-474, into Phase 2 clinical trials for which the Company received milestone payments as further set forth in the Amended Sanofi Agreement. Phase 2 clinical trials of KT-474 are initially investigating its potential in HS and AD with the clinical trial for both indications having been initiated and commenced dosing in 2023.

In September 2023, the Company and Sanofi mutually agreed to cease activities related to Collaboration Target 2.

Operating expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative expenses.

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of targeted protein degradation therapeutics. These research efforts and costs include external research costs, personnel costs, supplies, license fees and facility-related expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with organizations that support our platform program development;
- contract manufacturing organizations, or CMOs, that are primarily engaged to provide drug substance and product for our preclinical research and development programs, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing and nonclinical trial materials, including manufacturing registration and validation batches;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any future product candidates.

Our future clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;

•the number of doses that patients receive;

•the drop-out or discontinuation rates of patients;

•potential additional safety monitoring requested by regulatory agencies;

•the duration of patient participation in the trials and follow-up;

•the cost and timing of manufacturing our product candidates;

•the phase of development of our product candidates; and

•the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

•the timing and progress of nonclinical and clinical development activities;

•the number and scope of nonclinical and clinical programs we decide to pursue;

•the ability to raise necessary additional funds;

•the progress of the development efforts of parties with whom we may enter into collaboration arrangements;

•our ability to maintain our current development program and to establish new ones;

•our ability to establish new licensing or collaboration arrangements;

•the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;

•the receipt and related terms of regulatory approvals from applicable regulatory authorities;

•the availability of drug substance and drug product for use in production of our product candidates;

•our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;

•our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;

•our ability to protect our rights in our intellectual property portfolio;

•our ability to obtain and maintain third-party insurance coverage and adequate reimbursement;

•the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;

•the impact of competition with other products;

•the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis; and

•our ability to maintain a continued acceptable safety profile for our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in 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 administrative consulting services, insurance costs, administrative travel expenses, marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support development of our product candidates and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as legal, investor and public relations expenses associated with being a public company.

Other Income (Expense)

Interest and other income and expense, net

Interest and other income and expense consists of interest earned on our invested cash balances and interest expense related to our financing leases.

Results of Operations

Comparison of three months ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		Change
	2024	2023	
	(in thousands)		
Collaboration Revenue	$ 10,287	$ 9,466	$ 821
Operating expenses:			
Research and development	48,819	42,227	6,592
General and administrative	14,374	12,565	1,809
Impairment of long-lived assets	4,925	—	4,925
Total operating expenses	68,118	54,792	13,326
Loss from operations	(57,831)	(45,326)	(12,505)
Other income, net	9,274	4,398	4,876
Net loss	$ (48,557)	$ (40,928)	$ (7,629)

Collaboration revenue

We recognize revenue under our collaboration agreements based on our pattern of performance related to the respective identified performance obligations, which is the period over which we will perform research services under each of the respective agreements.

Collaboration revenues were $10.3 million for the three months ended March 31, 2024, the entirety of which is attributable to our collaboration agreement with Sanofi. Collaboration revenues were $9.5 million for the three months ended March 31, 2023, of which $7.7 million and $1.8 million were attributable to our collaboration agreements with Sanofi and Vertex, respectively.

Research and development expenses

The following table summarizes our research and development expenses for each period presented (program expenses are not disclosed prior to formal development candidate nomination):

	Three Months Ended March 31,		Change
	2024	2023	
	(in thousands)		
External research and development costs:			
IRAK4	$ 1,810	$ 2,568	$ (758)
STAT3	2,180	2,359	(179)
MDM2	2,204	2,748	(544)
STAT6	2,679	—	2,679
Other	11,823	11,943	(120)
Internal research and development costs	28,123	22,609	5,514
Total research and development expenses	48,819	42,227	
	$	$	$ 6,592

Research and development expenses were $48.8 million for the three months ended March 31, 2024, compared to $42.2 million for the three months ended March 31, 2023. The increase of $6.6 million was primarily due to a $5.5 million increase in personnel, stock-based compensation, and occupancy related costs due to increases in employee headcount in the research and development functions and a $2.6 million increase in costs related to our STAT6 and discovery programs. These increases were partially offset by a $1.5 million reduction in activities related to our IRAK4, STAT3 and MDM2 programs.

General and administrative expenses

General and administrative expenses were $14.4 million for the three months ended March 31, 2024, compared to $12.6 million for the three months ended March 31, 2023. This increase was primarily due to an increase in legal and professional service fees, personnel, facility, occupancy, and other expenses to support our growth. Stock based compensation expenses included in general and administrative expenses were $5.8 million and $4.7 million for the three months ended March 31, 2024 and March 31, 2023, respectively.

Impairment of long-lived assets

Impairment on long-lived assets was $4.9 million for the three months ended March 31, 2024, compared to $0 for three months ended March 31, 2023. The increase of $4.9 million was as a result of the occupancy of the 2021 Lease facility in February of 2024 and the corresponding exit of the 2019 Lease facility, resulting in an impairment charge of $4.9 million in the three months ended March 31, 2024.

Other Income, Net

Other income, net was $9.3 million for the three months ended March 31, 2024, compared to $4.4 million for the three months ended March 31, 2023. The $4.9 million increase was primarily due to the increase in our investments balance as a result of the 2024 financing activities as well as prevailing interest rates in the respective periods.

Liquidity and capital resources

We have not yet generated any revenue from any product sales, and we have incurred significant operating losses since our inception. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have received gross proceeds of $1.45 billion from sales of our convertible preferred stock, the sale of common stock including our August 2020 IPO and concurrent private placement, our July 2021 follow-on offering and concurrent private placement, our August 2022 PIPE offering, January 2024 follow-on offering, our sales agreement with Cowen and Company, LLC., and through our corporate collaborations. As of March 31, 2024 we had cash and cash equivalents and marketable securities of $744.9 million.

In October 2021, we entered into a sales agreement, or Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we may offer and sell shares of our common stock having aggregate gross proceeds of up to $250.0 million from time to time in "at-the-market" offerings through Cowen, as our sales agent. We agreed to pay Cowen a commission of up to 3.0% of the gross proceeds of any shares sold by Cowen under the Sales Agreement. As of March 31, 2024 we have sold 1,519,453 shares of common stock under the Sales agreement resulting in gross proceeds of approximately $50 million.

Cash flows

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

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (39,591)	$ (43,968)
Cash provided by investing activities	(330,607)	24,584
Cash provided by financing activities	353,756	1,159
Net increase in cash, cash equivalents and restricted cash	$ (16,442)	$ (18,225)

Cash Flow used in Operating Activities

During the three months ended March 31, 2024, cash used in operating activities was $39.6 million, primarily resulting from our net loss of $48.6 million during the period and the $8.3 million change in deferred revenue related to our collaboration agreements. These were offset by a $2.0 million net decrease in other operating assets and liabilities primarily driven by changes in accounts receivable, accounts payable, accrued expenses and operating lease liabilities. and adjustments for non-cash items of $15.3 million (primarily consisting of stock-based compensation, lease impairment charge, depreciation & amortization and premiums & discounts on available-sale-securities).

