UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41837

Mural Oncology plc

(Exact Name of Registrant as Specified in its Charter)

Ireland	**98-1748617**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10 Earlsfort Terrace Dublin 2, D02 T380, Ireland	**Not Applicable**
(Address of principal executive offices)	**(Zip Code)**

+353-1-905-8020

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, nominal value $0.01 per share	MURA	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 December 1, 2023, the registrant had 16,689,733 ordinary shares, nominal value $0.01 per share, outstanding.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report in Form 10-Q includes forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements in this Quarterly Report, other than statements of historical facts, including statements about future events, future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words “may,” “will,” “would,” “could,” “should,” “believes,” “estimates,” “projects,” “potential,” “expects,” “plans,” “seeks,” “intends,” “evaluates,” “pursues,” “anticipates,” “continues,” “designs,” “impacts,” “affects,” “forecasts,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal” or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- our post-separation relationships with Alkermes, third parties, collaborators and our employees;
- our ability to operate as a standalone company and execute our strategic priorities;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, 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 efficiently discover and develop product candidates;
- our ability and the potential of third parties to successfully manufacture our drug substances 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;
- the safety profile and related adverse events of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our products, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, revenue, 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 product, if approved;
- 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 U.S. and relevant non-U.S. countries;

•our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

•our ability to manufacture, or have manufactured, our products or product candidates;

•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 U.S. and non-U.S. laws and regulations;

•developments relating to our competitors and our industry;

•potential indemnification liabilities that we may owe to Alkermes following the separation;

•the tax treatment of the separation and distribution and the limitations imposed on us under the tax matters agreement that we have entered into with Alkermes;

•the impact of global economic and political developments on our business, including rising inflation and interest rates, capital market disruptions, bank failures, government shutdowns, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our ordinary shares and our ability to access capital markets; and

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

See Part II, Item 1A, “Risk Factors” for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this Quarterly Report. If any of these risks materialize, or if any of the above assumptions underlying forward-looking statements prove incorrect, actual results and developments may differ materially from those made in or suggested by the forward-looking statements contained in this Quarterly Report. For the reasons described above, we caution you against relying on any forward-looking statements, which should also be read in conjunction with the other cautionary statements that are included elsewhere in this Quarterly Report and our other filings with the Securities and Exchange Commission. Any forward-looking statement made by us in this Quarterly Report speaks only as of the date thereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update or to revise any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by law.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks that, if realized, could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the “Risk Factors” section of this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

•Because we have a very limited operating history as a standalone company, valuing our business and predicting our prospects is challenging. In addition, we may not achieve some or all of the expected benefits of our separation from Alkermes in November 2023 pursuant to which we became an independent company following the distribution by Alkermes of our ordinary shares to Alkermes shareholders.

•Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future. We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

•We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.

•Our business is highly dependent on the success of our lead product candidate, nemvaleukin, as well as the other product candidates in our pipeline. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize our product candidates, or if we experience delays in doing so, our business will be materially harmed.

•Biopharmaceutical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

•Delays or difficulties in the enrollment of patients in our clinical trials could cause our clinical development activities to be delayed or otherwise adversely affected, which could materially impact our business.

•If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

•Side effects, serious adverse events, or other undesirable properties or outcomes could be discovered or arise from the use of our product candidates and, in turn, could delay or halt clinical trials, delay or prevent regulatory approval, result in a restrictive label being required for our products, if approved, or result in significant negative consequences following any marketing approval.

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

•The regulatory approval process for our product candidates will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

•Manufacturing of biological products is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.

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

•We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

•We have not yet manufactured our product candidates on a commercial scale and expect to rely on third parties to produce and process commercial quantities of our product candidates, if approved.

•We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates, or the scope of our patent protection could be insufficiently broad, which could result in competition and a decrease in the potential market share for our product candidates.

•If the separation and distribution, in relevant part and together with certain related transactions, do not qualify as transactions that are tax-free for U.S. federal income tax purposes, certain U.S. subsidiaries of Alkermes and Alkermes' shareholders could be subject to significant tax liabilities, and we could be required to indemnify Alkermes or its subsidiaries for material taxes pursuant to indemnification obligations under the tax matters agreement which we entered into with Alkermes in connection with the separation.

•We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors.

•The price of our ordinary shares could be subject to volatility related or unrelated to our operations. An active trading market for our ordinary shares may not develop or be sustained and our shareholders may not be able to resell their ordinary shares.

•We are incorporated under the laws of Ireland. Irish law differs from the laws in effect in the U.S. and might afford less protection to the holders of our securities, and any actual or potential takeover offer for us will be subject to the Irish Takeover Rules.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Mural Oncology plc
Condensed Combined Balance Sheets
(Unaudited)

	September 30, 2023	December 31, 2022
	(In thousands)	
ASSETS		
CURRENT ASSETS:		
Prepaid expenses	$ 2,258	$ 2,987
Other current assets	2,703	1,830
Total current assets	4,961	4,817
Property and equipment, net	10,907	10,617
Right-of-use assets	14,153	18,316
Other assets	181	—
TOTAL ASSETS	$ 30,202	$ 33,750
LIABILITIES AND NET PARENT INVESTMENT		
CURRENT LIABILITIES:		
Accounts payable	$ 3,501	$ 2,966
Accrued expenses	16,894	32,750
Operating lease liabilities—short-term	6,013	5,844
Total current liabilities	26,408	41,560
Operating lease liabilities—long-term	10,467	13,542
Other long-term liabilities	219	304
Total liabilities	37,094	55,406
Commitments and contingencies (Note 8)		
Net parent investment	(6,892)	(21,656)
Total net parent investment	(6,892)	(21,656)
TOTAL LIABILITIES AND NET PARENT INVESTMENT	$ 30,202	$ 33,750

See accompanying notes to the unaudited condensed combined financial statements.