During the three months ended March 31, 2023, cash used in operating activities was $44.0 million, primarily resulting from our net loss of $40.9 million during the period, the $6.1 million change in deferred revenue under our collaboration agreements, and a $5.9 million net decrease in other operating assets and liabilities primarily driven by changes in accounts receivable, accounts payable, accrued expenses and operating lease liabilities. These were offset by adjustments for non-cash items of $8.9 million (primarily consisting of stock-based compensation, depreciation & amortization and premiums & discounts on available-sale-securities).

Cash Flow provided by Investing Activities

During the three months ended March 31, 2024, cash used in investing activities was $330.6 million comprised of purchases of marketable securities of $422.7 million and purchases of property and equipment of $7.4 million, partially offset by maturities of marketable securities of $99.5 million

During the three months ended March 31, 2023, cash provided by investing activities was $24.6 million comprised of maturities of marketable securities of $90.4 million, partially offset by purchases of marketable securities of $61.8 million and purchases of property and equipment of $4.0 million.

Cash Flow provided by Financing Activities

During the three months ended March 31, 2024, net cash provided by financing activities was $353.8 million, consisting of $301.4 million in proceeds from issuance of common stock and accompanying pre-funded warrants, net of offering costs, $48.7 million in proceeds from the issuance of common stock through an at-the-market sales agreement, net of issuance costs, $3.9 million in proceeds from the exercise of employee stock options, partially offset by finance lease payments of $0.3 million.

During the three months ended March 31, 2023, net cash provided by financing activities was $1.2 million, consisting of $1.5 in proceeds from the exercise of employee stock options, partially offset by finance lease payments of $0.3 million.

Future funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the later-stage clinical development of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company.

Because of the numerous risks and uncertainties associated with the development of our product candidates and programs and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our product candidates or any future product candidates we may develop;
- our ability to maintain our relationships with key collaborators;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- the costs of continuing to grow our business, including hiring key personnel and maintaining or acquiring operating space;
- the degree of market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We believe the existing cash, cash equivalents and marketable securities of $744.9 million as of March 31, 2024, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect that we will require additional funding to continue the clinical development of our clinical programs, commercialize our product candidates if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Market volatility resulting from macroeconomic factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

There were no material changes to our contractual obligations and commitments described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2024, there were no material changes to our critical accounting policies from those described in our Annual Report Form 10-K filed with the SEC on February 22, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in the form of money market funds and marketable securities and are invested in U.S. treasury or government obligations and corporate securities. However, because of the short-term nature of the duration of our portfolio and the low-risk profile of our investments, we believe an immediate 10% change in market interest rates would not be expected to have a material impact on the fair market value of our investments portfolio or on our financial condition or results of operations.

We are also exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located in Asia and Europe and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of March 31, 2024, we had no significant liabilities denominated in foreign currencies.

Inflation generally affects us by increasing our cost of labor, third party vendors, and clinical trial costs. The global macroeconomic environment has experienced, and continues to experience, extraordinary challenges. These macroeconomic factors have contributed, and we expect will continue to contribute, to increased costs, among other concerns. We cannot predict how long these inflationary pressures will continue, or how they may change over time, but we expect to see continued impacts on the global economy, our industry and our company. If inflationary pressures continue to persist, they may continue to have an adverse impact on our consolidated financial position, results of operations and/or cash flows. As a result of the inflationary environment, however, interest rates have increased, which has resulted in higher interest income rates than were previously realized.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer, who serves as our Principal Executive Officer, and our Chief Financial Officer, who serves as our Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024, the end of the period covered by this Quarterly Report. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, the Quarterly Report. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current activities, plans and expectations that involve risks, uncertainties and assumptions, such as express or implied statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position and Need for Additional Capital

We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. Since our formation in 2015 and our initial funding in 2016, our operations to date have been limited primarily to organizing and staffing our company, business planning, raising capital, researching and developing our drug discovery technology, developing our pipeline, building our intellectual property portfolio, undertaking preclinical studies and conducting Phase 1 clinical trials of our product candidates. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our current product candidates. Typically, it takes many years to develop one new pharmaceutical drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the pandemics or developments relating to macroeconomic conditions. We will need to transition from a company with a research and development focus to a company capable of supporting late-stage development and commercial activities. We may not be successful in such a transition.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Since inception, we have focused substantially all of our efforts and financial resources on developing our proprietary targeted protein degradation drug discovery platform, or the PegasusTM platform, and initial product candidates as well as supporting our collaborations and partnerships. To date, we have financed our operations primarily through the issuance and sale of our convertible preferred stock to outside investors and collaborators in private equity financings, upfront payments under our collaborations and our initial public offering (IPO), follow-on offerings, PIPE offering and at-the market sales program. From our inception through March 31, 2024, we raised an aggregate of approximately $1.45 billion of gross proceeds from such transactions and through our collaborations. As of March 31, 2024, our cash and cash equivalents and investments were $744.9 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $579.3 million as of March 31, 2024. For the years ended December 31, 2023, 2022 and 2021, we reported net losses of $147.0 million, $154.8 million, $100.2 million, respectively. We reported net losses of $48.6 million and $40.9 million for the three months ended March 31, 2024 and 2023, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- initiate and complete preclinical studies and clinical trials for current or future product candidates

•prepare and submit Investigational New Drug applications, or INDs, with the FDA, for future product candidates;

•develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;

•secure facilities to support continued growth in our research, development and commercialization efforts;

•advance research and development related activities to expand our product pipeline;

•expand and improve the capabilities of our Pegasus™ platform;

•seek regulatory approval for our product candidates that successfully complete clinical development;

•contract to manufacture our product candidates;

•maintain, expand and protect our intellectual property portfolio;

•hire additional staff, including clinical, scientific and management personnel; and

•incur additional costs associated with continuing to operate as a public company.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Risks Related to Future Financial Condition

We will need to raise substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or future commercialization efforts.

The development of pharmaceutical drugs is capital-intensive. We are engaged in clinical development activities on various programs and are also currently advancing multiple development candidates through preclinical development across a number of potential indications. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, product manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

As of March 31, 2024, we had approximately $744.9 million of cash and cash equivalents and investments. In August 2020, we completed an IPO of our common stock by issuing 9,987,520 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,302,720 additional shares of common stock, at a public offering price of $20.00 per share. The aggregate gross proceeds to us from the offering, before deducting underwriting discounts and commissions, and other estimated offering expenses payable by us, were approximately $199.8 million. Concurrent with the IPO, we announced the sale of 676,354 common shares at the public offering price per share in a private placement to Vertex. The aggregate gross proceeds to us from the concurrent private placement were approximately $13.5 million. The concurrent private placement also closed in August 2020. In July 2021, we completed a follow-on offering of our common stock and an additional private placement transaction with Vertex resulting, in the aggregate, in net proceeds of approximately, $243.1 million. In August 2022, we completed a PIPE offering of our common stock and pre-funded warrants resulting in gross proceeds of $150.0 million. In January 2024, we completed a follow-on offering of our common stock and pre-funded warrants resulting in gross proceeds of $316.2 million before deducting underwriting discounts and commissions and estimated offering expenses. In February 2024, we received $50 million before deduction sales commissions from sales of common stock under our sales agreement with Cowen and Company, LLC. We expect that the approximately $744.9 million of cash and cash equivalents and investments at March 31, 2024, will be sufficient to fund our operations into the first half of 2027. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner

than we currently expect. This estimate also assumes that we do not obtain any additional funding through collaborations or other strategic alliances. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans (including any supply related matters);
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any existing or additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our current or future product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current or future product candidates. Disruptions in the financial markets in general may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. We were required to implement these requirements beginning in 2022 and incurred unexpected expenses in

connection with such implementation. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Since that date, SVB has announced they have been acquired by First Citizens Bank and have resumed mostly normal operations. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with whom we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a supplier may determine that it will no longer deal with us as a customer. In addition, a supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any supplier bankruptcy or insolvency, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

Risks Related to Drug Development and Regulatory Approval

Risks Related to Preclinical and Clinical Development

We are very early in our development efforts and our IRAK4, STAT3 and MDM2 programs are in early clinical development. If we are unable to advance them through the clinic for safety or effective reasons or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our ability to become profitable depends upon our ability to generate revenue. To date, while we have generated collaboration revenue, we have not generated any revenue from our product candidates, and we do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue from product sales unless and until we complete the development of, obtain marketing approval for, and begin to sell, one or more of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the results of ongoing or planned clinical trials of our product candidates;
- the results of preclinical studies and timing of IND clearances of future product candidates, and/or clinical trial costs for current and future product candidates;
- our successful initiation, enrollment of and completion of clinical trials for current and future product candidates, including our ability to generate positive data from any such clinical trials;
- our ability to receive regulatory approvals from applicable regulatory authorities;
- the initiation and successful completion of all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;

•the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;

•our ability to establish and maintain manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;

•obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;

•launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

•obtaining and maintaining acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;

•effectively competing with other therapies;

•obtaining and maintaining healthcare coverage and adequate reimbursement;

•the success of our existing collaborations as well as the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;

•our ability to enforce and defend intellectual property rights and claims; and

•our ability to maintain a continued acceptable safety profile of our product candidates following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

Our approach to the discovery and development of product candidates based on our Pegasus platform is novel and unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products.

Our Pegasus™ platform utilizes a method known as targeted protein degradation, or TPD, to discover and develop product candidates. Our future success depends on the successful development of this novel therapeutic approach. No product candidate using a heterobifunctional degrader has been approved in the United States or Europe, and the data underlying the feasibility of developing such therapeutic products is both preliminary and limited. In addition, we have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. In particular, our ability to successfully achieve TPD with a therapeutic result requires the successful development of heterobifunctional molecules that were intentionally designed with a rational drug development process and developing those molecules with the right combination of protein targets and E3 ligases. This is a complex process requiring a number of component parts or biological mechanisms to work in unison to achieve the desired effect. We cannot be certain that we will be able to discover degraders by matching the right target with the ideal E3 ligase and the right linker in a timely manner, or at all. All of our product candidates are in preclinical or early clinical development. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our Pegasus™ platform, or any similar or competitive platforms, will result in the development and marketing approval of any products. Any development problems we experience in the future related to our Pegasus™ platform or any of our research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies and clinical trials or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

We may not be successful in our efforts to identify or discover additional product candidates or 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.

A key element of our strategy is to apply our Pegasus™ platform and product pipeline to address a broad array of targets and new therapeutic areas. The therapeutic discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating oncology, inflammation, immunology or genetic diseases. Our research programs may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. We are currently focused on our immunology portfolio, consisting of IRAK4, STAT6 and TYK2 programs, which target key signaling pathways implicated in multiple inflammatory and autoimmune diseases, as well as our oncology portfolio, consisting of our STAT3 and MDM2 programs, which target numerous cancers. In some instances, we may decide to discontinue our investment in programs. For example, in November 2023, we announced the decision to discontinue the development of our KT-413 (IRAKIMID) program in order to focus resources to support our growing immunology pipeline. As a result, we may forego or delay pursuit of opportunities with other current or future 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 drugs or profitable market opportunities. Our spending on current and future research and development programs and current or future product candidates for specific indications may not yield any commercially viable drugs. 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 future 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.

We depend heavily on the successful development of our lead programs. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

We currently have no product candidates approved for sale and may never be able to develop marketable product candidates. Our business depends heavily on the successful development, regulatory approval and commercialization of our current or future product candidates. The preclinical studies and clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies and clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Commission following scientific evaluation by the European Medicines Agency, or EMA. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed or commercialized. For example, in December 2020, we submitted an IND application for KT-474 to initiate a first-in-human Phase 1 randomized, double-blind, placebo-controlled clinical trial in healthy volunteers and patients with HS or AD. The program was initially placed on partial clinical hold regarding the multiple ascending dose, or MAD, portion of the Phase 1 trial, pending FDA review of the interim data in healthy volunteers from the SAD portion of the trial. In June 2021, the FDA lifted the partial clinical hold on the MAD portion of the Phase 1 trial of KT-474 following review of interim SAD results, and the Phase 1 trial has since been completed.

We are not permitted to market our current or future product candidates in the U.S. until we receive approval of a New Drug Application, or an NDA, from the FDA, in the European Union, or EU, until we receive approval of a marketing authorization application, or an MAA, from the European Commission following scientific evaluation by the EMA, or in any other foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of any of our current or future product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agency;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agency for marketing approval;
- the FDA or applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may require that we conduct additional preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our current or future product candidates;

•the contract research organizations, or CROs, that we retain to conduct our preclinical studies and clinical trials may take actions outside of our control that materially adversely impact our preclinical studies and clinical trials;

•the FDA or applicable foreign regulatory agency may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;

•the FDA or applicable foreign regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical trials;

•the FDA or applicable foreign regulatory agency may not accept data generated at our preclinical studies and clinical trial sites;

•if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

•the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;

•the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs;

•the FDA or applicable foreign regulatory agency may be delayed in its review processes due to staffing or other constraints; or

•the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

If we experience delays or difficulties in the initiation or enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

There may be delays in trial initiation, and we may not be able to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Moreover, some of our competitors have ongoing clinical trials for current or future product candidates that treat the same patient populations as our current or future product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates.