Mural Oncology plc
Condensed Combined Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands except share and per share amounts)			
Operating expenses				
Research and development	$ 40,354	$ 44,774	$ 123,290	$ 124,798
General and administrative	5,959	4,529	14,436	12,763
Total operating expenses	46,313	49,303	137,726	137,561
Operating loss	(46,313)	(49,303)	(137,726)	(137,561)
Income tax provision	4,966	1,341	10,185	3,664
Net loss and comprehensive loss	$ (51,279)	$ (50,644)	$ (147,911)	$ (141,225)
Loss per share attributable to Mural Oncology plc shareholders - basic and diluted	$ (3.07)	$ (3.03)	$ (8.86)	$ (8.46)
Number of basic and diluted shares outstanding	16,689,733	16,689,733	16,689,733	16,689,733

See accompanying notes to the unaudited condensed combined financial statements.

Mural Oncology plc
Condensed Combined Statements of Changes in Net Parent Investment
(Unaudited)

	Total Net Parent Investment (In thousands)
Balance, December 31, 2022	$ (21,656)
Net loss	(46,844)
Share-based compensation expense	2,753
Net transfers from parent	56,512
Balance, March 31, 2023	$ (9,235)
Net loss	(49,788)
Share-based compensation expense	3,141
Net transfers from parent	45,649
Balance, June 30, 2023	$ (10,233)
Net loss	(51,279)
Share-based compensation expense	2,983
Net transfers from parent	51,637
Balance, September 30, 2023	$ (6,892)

	Total Net Parent Investment (In thousands)
Balance, December 31, 2021	$ (17,879)
Net loss	(47,262)
Share-based compensation expense	1,961
Net transfers from parent	56,443
Balance, March 31, 2022	$ (6,737)
Net loss	(43,319)
Share-based compensation expense	3,294
Net transfers from parent	39,632
Balance, June 30, 2022	$ (7,130)
Net loss	(50,644)
Share-based compensation expense	3,479
Net transfers from parent	39,995
Balance, September 30, 2022	$ (14,300)

See accompanying notes to the unaudited condensed combined financial statements.

Mural Oncology plc
Condensed Combined Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (147,911)	$ (141,225)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	1,954	1,043
Share-based compensation expense	8,877	8,734
Changes in assets and liabilities:		
Prepaid expenses	729	(1,064)
Other assets	(1,054)	(1,276)
Right-of-use assets	5,648	4,452
Accounts payable and accrued expenses	(15,291)	3,131
Operating lease liabilities	(4,391)	(4,448)
Other long-term liabilities	(85)	(49)
Cash flows used in operating activities	(151,524)	(130,702)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property and equipment	(2,274)	(5,368)
Cash flows used in investing activities	(2,274)	(5,368)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net transfers from parent	153,798	136,070
Cash flows provided by financing activities	153,798	136,070
Net increase in cash, cash equivalents and restricted cash	—	—
Cash, cash equivalents and restricted cash—Beginning of period	—	—
Cash, cash equivalents and restricted cash—End of period	$ —	$ —
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 345	$ 392

See accompanying notes to the unaudited condensed combined financial statements.

1. Organization and Description of Business

The accompanying carve-out financial statements present the condensed combined, historical financial position, results of operations, net parent investment and cash flows of Alkermes plc, an Irish public limited company, and its consolidated subsidiaries' ("Alkermes" or the "Parent") oncology business (the "oncology business") as it was historically managed as part of Alkermes prior to the completion of the separation of Alkermes' oncology business from Alkermes' neuroscience business, and the creation, as a result of the distribution (as defined below) of an independent, publicly traded company, Mural Oncology plc, an Irish public limited company ("Mural" or "the Company"), which held the assets, liabilities and operations associated with the oncology business, as of November 15, 2023.

Mural is a clinical-stage oncology business focused on discovering and developing immunotherapies that may meaningfully improve the lives of patients with cancer. Mural's lead product candidate, nemvaleukin alfa, is an investigational, engineered interleukin-2 cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human interleukin-2, while mitigating its hallmark toxicities. By leveraging its core competencies in immune cell modulation and protein engineering, Mural has developed a portfolio of investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers.

Mural is subject to risks and uncertainties common to early-stage companies in the biotechnology industry. There can be no assurance that Mural's research and development ("R&D") will be successfully completed, that any products developed will obtain necessary government regulatory approval or that any products, if approved, will be commercially viable. Mural operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnological companies. In addition, Mural is dependent upon the services of its employees, consultants and service providers. Even if Mural's product development efforts are successful, it is uncertain when, if ever, Mural will realize significant product revenue from product sales.

The Separation

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore separation (the "Separation") of its neuroscience business and oncology business. On November 14, 2023, in connection with the Separation, Mural received a cash contribution of $275.0 million from Alkermes. Alkermes effected the Separation through the distribution of the ordinary shares of Mural to Alkermes' shareholders (the "Distribution") on November 15, 2023.

As part of the Separation and subsequent to September 30, 2023, Alkermes transferred the assets, liabilities and operations of the historical oncology business to Mural, pursuant to the terms of a separation agreement, entered into between Mural and Alkermes. On the effective date of the Distribution, each Alkermes shareholder received one ordinary share of Mural for every ten ordinary shares of Alkermes held as of the close of business on November 6, 2023. Registered shareholders received cash in lieu of any fractional Mural ordinary shares that they would have received as a result of the application of the distribution ratio. Following the Separation and Distribution, Mural operates as an independent, publicly traded company. The Distribution was subject to the satisfaction or waiver by Alkermes of certain conditions. See Note 12, *Subsequent Events*, for further discussion of the Separation and Distribution.

Going Concern

The management of Mural has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about Mural's ability to continue as a going concern within one year after the date that the unaudited condensed combined financial statements are issued.