Patient enrollment may be affected by other factors including:

•the size and nature of the patient population;

•competition with other companies for clinical sites or patients;

•the willingness of participants to enroll in our clinical trials in our countries of interest;

•the severity of the disease under investigation;

•the eligibility criteria for the clinical trial in question;

•the availability of an appropriate screening test for the indications we are pursuing;

•the perceived risks and benefits of the product candidate under study;

•the efforts to facilitate timely enrollment in and completion of clinical trials;

•the patient referral practices of physicians;

•the ability to monitor patients adequately during and after treatment;

•the proximity and availability of clinical trial sites for prospective patients; and

•factors we may not be able to control, such as potential pandemics that may limit subjects, principal investigators or staff or clinical site availability

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, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is 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. For example, in December 2023, we announced positive interim results from our Phase 1 trial of KT-333 and in November 2023, we announced positive interim results from our Phase 1a trial of KT-253. However, there can be no assurance that the final topline data from either trial will be consistent with such results or otherwise viewed as positive. 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 topline or preliminary results that we 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. Topline 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, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete, including data from of our clinical trials, 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 or as patients from our clinical trials continue other treatments for their diseases. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors 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 based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition.

Positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies of our current or future product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

Positive results from our preclinical studies of our current or future product candidates, and any positive results we may obtain from our early clinical trials of our current or future product candidates, including the ongoing clinical trials of KT-474, KT-333 and KT-253 may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our current or future product candidates according to our current development timeline, the positive results from such preclinical studies and/or clinical trials of our current or future product candidates, including KT-474, KT-621, KT-294, KT-333 and KT-253, may not be replicated in subsequent preclinical studies or clinical trials. In particular, while we have conducted certain preclinical studies of KT-621 and KT-294, we do not know whether either of these product candidates will perform in our planned clinical trials as it has performed in these prior preclinical studies. For example, in preclinical studies, (i) KT-621 demonstrated full inhibition of IL-4/IL-13 pathway in all relevant human cell contexts with picomolar potency that was superior to dupilumab, and equivalent or superior activity to dupilumab, and (ii) KT-294 demonstrated picomolar to nanomolar potencies across all relevant human cell types evaluated. However, there is no guarantee these preclinical results will be replicated in clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or comparable foreign regulatory authority. If we fail to produce positive results in our planned preclinical studies or clinical trials of any

of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Additionally, our planned or future clinical trials may utilize an "open-label" trial design, such as the open-label patient portion of our Phase 1 clinical trials of KT-474, KT-333 and KT-253. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial, including our Phase 1 trials of KT-474, KT-333 and KT-253, may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. 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, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and prevalence for the indications being pursued by our current and future product candidates are currently unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. We are developing KT-474 for the treatment of a broad set of immunology-inflammation diseases, such as HS, an inflammatory skin disease, AD, and rheumatoid arthritis. The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, their proven safety and efficacy, the diagnosis criteria included in the final label for each, whether our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients for our product candidates in the United States and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidate.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. For example, in December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19, surfaced in Wuhan, China and has since spread worldwide, including to Eastern Massachusetts where our primary office and laboratory space is located. The pandemic and policies and regulations implemented by governments in response to the pandemic, most of which have been lifted, have had a significant impact, both direct and indirect, on businesses and commerce. The coronavirus pandemic has evolved considerably, and led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures which now have been lifted. The extent to which any future pandemic impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of disease and the actions to contain the disease or treat its impact, among others. For example, similar to other biopharmaceutical companies, we may experience delays in enrolling subjects in our clinical trials. Infectious diseases may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, the patient populations that our lead and other core product candidates target may be particularly susceptible to infectious diseases or its variants, which may make it more difficult for us to identify patients able to enroll in our clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact that any future infectious disease spread has to patient enrollment or treatment, or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. Some factors from any public health crisis that may delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

•the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;

•limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our clinical trials;

•the potential negative affect on the operations of our third-party manufacturers and the supply chain for our product candidates. For example, in February 2020, one of our vendors for active pharmaceutical ingredient, or API, starting materials based in Wuhan, China ceased its operations for several weeks due to the COVID-19 pandemic, which caused a minor delay in the delivery of API starting materials to a separate vendor who manufactures API;

•interruptions in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our current and prospective clinical trials; and

•business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We cannot presently predict the scope and severity of additional planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC or FDA. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates. Other global health concerns could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

All of our product candidates are in preclinical or early clinical development, and there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time. Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with many treatments for inflammatory and autoimmune diseases, cancer or other diseases, it is likely that there may be adverse side effects associated with the use of our product candidates. Additionally, a potential risk in any protein degradation product is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein in itself could cause adverse events, undesirable side effects, or unexpected characteristics. It is possible that healthy proteins or proteins not targeted for degradation could be degraded using our degrader molecules in any of our current or future clinical studies. There is also the potential risk of delayed adverse events following treatment using any of our current or future product candidates.

These side effects could arise due to off-target activity, allergic reactions in trial subjects, or unwanted on-target effects in the body. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or future product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to abandon their development or limit 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. Many compounds that initially showed promise in early-stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further development of the compound.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our current or future product candidates receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such current or future product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such current or future product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

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

The process of manufacturing our current or future product candidates is complex and highly regulated. We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties for the manufacture of our current or future product candidates. These third-party contract manufacturing organizations, or CMOs, may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We 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, such as any impacting the product formulation, could negatively impact our manufacturing, including by resulting in product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates. Changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Legislative proposals are pending that, if enacted, could negatively impact U.S. companies and institutions that accept U.S. funding for projects that utilize biotechnology equipment and services produced or provided by certain biotechnology providers having relationships with foreign adversaries and which pose a threat to national security. This includes proposed legislation currently pending in the U.S. Senate, following a vote by the Senate Homeland Security and Government Affairs Committee in March of this year. The potential downstream adverse impacts on entities having only commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays. Though we do not currently receive U.S. government funding, we are currently evaluating steps to mitigate any potential impact of any future stricter legislation towards foreign entities providing services to U.S. based companies. Depending on the terms of the final legislation enacted, these steps could result in additional costs and potential delays in development timelines resulting from related transition efforts.

If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. This could significantly delay our clinical trials supply as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates or products, if approved, may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In

addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, as our current or future product candidates progress through preclinical studies and clinical trials towards potential 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 current or future product candidates and additional bridging studies or trials may be required between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Any such delay could have a material adverse impact on our business, results of operations and prospects.