As Alkermes managed Mural's cash and financing arrangements prior to the Separation, excess cash generated, if any, was deemed remitted to the Parent and all sources of cash were deemed funded by the Parent. Mural has generated operating losses for all the historical periods presented and expects to continue to generate operating losses for the foreseeable future.

Mural expects to fund its operations and capital needs through the funding received from the Parent through the date of the Separation. As described in Note 12, Subsequent Events, on November 14, 2023, in connection with the Separation, Mural received a cash contribution of $275.0 million from the Parent, which alleviated the conditions that previously raised substantial doubt about Mural's ability to continue as a going concern. Mural believes that its cash resources, including the funding received subsequent to September 30, 2023, will be sufficient to fund its anticipated operations and capital needs for at least twelve months from the date these financial statements were issued. See Note 12, *Subsequent Events,* for further discussion of the cash contribution.

Mural's continued operations are dependent on the funding received from the Parent through the Separation and on its ability to generate cash from operating activities and to raise additional capital to finance its future operations subsequent to the Separation. If Mural is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of the planned research or development programs or be unable to expand or continue operations. There is no assurance that Mural will be successful in obtaining sufficient funding on terms acceptable to Mural to fund continuing operations, if at all.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed combined financial statements of Mural have been prepared on a standalone basis and are derived from Alkermes' consolidated financial statements and accounting records. The unaudited condensed combined financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and reflect the historical results of operations, financial position and cash flows of Mural, as included in the consolidated financial statements of the Parent and using the Parent's historical accounting policies. These unaudited condensed combined financial statements do not purport to reflect what Mural's results of operations, financial position or cash flows would have been had Mural operated as a standalone public company during the periods presented, nor are they necessarily indicative of Mural's future results of operations, financial position, or cash flows.

As Mural's operations were not held by a single legal entity or separate legal entities prior to the Separation, net parent investment is shown in lieu of stockholders' equity in the unaudited condensed combined financial statements. Net parent investment represents the cumulative investment by the Parent in Mural through the dates presented, inclusive of operating results. All transactions between Mural and the Parent are considered to be effectively settled in the unaudited condensed combined financial statements at the time the transaction is recorded. The effects of the settlement of these transactions between Mural and the Parent are reflected in the unaudited condensed combined statements of cash flows as "Net transfers from parent" within financing activities and in the unaudited condensed combined balance sheets and unaudited condensed combined statements of changes in net parent investment as "Net parent investment." All intercompany transactions and accounts within Mural have been eliminated.

Historically, Mural was dependent upon the Parent for all of its working capital and financing requirements, as the Parent uses a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to Mural for the historical periods presented; therefore, cash and cash equivalents have not been included in the unaudited condensed combined financial statements. Financing transactions related to the Parent are accounted for as a component of net parent investment in the unaudited condensed combined balance sheets and as a financing activity on the accompanying unaudited condensed combined statements of cash flows.

The unaudited condensed combined financial statements of Mural include the assets, liabilities, and expenses of the Parent that management has determined are specifically identifiable to Mural, such as those related to direct internal and external R&D activities as well as leases and fixed assets specifically identifiable to the oncology business. Based on the nature of Mural as a pre-revenue, development-stage biotechnology company, the unaudited condensed combined financial statements of Mural do not include any revenue or commercial expenses of the Parent. The unaudited condensed combined financial statements of Mural also include an allocation of costs that are not directly attributable to the operations of Mural, including the costs of general and administrative support functions that are provided by the Parent, such as senior management, information technology, legal, accounting and finance, human resources, facility, and other corporate services. In addition, Mural's unaudited condensed combined financial statements include an allocation of certain R&D costs not directly attributable to individual programs. These costs have been allocated to Mural for the purposes of preparing the unaudited condensed combined financial statements based on proportional cost allocation methods using headcount, square footage or proportional hours worked supporting Mural and other organizational activities, as applicable, which are considered to be reasonable reflections of the utilization of services provided or benefit received by Mural during the periods presented. Management considers that such allocations have been made on a reasonable basis; however, these allocations may not necessarily be indicative of the costs that would have been incurred if Mural had operated on a standalone basis for the periods presented and, therefore, may not reflect Mural's results of operations, financial position, and cash flows had Mural operated as a standalone entity during the periods presented. See Note 9, *Related Parties*, for additional information regarding related-party transactions with the Parent.

Following the Separation, Mural has incurred and expects to continue to incur additional operating expenses to operate as an independent publicly traded company, including various corporate functions, incremental information technology-related costs and incremental costs to operate standalone accounting, legal and other administrative functions. These functions were provided to Mural by the Parent prior to the Separation and will continue under transition services agreements with the Parent or will be performed using Mural's own resources.

Unaudited Interim Financial Information

The accompanying unaudited condensed combined balance sheet as of September 30, 2023 and the unaudited condensed combined statements of operations and comprehensive loss, of changes in net parent investment for the three and nine months ended September 30, 2023 and 2022, and of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The unaudited interim condensed combined financial statements have been prepared on the same basis as the audited annual combined financial statements included in Exhibit 99.1 to Mural's Registration Statement on Form 10, which was most recently filed with the Securities and Exchange Commission (the "SEC") on October 26, 2023 (the "Form 10") and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of Mural's financial position as of September 30, 2023, the results of its operations for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are also unaudited. The condensed combined balance sheet as of December 31, 2022 was derived from the Parent's audited financial statements but does not include all disclosures required by GAAP. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the SEC for interim financial statements. These unaudited interim condensed combined financial statements should be read in conjunction with the audited annual combined financial statements as of and for the year ended December 31, 2022 and the notes thereto, which are included in the Form 10.

Use of Estimates

The preparation of Mural's unaudited condensed combined financial statements in accordance with GAAP requires Mural to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities. On an ongoing basis, Mural evaluates its estimates and judgments and methodologies, including but not limited to, those related to allocations of expenses, assets and liabilities from the Parent's historical financials to Mural, the impairment of long-lived assets, share-based compensation, leases, and income taxes including the valuation allowance for deferred tax assets. Mural bases its estimates on historical experience of the Parent and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Significant Accounting Policies

The significant accounting policies used in preparation of these unaudited condensed combined financial statements for the three and nine months ended September 30, 2023 and 2022 are consistent with those discussed in Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, within the combined financial statements for the year ended December 31, 2022 included in the Form 10.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standard-setting bodies that are adopted by Mural as of the specified effective date. Unless otherwise discussed, Mural believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280)*. The update requires public entities to disclose significant segment expenses that are regularly provided to the chief operating decision maker and to disclose how reported measures of segment profit or loss are used in assessing segment performance and allocating resources. The amendments in this ASU are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Mural is evaluating the impact of the adoption of this ASU on its consolidated financial statements and disclosures.

3. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Furniture, fixtures and equipment	$ 20,157	$ 17,470
Leasehold improvements	23,229	22,510
Construction in progress	827	1,989
Subtotal	44,213	41,969
Less: accumulated depreciation and amortization	(33,306)	(31,352)
Total property and equipment, net	$ 10,907	$ 10,617

4. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Accrued external research and development services	$ 11,002	$ 25,298
Accrued compensation	5,682	7,104
Accrued general and administrative	157	302
Accrued other	53	46
Total accrued expenses	$ 16,894	$ 32,750

5. Leases

Mural's only lease as of September 30, 2023 and December 31, 2022 was an operating lease for approximately 180,000 square feet of corporate office space, administrative areas and laboratories at 850 and 852 Winter Street in Waltham, Massachusetts (the "Winter Street Lease"), which includes 34,000 square feet of laboratory space. The original lease commenced in 2010 and was extended, at the Parent's option, for approximately five years in 2020. The lease extension commenced in March 2021 for approximately 163,000 square feet of space and in September 2021 for the remaining approximately 17,000 square feet of space. The Winter Street Lease expires in 2026 and includes a tenant option to extend the term of the lease for an additional period, which Mural is not reasonably certain to exercise. The Winter Street Lease was assigned to Mural in connection with the Separation and will be used solely for operations of Mural. The Parent has been primarily obligated to the landlord for the Winter Street Lease, and, following the Separation, the Parent will be jointly and severally liable with Mural for, and will continue to guarantee, all obligations under the Winter Street Lease. Furthermore, the Parent is the applicant with respect to the letter of credit security deposit that secures the obligations of the tenant under the Winter Street Lease. The Parent maintained a $1.9 million collateralized letter of credit (the "Letter of Credit") related to such security deposit as of September 30, 2023. As Mural did not have legal ownership over any bank accounts as of September 30, 2023, there were no cash or cash equivalents balances specifically attributable to Mural for the historical periods presented and, accordingly, no amount is reflected in the combined financial statements related to the letter of credit.

The following table summarizes the effect of lease costs in Mural's unaudited condensed combined statements of operations:

(In thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating lease cost	$ 1,419	$ 1,550	$ 4,388	$ 4,651
Variable lease cost	1,158	968	3,741	2,646
Total lease costs	$ 2,577	$ 2,518	$ 8,129	$ 7,297

Future lease payments under non-cancelable leases as of September 30, 2023 consisted of the following:

(In thousands)	September 30, 2023
Remainder of 2023	$ 1,600
2024	6,496
2025	6,642
2026	2,484
Total operating lease payments	$ 17,222
Less: imputed interest	(742)
Total operating lease liabilities	$ 16,480

As of September 30, 2023, the incremental borrowing rate and the remaining lease term for the Winter Street Lease were 3.52% and 3.1 years, respectively. During the three and nine months ended September 30, 2023, cash paid by the Parent for amounts included for the measurement of lease liabilities was $1.6 million and $4.8 million, respectively. During the three and nine months ended September 30, 2022, cash paid by the Parent for amounts included for the measurement of lease liabilities was $1.6 million and $4.6 million, respectively. These cash payments are included within cash flows from operating activities.

6. Share-Based Compensation

The following table represents share-based compensation expense included in Mural's unaudited condensed combined statements of operations and comprehensive loss:

(In thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Research and development	$ 1,401	$ 2,712	$ 6,000	$ 6,962
General and administrative	1,582	767	2,877	1,772
Total share-based compensation expense	$ 2,983	$ 3,479	$ 8,877	$ 8,734

7. Income Taxes

During the three months ended September 30, 2023 and 2022, Mural recorded income tax provisions of $5.0 million and $1.3 million, respectively, related to its U.S. entity. During the nine months ended September 30, 2023 and 2022, Mural recorded income tax provisions of $10.2 million and $3.7 million, respectively, related to its US entity. The income tax provisions were primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Internal Revenue Code of 1986, as amended. The increased tax provisions for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 and for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022 were primarily due to lower R&D tax credits available in 2023. The provisions were calculated on a separate return basis and are not necessarily representative of the tax provision that may arise in the future. Net operating losses previously reported by the Parent will not carry over to Mural after the Separation.

On a quarterly basis, the Company reassesses the valuation allowance on its deferred tax assets, weighing positive and negative evidence to determine the recoverability of such deferred tax assets. In the third quarter of 2023, the Company reassessed the valuation allowance and considered all positive and negative evidence, including its cumulative losses over the year ended December 31, 2022 and concluded that it should maintain the valuation allowance on its Irish net operating losses and other Irish and U.S. deferred tax assets as of September 30, 2023.

8. Commitments and Contingencies

Mural, from time to time, may be involved with lawsuits arising in the ordinary course of business. Mural is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows.

See Note 5, *Leases*, for information related to Mural's lease obligations.