Risks Related to Regulatory Approval

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current and future product candidates, we must obtain marketing approval from the regulatory authorities in the relevant jurisdictions. We have not received approval to market any of our current product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our current product candidates, nor any product candidates we may seek to develop in the future, will ever obtain regulatory approval. As a company, we have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities and often clinical sites by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the U.S. and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA or equivalent application type outside the U.S., may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our current or future product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our current or future product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;

•the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

•the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may seek Breakthrough Therapy Designation and/or Fast Track Designation for any of our current or future product candidates. These designations, even if granted by the FDA, may not lead to a faster development, regulatory review or approval process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We may seek a Breakthrough Therapy Designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our current or future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a current or future product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our current or future product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track Designation for one or more of our current or future product candidates. In the third quarter of 2023, the U.S. Food and Drug Administration granted Fast Track designation to KT-333 for the treatment of both relapsed/refractory CTCL and relapsed/refractory PTCL. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular current or future product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation for certain current or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek approval of KT-474, KT-621, KT-294, KT-333, KT-253 or any other future product candidate, where applicable, under the FDA's accelerated approval pathway. This pathway may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek accelerated approval of KT-474, KT-621, KT-294, KT-333, KT-253 or future product candidates. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of accelerated approval, the FDA likely would require that we perform adequate and well-controlled post-marketing clinical trials, and under FDORA the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on

an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the Agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We have obtained orphan drug designation for some of our product candidates. We may also seek Orphan Drug Designation for certain of our other current or future product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

The FDA has granted Orphan Drug Designation for KT-333 for the treatment of peripheral T cell lymphoma and cutaneous T cell lymphoma and for KT-253 for the treatment of acute myeloid leukemia. As part of our business strategy, we may also seek Orphan Drug Designation for certain indications of our other current or future product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, may grant orphan designation with respect products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be of significant benefit to those affected by the applicable condition). Additionally, designation may be granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in developing the product. In the European Union, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if at the end of the fifth year, it is established that a product no longer meets the criteria for Orphan Designation, including where it is shown that the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain Orphan Drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its Orphan Drug regulations and policies, our business could be adversely impacted.

Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, tracking and tracing, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, and continued compliance with cGMPs and Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner 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, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. 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 product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, 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 could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Foreign Regulatory Approval and Foreign Markets

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. In order to market any product outside of the U.S., however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the U.S. may take longer and be more costly than obtaining approval in the U.S.;
- our customers' ability to obtain reimbursement for our current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- 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;

•difficulties staffing and managing foreign operations;

•workforce uncertainty in countries where labor unrest is more common than in the U.S.;

•potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

•the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;

•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.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We may in the future conduct clinical trials for current or future product candidates outside the U.S., 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 U.S., including in Europe. The acceptance of study data from clinical trials conducted outside the U.S. 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 U.S., the FDA will generally not approve the application on the basis of foreign data alone 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 may be 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. 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 U.S. 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 current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, including the Foreign Corrupt Practices Act (FCPA), anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. As we increase our activities outside the United States, which may include increased interactions with officials and employees of government agencies or state-owned or -affiliated entities, our risks under these laws may increase. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, adverse media coverage, and other consequences. Any investigations, actions or sanctions could harm our business, results of operations, and financial condition. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and 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 addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of products such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Risks Related to Compliance with Healthcare and Other Regulations

Even if we are able to commercialize any current or future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S. and in other countries, sales of any products for which we may receive regulatory marketing approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government healthcare programs (e.g., Medicare and Medicaid), managed care providers, private health insurers, health maintenance organizations and other organizations. These third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as targeted protein degradation therapies.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. 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 a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to commercialize any current or future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these current or future product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. We cannot be sure that coverage will be available for any product candidate that we commercialize. If coverage is available, but reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

In the U.S., no uniform policy exists for coverage and reimbursement for products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate a payor will pay for the product. One third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service. Third-party payors may limit coverage to specific products on an approved list or formulary, which may not include all FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded product on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price,

or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Despite our best efforts, our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Finally, in some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the EU pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU Member States' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the U.S. and prices generally tend to be significantly lower.

Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes intended to broaden access to healthcare, improve the quality of healthcare, and contain or lower the cost of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. In addition, President Biden has issued multiple executive orders that have sought to address the issue of prescription drug costs. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example,

•The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress that included, along with subsequent legislation, aggregate reductions of Medicare payments to providers of up to 2% per fiscal year will remain in effect through 2032 unless additional Congressional action is taken.

•The American Taxpayer Relief Act of 2012 among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

•The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

•On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

•The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the annual out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on many drugs reimbursed under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition; and require companies to pay rebates to Medicare for drug prices that increase faster than inflation. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and has further resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. On December 2, 2020, HHS published 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 rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and the IRA further delayed implementation of this rule to January 1, 2032. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing 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. Legally mandated price controls on payment amounts by third-party payors or other

restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with customers, health care providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished future profits and earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors and customers may expose us to broadly applicable federal and state laws relating to fraud and abuse, as well as other healthcare laws and regulations. Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment. These laws may impact, among other things, the business or financial arrangements and relationships through which we market, sell and distribute any current or future product candidates for which we obtain marketing approval. See the section of this report titled “Government Regulation -other Regulatory Matters – Other Healthcare Laws” for additional information.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do 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 civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. 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 similar actions, penalties, and sanctions.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed.

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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 the success of 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 and radioactive 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 biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare 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. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Risks Related to Commercialization

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

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

The development and commercialization of new drugs is highly competitive. We face and will continue to face competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. 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 of new drugs.

Competitors in our efforts to develop small molecule protein degraders therapies for patients, include, but are not limited to, Arvinas, Inc., C4 Therapeutics, Inc., Foghorn Therapeutics Inc. and Nurix Therapeutics, Inc., some of which have entered clinical development. Further, several large pharmaceutical companies have disclosed preclinical and clinical investments in this field. Our competitors will also include companies that are or will be developing other targeted protein degradation methods as well as small molecule, antibody, or gene therapies for the same indications that we are targeting. In addition to the competitors we face in developing small molecule protein degraders, we will also face competition in the indications we expect to pursue with our IRAK4, STAT6, TYK2, STAT3 and MDM2 programs. Many of these indications already have approved standards of care which may include more traditional therapeutic modalities. In order to compete effectively with these existing therapies, we will need to demonstrate that our protein degrader therapies are favorable to existing therapeutics.

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any current or future product candidates that we may develop.

We do not yet maintain product liability insurance, and we anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

We do not currently have a sales or marketing infrastructure and have no experience in the sales, marketing, patient support or distribution of drugs. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our ongoing and planned preclinical studies and clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations and strategic partners to help conduct our preclinical studies. We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support clinical trials for our current product candidates, and we expect to rely on such third parties for our future product candidates. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area

and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with fail to comply with applicable GCP, 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, the FDA will determine that any of our clinical trials will comply with GCP. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations. Our failure or the failure of third parties that we may contract with to comply with these regulations may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed the Phase 1 trials of KT-474, KT-333 and KT-253, and intend to design other clinical trials for our current or future product candidates, or be involved in the design when other parties sponsor the trials, we anticipate that third parties will conduct all of our clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing will be outside of our direct control. Our reliance on third parties to conduct clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. 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 clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

The third parties upon whom we rely for the supply of the API, drug product, and starting materials used in our product candidates are limited in number, and the loss of any of these suppliers could significantly harm our business.