9. Related Parties

Corporate expenses represent shared costs of the Parent that have been allocated to Mural based on a systematic and rational methodology and are reflected as expenses in these unaudited condensed combined financial statements. These amounts include, but are not limited to, items such as general management and executive oversight, costs to support Mural's information technology infrastructure, facilities, compliance, human resources, legal and finance functions, risk management, and share-based compensation administration, all of which support the operations of the Parent as a whole. Corporate expense allocations in the periods prior to the Separation were generally allocated to Mural based on proportional cost allocation methods using headcount, square footage, or proportional hours worked supporting Mural and other organizational activities, as applicable, which are considered to be reasonable reflections of the utilization of services provided or benefit received by Mural during the periods presented. Total corporate expense allocations in general and administrative were $2.5 million and $8.8 million during the three and nine months ended September 30, 2023, respectively. Total corporate expense allocations in general and administrative were $2.8 million and $8.8 million during the three and nine months ended September 30, 2022, respectively.

Management considers the allocation methodologies used to be reasonable and appropriate reflections of the related expenses attributable to Mural for purposes of the unaudited condensed combined financial statements; however, the expenses reflected in these unaudited condensed combined financial statements may not be indicative of the actual expenses that would have been incurred during the periods presented if Mural had operated as a standalone entity. In addition, the expenses reflected in the unaudited condensed combined financial statements may not be indicative of expenses that will be incurred in the future by Mural.

See Note 1, *Organization and Description of Business*, for details of Mural's cash and financing arrangements. As of the date these unaudited condensed combined financial statements were available for issuance, there was no existing intercompany debt or other financing agreement in place with the Parent.

10. Restructuring

On July 12, 2023, in conjunction with the Parent's ongoing review of operations and the planned separation of the oncology business, the Parent executed a restructuring plan, which included the elimination of certain positions that were intended to transition to Mural (the "Restructuring"). Of the charge the Parent recorded in the third quarter of 2023 as a result of the Restructuring, $1.6 million was attributable to Mural. Such charge consists of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures by the Parent, and substantially all of which were paid by the Parent as of September 30, 2023. Substantially all of the charge related to the Restructuring was included in research and development expenses in the Company's unaudited condensed combined statements of operations and comprehensive loss for the three and nine months ended September 30, 2023.

11. Earnings per Share

On November 15, 2023, the effective date of the Distribution, 16,689,733 ordinary shares of Mural were distributed to Alkermes shareholders of record as of November 6, 2023, the record date. This share amount was utilized for the calculation of basic and diluted earnings per share for all periods prior to the Separation. For the three and nine months ended September 30, 2023 and 2022, these shares were treated as issued and outstanding for the purpose of calculating historical earnings per share. There were no dilutive equity instruments as there were no equity awards of Mural outstanding prior to the Separation.

12. Subsequent Events

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore the Separation of its neuroscience business and oncology business. Alkermes effected the Separation through the Distribution of the ordinary shares of Mural to Alkermes' shareholders on November 15, 2023.

In connection with the Separation, on November 13, 2023, Mural entered into certain agreements with the Parent to provide a framework for Mural's relationship with the Parent following the Separation. These agreements were summarized in the Form 10 and include:

- a separation agreement, which set forth Mural's agreements with the Parent regarding the principal actions to be taken in connection with the separation, including the distribution;

•a tax matters agreement, which governs Mural's and the Parent's respective rights, responsibilities, and obligations with respect to taxes, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters;

•an employee matters agreement, which governs Mural's and the Parent's rights, responsibilities, and obligations after the Separation with respect to employment, benefits and compensation matters;

•a lease assumption agreement, under the terms of which Mural assumed all of the Parent's obligations under the Winter Street Lease; and

•transition services agreements, pursuant to which, the Parent will provide, on an interim, transitional basis, various services to Mural and Mural will provide, on an interim, transitional basis, various services to the Parent.

On November 14, 2023, in connection with the Separation, Mural received a cash contribution of $275.0 million from the Parent. $1.9 million of the cash contribution will be restricted after the Separation for use pertaining to the Letter of Credit for the Winter Street Lease and for corporate credit cards.

On November 15, 2023, the Parent completed the Separation of its oncology business into Mural, a new, independent, publicly-traded company. As part of the Separation, Alkermes transferred the assets, liabilities and operations of the historical oncology business to Mural, pursuant to the terms of a separation agreement entered into between Mural and Alkermes. Liabilities incurred prior to the Separation remained obligations of Alkermes unless otherwise specified in the agreements entered into between Mural and Alkermes. On the effective date of the Distribution, each Alkermes shareholder received a one ordinary share of Mural for every ten ordinary shares of Alkermes held. Registered shareholders received cash in lieu of any fractional Mural ordinary shares that they would have received as a result of the application of the distribution ratio. Following the Separation and Distribution, Mural operates as an independent, publicly traded company. The Distribution was subject to the satisfaction or waiver by Alkermes of certain conditions. As a result of the Separation and Distribution, Mural became an independent public company and commenced regular way trading under the symbol "MURA" on the Nasdaq Global Market on November 16, 2023.

In connection with the Separation, the Company adopted the Mural Oncology plc 2023 Stock Option and Incentive Plan. Under the employee matters agreement, Mural is obligated to convert all outstanding Alkermes stock options and Alkermes restricted stock units held by Mural employees as of the date of the Separation into Mural stock options and Mural restricted stock units in accordance with the terms of the employee matters agreement. The conversion of outstanding Alkermes awards is expected to be completed in December 2023.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying unaudited condensed combined financial statements and related notes included in this quarterly report on Form 10-Q and the audited annual combined financial statements as of and for the year ended December 31, 2022 and the related notes included in Exhibit 99.1 to our Registration Statement on Form 10, which was most recently filed with the Securities and Exchange Commission (the "SEC") on October 26, 2023 (the "Form 10"). This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, including those set forth under "Risk Factors" appearing elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage oncology business focused on discovering and developing immunotherapies that may meaningfully improve the lives of patients with cancer. By leveraging our core competencies in immune cell modulation and protein engineering, we have developed a portfolio of investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers. Our lead product candidate, nemvaleukin alfa ("nemvaleukin"), is an investigational, engineered interleukin-2 ("IL-2") cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human IL-2, while mitigating its hallmark toxicities. In our clinical proof of concept study, nemvaleukin generated durable responses as a single agent and in combination with pembrolizumab across a range of tumor types. Nemvaleukin is currently in two potentially registrational studies, one for the treatment of mucosal melanoma as a monotherapy and one for the treatment of platinum-resistant ovarian cancer ("PROC") in combination with pembrolizumab. We plan to report topline results from both of these trials in the first quarter of 2025. In addition to nemvaleukin, we are also developing engineered therapies targeting the interleukin-18 ("IL-18") and interleukin-12 ("IL-12") pathways, which have demonstrated therapeutic potential in third-party preclinical and clinical studies. We are currently conducting discovery-phase activities for our IL-18 and IL-12 programs, and we plan to nominate a product candidate in each program in 2024.

ARTISTRY-1, our Phase 1/2 clinical proof of concept study for nemvaleukin in which nemvaleukin is administered intravenously, was designed to assess whether nemvaleukin could recapitulate the anti-tumor activity of high-dose rhIL-2 and to assess nemvaleukin's safety profile. ARTISTRY-2 is a Phase 1/2 open-label study of subcutaneous nemvaleukin in combination with pembrolizumab in patients with advanced solid tumors. ARTISTRY-3 is a Phase 1/2 open-label study of IV nemvaleukin in patients with advanced solid tumors after treatment failure or intolerance to one to three prior FDA-approved targeted therapies. In addition, we are currently evaluating nemvaleukin in two potentially registrational studies: ARTISTRY-6, a Phase 2 study in which Cohort 2 is evaluating nemvaleukin as a monotherapy in patients with advanced mucosal melanoma, and ARTISTRY-7, a Phase 3 study which is evaluating nemvaleukin in combination with pembrolizumab in patients with PROC.

Separation from Alkermes

On November 2, 2022, Alkermes plc (the "Parent" or "Alkermes") announced its intent, as approved by its board of directors, to explore separation (the "Separation") of its neuroscience business and oncology business. On November 14, 2023, in connection with the Separation, Mural received a cash contribution of $275.0 million from Alkermes. Alkermes effected the Separation through the distribution of the ordinary shares of Mural to Alkermes' shareholders (the "Distribution") on November 15, 2023.

As part of the Separation on November 15, 2023, Alkermes transferred the assets, liabilities and operations of the historical oncology business to us, pursuant to the terms of a separation agreement, entered into between Alkermes and us. On the effective date of the Distribution, we issued our ordinary shares to Alkermes shareholders on a pro rata basis, with each Alkermes shareholder receiving one ordinary share of Mural for every ten ordinary shares of Alkermes held as of close of business on November 6, 2023, the record date for the Distribution. Registered shareholders received cash in lieu of any fractional Mural ordinary shares that they would have received as a result of the application of the distribution ratio. Following the Separation and Distribution, we operate as an independent, publicly traded company. For additional information on the Separation and Distribution, see Note 12, *Subsequent Events*, in the notes to our unaudited condensed combined financial statements included elsewhere in this Form 10-Q.

Our historical financial statements have been prepared on a standalone basis and are derived from Alkermes's consolidated financial statements and accounting records. Our unaudited condensed combined financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. ("GAAP"). See Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, in the notes to our unaudited condensed combined financial statements for additional information on the preparation and basis of presentation of our audited combined financial statements and unaudited condensed combined financial statements. Our financial position, results of operations and cash flows historically operated as part of Alkermes' financial position,

results of operations and cash flows prior to and until the Distribution. The unaudited condensed combined financial statements may not be indicative of our future performance and do not necessarily reflect what our results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company during the periods presented. We expect that changes will occur in our operating structure and our capitalization as a result of the Separation from Alkermes.

Components of Results of Operations

Historically, our operations have been managed in the normal course of business as part of the Parent. Accordingly, certain shared costs have been allocated to us and reflected as expenses in the unaudited condensed combined financial statements, as described in greater detail in the notes to the unaudited condensed combined financial statements appearing elsewhere in this report. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical Parent expenses attributable to us for purposes of the standalone financial statements. The expenses reflected in the unaudited condensed combined financial statements may not be indicative of expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believe are necessary for an understanding of our unaudited condensed combined financial statements.

Revenue

To date, we have not recognized any revenue and do not expect to generate substantial product revenue in the near future, if at all, as we do not currently have an approved product. If our development efforts for our product candidates are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from such collaboration or license agreements, or a combination of product sales and payments from such agreements.

Research and Development Expenses

Research and development (“R&D”) expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in R&D are capitalized until the goods or services are received. Our R&D expenses include both external and internal expenses. External R&D expenses include fees for clinical and non-clinical activities performed by contract research organizations (“CROs”), consulting fees and costs related to laboratory services, the purchase of drug product materials and third-party manufacturing development activities. Internal R&D expenses related to the oncology programs include employee-related expenses, occupancy costs and depreciation related to the oncology business.

The amounts set forth in the tables below are not necessarily predictive of future R&D expenses. In an effort to allocate our R&D spending most effectively, we continually evaluate our product candidates under development based on the performance of such product candidates in preclinical and/or clinical trials, our expectations regarding the likelihood of their regulatory approval and our view of their future potential commercial viability, among other factors. For more information regarding risks related to future R&D expenses, please see “Risk Factors—Risks Related to Discovery, Product Development and Regulatory Approval of Our Product Candidates.”