The drug substance and drug product in our product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of all drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason. Any delays in the delivery of our drug substance, drug product or starting materials could have an adverse effect and potentially harm our business. For example, in February 2020, one of our vendors for API starting materials based in Wuhan, China ceased its operations for several weeks due to the COVID-19 pandemic, which caused a minor delay in the delivery of API starting materials to a separate vendor who manufactures API.

Legislative proposals are pending that, if enacted, could negatively impact U.S. companies and institutions that accept U.S. funding for projects that utilize biotechnology equipment and services produced or provided by certain biotechnology providers having relationships with foreign adversaries and which pose a threat to national security. This includes proposed legislation currently pending in the U.S. Senate, following a vote by the Senate Homeland Security and Government Affairs Committee in March of this year. The potential downstream adverse impacts on entities having only commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays. Though we do not currently receive U.S. government funding, we are currently evaluating steps to mitigate any potential impact of any future stricter legislation towards foreign entities providing services to U.S. based companies. Depending on the terms of the final legislation enacted, these steps could result in additional costs and potential delays in development timelines resulting from related transition efforts.

For all of our current or future product candidates, we intend to identify and qualify additional manufacturers to provide such API, drug product and drug substance prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner, could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures. We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.

We have entered into a collaboration and licensing arrangement with Sanofi and may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current 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 acquisition or other alternative arrangements for our current or future 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 current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our technologies or current or future 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 current or future product candidates or may elect not to continue or renew development or commercialization of our current or future 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 current or future 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 current or future 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 current or future product candidates;

•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; and

•collaborators may not pay milestones and royalties due to the company in a timely manner.

As a result, we may not be able to realize the benefit of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, collaborations or license arrangements we may enter into 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, license, collaboration or other business development partnership, 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 current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies or for certain indications, which would harm our business prospects, financial condition and results of operations.

As discussed elsewhere in our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, our collaboration partner, Sanofi, is conducting a randomized Phase 2 clinical trial evaluating KT-474 in HS and a second randomized Phase 2 trial in AD. Sanofi will have significant discretion in determining the efforts and resources that it will apply to advance those clinical trials. As a result of the factors noted above, we may not be able to realize the benefit of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, collaborations or license arrangements we may enter into, which could delay our timelines or otherwise adversely affect our business.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our preclinical and clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and 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 materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. 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 Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain and maintain patent or other intellectual property protection in the U.S. and other countries for our current or future product candidates and our core technologies, including our proprietary Pegasus™ platform, our initial IRAK4, STAT3 and MDM2 programs, which are our most advanced development programs, as well as our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We own patent applications and one patent related to our platform E3 ligase ligand technology and our novel bifunctional degrader compounds, including claims to compositions of matter, pharmaceutical compositions, methods of use, methods of treatment, and other related methods.

As of March 31, 2024, our patent portfolio covering novel compounds, and the methods of making and using thereof, included 103 patent families. Patent term adjustments, supplementary protection certificate filings, or patent term extensions could result in later expiration dates in various countries, while terminal disclaimers could result in earlier expiration dates in the U.S.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our Pegasus™ platform and our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs. Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of the patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates or technologies, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in opposition, derivation, reexamination, inter partes review, or post-grant review proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to third-party submissions to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may challenge our issued patents or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by showing an administrative patent authority or judge that the invention was not patent-eligible, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could assert that our patents are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business. Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

We will not obtain patent or other intellectual property protection for all current or future product candidates in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates, the Pegasus™ platform, or other technologies in all countries. Filing, prosecuting and defending patents on current or future product candidates, the Pegasus™ platform, and other technologies in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some

countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from infringing on our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future 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 or other forms of compensation. 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. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in our current or any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patents, know-how and proprietary technology, both our own and in-licensed from Sanofi and other collaborators. Our commercial success depends upon our ability to develop, manufacture, market and sell our current or future product candidates and use our and our licensors' proprietary technologies without infringing the proprietary rights of third parties. Sanofi and other collaborators may have the right to terminate their respective license agreements in full in the event that we materially breach or default in the performance of any of the obligations under such license agreements. Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, the Pegasus™ platform, or other technologies, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours, and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

•the scope of rights granted under the license agreement and other interpretation-related issues;

•whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the licensing agreement;

•our right to sublicense patent and other rights to third parties under collaborative development relationships;

•our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;

•the priority of invention of any patented technology; and

•the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. 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 technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain current or future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates or technologies, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

•patent applications that we own or may in-license may not lead to issued patents;

•patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;

•others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;

•third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;

•we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;

•we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;

•others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;

•our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

•we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;

•third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;

•we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;

•we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

•we may not develop or in-license 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, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Patent Protection

Obtaining and maintaining our patent protection, including patent term, depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we miss a filing deadline for patent protection on these inventions or otherwise fail to comply with these requirements.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as 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. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or 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 ability to generate revenues could be materially adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future 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 both technological and legal complexity and are therefore costly, time consuming and inherently uncertain.

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. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to our Trademarks, Trade Names and Trade Secrets

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different or less effective trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade name may be challenged, infringed, diluted, circumvented, declared generic, or determined to be infringing on other marks. In such a circumstance, we may not be able to protect our rights to these marks or may be forced to stop using product names, which we need for name recognition by potential partners and customers in our markets of interest.

In addition, during the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions refusing registration of our trademarks. For example, in April 2021 and October 2022, respectively, the USPTO issued preliminary office action refusals against our applications to register E3 LIGASE WHOLE BODY ATLAS and E3 HUMAN ATLAS and our K & Design logo mark. While E3 LIGASE WHOLE BODY ATLAS and E3 HUMAN ATLAS have since been published and notices of allowance issued, we do not yet know whether the USPTO will issue a subsequent office action against our application for our logo mark, to which we will have to respond, and which we may not ultimately be able to overcome, or if this application will be approved for publication as well.

In the USPTO and in comparable agencies in many foreign jurisdictions, third parties are also given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. For example, in November 2019, Novartis AG filed actions in the U.S. and European Union trademark offices opposing our applications to register KYMERA and KYMERA THERAPEUTICS for pharmaceuticals and drug development services on the basis of its claimed rights in the KYMRIAH mark. This dispute was amicably settled in October 2020 and the involved applications for KYMERA and KYMERA THERAPEUTICS are now registered or allowed in the United States and have proceeded to registration in the European Union.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

In the case of employees, we enter into agreements providing that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Intellectual Property Litigation and Infringement Claims

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any intellectual property we may own or in-license, including our patents and trademarks. In addition, any intellectual property we may own or in-license also may become the subject of a dispute, including those based on inventorship, priority, validity or unenforceability. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that any intellectual property we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents or other intellectual property we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our own applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could 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 substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any intellectual property we may own or in-license. Even if we detect infringement by a third party of any intellectual property we may own or in-license, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents or other intellectual property we may own or in-license against such third party.