General and Administrative Expenses

General and administrative (“G&A”) expenses consist primarily of an allocation of salaries and related costs for personnel, including share-based compensation and travel expenses for the Parent’s employees in executive, operational, finance, legal, business development, information technology, and human resource functions. Other G&A expenses include an allocation of the Parent’s facility-related costs, professional fees for accounting, tax, legal and consulting services, directors’ fees and expenses associated with obtaining and maintaining patents. We recognize all G&A expenses as incurred. We expect G&A expenses to increase after the Separation as we operate as a standalone public company.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table sets forth our R&D expenses for the three months ended September 30, 2023 and 2022:

(In millions)	Three Months Ended September 30, 2023	2022	Change
External R&D expenses:			
Development programs:			
Nemvaleukin			
ARTISTRY-1	$ 1.0	$ 1.6	$ (0.6)
ARTISTRY-2	1.6	4.8	(3.2)
ARTISTRY-3	1.1	1.1	—
ARTISTRY-6	2.5	2.6	(0.1)
ARTISTRY-7	8.3	7.5	0.8
Other program spend	6.1	4.1	2.0
Early discovery programs	0.9	2.0	(1.1)
Other external R&D expenses	2.9	3.4	(0.5)
Total external R&D expenses	24.4	27.1	(2.7)
Internal R&D expenses:			
Employee-related	12.9	14.8	(1.9)
Occupancy	2.5	2.6	(0.1)
Depreciation	0.6	0.3	0.3
Total internal R&D expenses	16.0	17.7	(1.7)
Research and development expenses	$ 40.4	$ 44.8	$ (4.4)

The decrease in expenses related to nemvaleukin in the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 was primarily due to decreased spend on the ARTISTRY-2 and ARTISTRY-1 trials as activities related to these trials wind down, partially offset by increased spend on the ARTISTRY-7 trial. The decrease in employee-related expense was primarily related to a reduction in the headcount attributable to Mural.

General and Administrative Expenses

The following table sets forth our G&A expenses for the three months ended September 30, 2023 and 2022:

(In millions)	Three Months Ended September 30, 2023	2022	Change
General and administrative expense	$ 6.0	$ 4.5	$ 1.5

The increase in G&A expense was primarily due to an increase in allocable G&A expenses of the Parent, including fees for professional services, such as legal and audit fees, and costs specifically incurred for oncology-related market research.

Income Tax Provision

The following table sets forth our income tax provision for the three months ended September 30, 2023 and 2022:

(In millions)	Three Months Ended September 30, 2023	2022	Change
Income tax provision	$ 5.0	$ 1.3	$ 3.7

The income tax provisions were primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Internal Revenue Code of 1986, as amended (the “Code”). The increased tax provision for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 was primarily due to lower R&D tax credits available in 2023. The income tax provisions were calculated on a separate return basis and are not necessarily representative of the tax provision that may arise in the future. As noted in Note 7, *Income Taxes*, in the notes to our unaudited combined condensed financial

statements included elsewhere in this Form 10-Q, we continue to maintain a valuation allowance on our Irish net operating losses and other Irish and U.S. deferred tax assets as of September 30, 2023.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table sets forth our R&D expenses for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
(In millions)	**2023**	**2022**	**Change**
External R&D expenses:			
Development programs:			
Nemvaleukin			
ARTISTRY-1	$ 7.5	$ 12.1	$ (4.6)
ARTISTRY-2	3.8	9.1	(5.3)
ARTISTRY-3	2.7	1.4	1.3
ARTISTRY-6	6.1	5.8	0.3
ARTISTRY-7	20.5	12.3	8.2
Other program spend	19.0	17.6	1.4
Early discovery programs	3.3	4.8	(1.5)
Other external R&D expenses	9.3	10.3	(1.0)
Total external R&D expenses	72.2	73.4	(1.2)
Internal R&D expenses:			
Employee-related	41.6	43.2	(1.6)
Occupancy	8.0	7.4	0.6
Depreciation	1.5	0.8	0.7
Total internal R&D expenses	51.1	51.4	(0.3)
Research and development expenses	$ 123.3	$ 124.8	$ (1.5)

The increase in expenses related to nemvaleukin in the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to increased spend on the ARTISTRY-7 trial related to increased enrollment and associated clinical trial expenses, partially offset by decreased spend on the ARTISTRY-1 and ARTISTRY-2 trials as activities related to these trials wind down. The decrease in employee-related expense was primarily related to a reduction in the headcount attributable to Mural.

General and Administrative Expenses

The following table sets forth our G&A expenses for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
(In millions)	**2023**	**2022**	**Change**
General and administrative expense	$ 14.4	$ 12.8	$ 1.6

The increase in G&A expense in the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in allocable G&A expenses of the Parent, including fees for professional services, such as legal and audit fees.

Income Tax Provision

The following table sets forth our income tax provision for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
(In millions)	**2023**	**2022**	**Change**
Income tax provision	$ 10.2	$ 3.7	$ 6.5

The income tax provisions for the nine months ended September 30, 2023 and 2022 were primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Code. The increased tax provision for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022 was primarily due to lower R&D tax credits available in 2023. The provisions were calculated on a separate return basis and are not necessarily representative of the tax provision that may arise in the future. As noted in Note 7, *Income Taxes* , in the notes to our unaudited combined condensed financial statements included elsewhere in this Form 10-Q, we continue to maintain a valuation allowance on our Irish net operating losses and other Irish and U.S. deferred tax assets as of September 30, 2023.