Intellectual property litigation and administrative office challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In August 2021, we initiated a US patent office proceeding, a post-grant review, to challenge a third-party patent unrelated to our current product candidates. In response, the owner of the challenged third-party patent disclaimed that patent in full. We may challenge additional third-party patents in the future. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such

litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our preclinical studies and future clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, inter partes review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates, the Pegasus™ platform, and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, the Pegasus™ platform, or other technologies, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

While certain activities related to development and preclinical and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

•a court prohibiting us from developing, manufacturing, marketing or selling our current or future product candidates, or from using our proprietary technologies, including our Pegasus™ platform, unless the third-party licenses its product rights to us, which it is not required to do on commercially reasonable terms or at all;

•if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;

•redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and

•there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is “clear and convincing,” a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates or Pegasus™ platform may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on

reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates or technologies, which could harm our business significantly.

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 current or future 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 U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates or technologies that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

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

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Nello Mainolfi, Ph.D., our President and Chief Executive Officer, Jared Gollob, M.D., our Chief Medical Officer, Bruce Jacobs, our Chief Financial Officer, Ellen Chiniara, our Chief Legal Officer and Jeremy Chadwick, our Chief Operating Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to continue to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of March 31, 2024, we had 186 full-time employees, and we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, 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. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We or the third parties upon whom we depend may be adversely affected by unforeseen global events, natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Unforeseen global events, such as macroeconomic conditions, outbreaks of violence, or geopolitical instability could adversely impact our business. Such conflicts could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business.

Additionally, any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Data and Privacy

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of data from preclinical studies or clinical trials for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. 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. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. 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 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 EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. 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. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

We intend to sublease our current space in Watertown, Massachusetts for occupancy now that we have moved to our new facility. If we are unable to sublease our space on favorable terms or if our subtenants are unable to meet their obligations under any sublease, we may be responsible for unexpected costs, which could impact our financial performance.

We currently lease 34,522 square feet of research and development and office space in Watertown, Massachusetts, which lease expires on March 31, 2030. In December 2021, we entered into a lease for 100,624 square feet of office and laboratory space in Watertown, Massachusetts, which we began occupying in February 2024. We intend to sublease our original space to third parties. In the event that we are unable to sublease our excess space on favorable terms, or at all, or if we are able to sublease our space but our subtenants fail to make lease payments to us or otherwise default on their obligations to us, we could incur unanticipated payment obligations or further impairment.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile and fluctuate substantially, and investors may lose all or part of their investment.

Our stock price has been volatile and may continue to be subject to wide fluctuations in response to various factors. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, including in connection with conflicts in various regions of the world, increasing inflation rates, and interest rate changes, which have resulted in decreased stock prices for many companies notwithstanding

the lack of a fundamental change in their underlying business models or prospects. As a result of this volatility, you may lose all or part of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of preclinical studies and clinical trials of our current or future product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- 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 current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements regarding our collaboration agreements, including announcements regarding our collaboration agreement with Sanofi;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

These and other market and industry factors may cause the market price and demand for shares of our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock. The price of our common stock may be disproportionately affected as investors may favor traditional profit-making industries and companies during the times of market uncertainty and instability.

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, 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 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. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. 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.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. Although we have obtained research coverage from certain analysts, there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. In addition, if one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of March 31, 2024, the existing holdings of our executive officers, directors, principal stockholders and their affiliates represent beneficial ownership, in the aggregate, of approximately 30% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current trading price of our stock and have held their shares for a longer period, they may be more interested in selling our Company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders. Additionally, from time to time, any of our non-affiliated shareholders may accumulate or acquire significant positions in our common stock and may similarly be able to influence our business or matters submitted to our stockholders for approval.

The concentration of voting power among these stockholders may also have an adverse effect on the price of our common stock by delaying, deferring or preventing a change of control of us; impeding a merger, consolidation, takeover or other business combination involving us; or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have issued a substantial number of warrants and equity awards from our equity plans which are exercisable into shares of our common stock which could result in substantial dilution to the ownership interests of our existing stockholders.

As of March 31, 2024, approximately 11,640,594 shares of our common stock were reserved for issuance upon exercise of pre-funded warrants. Additionally, 10,602,152 shares of our common stock were reserved for issuance upon exercise of outstanding stock options and vested restricted stock units. The exercise or conversion of these securities will result in a significant increase in the number of outstanding shares and substantially dilute the ownership interests of our existing stockholders. The shares underlying the equity awards from our equity plans are registered on a Form S-8 registration statement. As a result, upon vesting these shares can be freely exercised and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of options and the subsequent sale of the underlying common stock could cause a decline in our stock price.
Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we issue additional equity securities to raise capital or pursuant to our equity incentive plans or other contractual obligations, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell or issue common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

In addition, sales of a substantial number of shares of our outstanding 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 of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock that many of them are now able to sell in the public market. Significant portions of these shares are held by a relatively small number of stockholders, none of whom have entered into agreements restricting their ability to sell their shares. Sales by our stockholders of a substantial number of shares or distributions of their holdings to their respective limited partners and other equity holders, or the expectation that such sales or distributions, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

Further, because we expect we will need to raise additional capital to fund our future activities, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. Future issuances of common stock or common stock-related securities, together with the exercise of outstanding stock options or warrants, the vesting and settlement of outstanding restricted stock units, and new equity awards granted under our equity incentive plans, if any, may result in further dilution. Pursuant to the sales agreement, or Sales Agreement, with Cowen and Company, LLC, or Cowen, we may offer and sell up to an aggregate amount of $250.0 million of our common stock from time to time in “at-the-market” offerings, subject to the limitations thereof. As of March 31, 2023, approximately $50 million worth of common stock had been sold under the Sales Agreement. To the extent that we sell additional shares of our common stock in the future pursuant to the Sales Agreement, investors purchasing shares of our common stock could experience further dilution.

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 of common stock intend to sell shares, could reduce the market price of our common stock.

Shares issued upon the exercise of stock options outstanding or settlement of restricted stock units under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed registration statements on Form S-8 registering the issuance of shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

The sale or issuance of our common stock to, or through, Cowen may cause significant dilution and the sale of the shares of common stock acquired by Cowen, or the perception that such sales may occur, could cause the price of our common stock to fall.

On October 1, 2021, we entered into a Sales Agreement with Cowen, pursuant to which we may offer and sell our common stock, subject to certain limitations in the Sales Agreement and compliance with applicable law, at any time throughout the term of the Sales Agreement. The number of shares that are sold by Cowen after delivering a placement notice will fluctuate based on the market price of the common stock during the sales period and limits we set with Cowen. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. Sales to, or through, Cowen by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. From October 1, 2021 through March 31, 2024, we have sold any 1,519,453 shares of common stock through the Cowen sales agreement.

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

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. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

We may be at an increased risk of securities class action litigation.

Historically, 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 biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Risks Related to Tax

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. These changes could subject us to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made and changes are likely to continue to occur in the future.

As we expand the scale of our business activities, any changes in the U.S. and non-U.S. taxation of such activities may increase our effective tax rate and harm our business, financial condition and results of operations. You are urged to consult your tax advisor regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations, and, as a result, unavailable to reduce our future tax liability

As of December 31, 2023, we had federal and state net operating loss carryforwards of $160.5 million and $161.3 million, respectively, which begin to expire in various amounts in 2036 (other than federal net operating loss carryforwards arising in taxable years beginning after December 31, 2017, which are not subject to expiration but the deductibility of such federal NOLs may be limited to 80% of our taxable income annually for tax years beginning after December 31, 2020). As of December 31, 2023, we also had federal and state research and development tax credit carryforwards of $19.5 million and $8.1 million, respectively, which begin to expire in 2036. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increases by more than 50 percentage points over the lowest ownership percentage of such stockholders or groups of stockholders within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and limit our ability to utilize NOLs or credit. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "Risk Factors—Risks Related to our Financial Position and Need for Additional Capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credit carryforwards that are subject to limitation by Sections 382 and 383 of the Code.

Risks Related to Our Controls and Reporting Requirements

If we fail to maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell any of our present or future product candidates that may receive regulatory approval.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, 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. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to Our Charter and Bylaws

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation and our second amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

•a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

•a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

•the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (3) any action asserting a claim pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled, and other state courts have upheld the validity of, that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
During the quarter ended March 31, 2024, we did not have any sales of unregistered securities.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
None.

Item 5. Other Information.

The following table discloses any officer (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) or director who adopted a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the three months ended March 31, 2024:

Name and Title	Type of Trading Arrangement	Action Taken (Date of Action)	Duration or End Date	Aggregate Number of Securities to be Sold	Description of Trading Arrangement
Joanna Horobin *Director*	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5- 1(c)	Adoption (March 8, 2024)	July 1, 2025	34,000	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan

Other than as disclosed above, no other officer or director adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the three months ended March 31, 2024.

Item 6. Exhibits.

Exhibit Number	Description
10.1#	Amended and Restated Non-Employee Director Compensation Policy dated March 27, 2024.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
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

# Indicates a management contract or any compensatory plan, contract or arrangement.
* This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

Kymera Therapeutics, Inc.

Date: May 2, 2024 By: /s/ Nello Mainolfi, Ph.D.
Nello Mainolfi, Ph.D.
President and Chief Executive Officer

Date: May 2, 2024 By: /s/ Bruce Jacobs, CFA, MBA
Bruce Jacobs, CFA, MBA
Chief Financial Officer

Exhibit 10.1

KYMERA THERAPEUTICS, INC.

AMENDED AND RESTATED

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Non-Employee Director Compensation Policy (the "Policy") of Kymera Therapeutics, Inc. (the "Company") is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiary ("Outside Directors"). In furtherance of the purpose stated above, all Outside Directors shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership: $40,000 for general availability and participation in meetings and conference calls of our Board of Directors, to be paid quarterly in arrears, pro-rated based on the number of actual days served by the director during such calendar quarter. No additional compensation will be paid for attending individual meetings of the Board of Directors.

Additional Annual Retainer for Chairperson of the Board:	$30,000
Additional Annual Retainer for Lead Independent Director of the Board:	$20,000
Additional Annual Retainers for Committee Membership:	
Audit Committee Chair:	$20,000
Audit Committee member:	$10,000
Compensation Committee Chair:	$15,000
Compensation Committee member:	$7,500
Nominating and Corporate Governance Committee Chair:	$10,000
Nominating and Corporate Governance Committee member:	$5,000

Chair and committee member retainers are in addition to retainers for members of the Board of Directors. No additional compensation will be paid for attending individual committee meetings of the Board of Directors.

Equity Retainers

Initial Award: An initial, one-time stock option award (the "Initial Award") to purchase 32,000 shares will be granted to each new Outside Director upon his or her election to the Board of Directors, which shall vest in 36 equal monthly installments over three years from the date of grant, provided, however, that all vesting shall cease if the director resigns from the Board of Directors or otherwise ceases to serve as a director of the Company. The Initial Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2020 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Annual Award: On each date of each Annual Meeting of Stockholders of the Company (the "Annual Meeting"), each continuing Outside Director, other than a director who has received an Initial Award in the same calendar year of the Annual Meeting for a particular year, will receive an annual stock option award (the "Annual Award") to purchase 16,000 shares, which shall vest in full upon the earlier of (i) the first anniversary of the date of grant or (ii) the date of the next Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the

circumstances warrant continuation of vesting. Such Annual Award shall expire ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2020 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

Value: For purposes of this Policy, "Value" means with respect to (i) any stock option award, the grant date fair value of the option (i.e., Black-Scholes Value) determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under Financial Accounting Standard Board ("FASB") Accounting Standards Codification ("ASC") Topic 718; and (ii) any award of restricted stock or restricted stock units the product of (A) the average closing market price on Nasdaq Global Market (or such other market on which the Company's common stock is then principally listed) of one share of the Company's common stock over the trailing 30-day period ending on the last day of the month immediately prior to the month of the grant date, and (B) the aggregate number of shares of common stock underlying such award.

Sale Event Acceleration: All outstanding Initial Awards and Annual Awards held by an Outside Director shall become fully vested and exercisable upon a Sale Event (as defined in the Company's 2020 Stock Option and Incentive Plan).

Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board of Directors or any committee thereof.

Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid by the Company to any Outside Director in a calendar year for services as an Outside Director period shall not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable Outside Director is initially elected or appointed to the Board of Directors; (or such other limits as may be set forth in Section 3(b) of the Company's 2020 Stock Option and Incentive Plan or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with FASB ASC Topic 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

Adopted August 11, 2020, subject to the effectiveness of the Company's Registration Statement on Form S-1.

Amended and Restated on January 17, 2022.

Amended and Restated on March 27, 2024.

Exhibit 31.1

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

I, Nello Mainolfi, Ph.D., certify that:

1.I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Kymera Therapeutics, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 2, 2024

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

Exhibit 31.2

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

I, Bruce Jacobs, CFA, MBA, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Kymera Therapeutics, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 2, 2024

By: /s/ Bruce Jacobs, CFO, MBA
Bruce Jacobs, CFO, MBA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Kymera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 2, 2024

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Kymera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 2, 2024

By: /s/ Bruce Jacobs, CFA, MBA
Bruce Jacobs, CFA, MBA
Chief Financial Officer
(Principal Financial Officer)