Liquidity and Capital Resources

We have historically participated in the Parent's centralized approach to cash management, and, therefore, there were no cash amounts specifically attributable to us for the historical periods presented. Historically, the primary source of liquidity for our business was funding by the Parent of the expenses allocated to the oncology business from the Parent. Prior to the Separation, transfers of cash to and from the Parent have been reflected in net parent investment in the unaudited condensed combined balance sheets, statements of cash flows and statements of changes in net parent investment. We have not reported cash or cash equivalents for the periods presented in the unaudited condensed combined balance sheets. The Parent continued to fund the cash needs of the oncology business through the date of the Separation. On November 14, 2023, in connection with the Separation, we received a cash contribution of $275.0 million from the Parent.

Funding Requirements

Our expenses may increase in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, following the Distribution, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Our expenses may also increase as we:

- leverage our programs to continue advancing our product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and scientific personnel;
- build out commercial infrastructure, as needed, in the event our products obtain marketing approval;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and our operations as a public company; and
- maintain, expand and protect our intellectual property portfolio.

We believe that the contribution of $275.0 million from the Parent to us immediately prior to and in connection with the Separation will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. 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.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. The scope of our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including medical affairs, manufacturing and distribution, if any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the cost of establishing sales, marketing and distribution capabilities if any of our product candidates receive regulatory approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates or products, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of holders of our ordinary shares. 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. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs, products or product candidates or grant licenses on terms that may not be favorable to us.

Furthermore, for the four-year period beginning two years before and ending two years after the Distribution, we will be restricted from entering into certain transactions pursuant to a tax matters agreement we entered into with the Parent. We will be prohibited under the tax matters agreement, except in specific circumstances, from certain actions, including: (i) entering into or approving any transaction involving the acquisition of outstanding or newly issued Mural equity that, when combined with other non-excepted changes in ownership of our ordinary shares, results in a change in ownership of more than a specified percentage; (ii) liquidating or partially liquidating, or merging or consolidating (unless we are the survivor); (iii) making or changing any entity classification election; (iv) ceasing to be engaged in an active trade or business, or selling, transferring or disposing of more than a specified percentage of the assets of any active trade or business or reducing the number of full-time employees engaged in any active trade or business by more than a specified percentage; (v) amending any of our organizational documents or taking any action affecting the voting rights of our ordinary shares; (vi) redeeming or otherwise repurchasing any of our outstanding shares or options; or (vii) taking or failing to take any other action that would prevent the separation and distribution, in relevant part and together with certain related transactions, from qualifying as transactions that are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. For more information, see “Risk Factors — Risks Related to Tax Matters”.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product candidate development or future commercialization efforts, or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and/or market ourselves. See section entitled “Risk Factors—Risks Related to Our Financial Position and Capital Needs.” We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.”

Going Concern

We have evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the unaudited condensed combined financial statements are issued.

As the Parent managed our cash and financing arrangements prior to the Separation, excess cash generated, if any, was deemed remitted to the Parent and all sources of cash were deemed funded by the Parent. We have generated operating losses for all historical periods presented and expect to continue to generate operating losses for the foreseeable future.

We expect to fund operations and capital needs through the funding received from the Parent through the date of the Separation. As described in Note 12, *Subsequent Events*, in the notes to the unaudited condensed combined financial statements, on November 14, 2023, in connection with the Separation, we received a cash contribution of $275.0 million from the Parent, which alleviated the conditions that previously raised substantial doubt about our ability to continue as a going concern. We believe that our cash

resources, including the funding received subsequent to September 30, 2023, will be sufficient to fund our anticipated operations and capital needs into the fourth quarter of 2025.

Our continued operations are dependent on the funding received from the Parent through the Separation and on our ability to generate cash from operating activities and to raise additional capital to finance our future operations subsequent to the Separation. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned R&D programs or be unable to expand or continue operations. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Cash Flows

As Alkermes managed Mural's cash and financing arrangements prior to the Separation, excess cash generated, if any, was deemed remitted to the Parent and all sources of cash were deemed funded by the Parent. The following table summarizes our cash flow activity:

	Nine Months Ended September 30,	
(In millions)	**2023**	**2022**
Cash, cash equivalents and restricted cash, beginning of period	$ —	$ —
Cash flows used in operating activities	$ (151.5)	$ (130.7)
Cash flows used in investing activities	$ (2.3)	$ (5.4)
Cash flows provided by financing activities	$ 153.8	$ 136.1
Cash, cash equivalents and restricted cash, end of period	$ —	$ —

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $151.5 million which was primarily the result of our net loss of $147.9 million, partially offset by non-cash charges of $10.8 million. The most significant non-cash charge we incurred was share-based compensation of $8.9 million. We also used $14.4 million in cash from working capital, primarily related to a $15.3 million decrease in accounts payable and accrued expenses and a $4.4 million decrease in operating lease liabilities, partially offset by a $5.6 million decrease in our right-of-use assets.

Net cash used in operating activities for the nine months ended September 30, 2022 was $130.7 million which was primarily the result of our net loss of $141.2 million, partially offset by non-cash charges of $9.8 million. The most significant non-cash charge we incurred was share-based compensation of $8.7 million. Working capital provided $0.7 million in cash, primarily related to a $4.5 million decrease in right-of-use assets and a $3.1 million increase in accounts payable and accrued expenses, partially offset by a $4.4 million decrease in operating lease liabilities.

Investing Activities

Net cash used in investing activities was $2.3 million and $5.4 million for the nine months ended September 30, 2023 and 2022, respectively, which was attributed to the purchase of property and equipment.

Financing Activities

As the Parent managed our cash and financing arrangements until the Separation, all sources of cash were deemed funded by the Parent. Net cash provided by financing activities for the nine months ended September 30, 2023 and 2022 was due to the funding of our operating and investing activities by the Parent.

Contractual Obligations and Commitments

Our only lease as of September 30, 2023 and December 31, 2022 was an operating lease for approximately 180,000 square feet of corporate office space, administrative areas and laboratories at 850 and 852 Winter Street in Waltham, Massachusetts, which includes 34,000 square feet of laboratory space (as amended, the "Winter Street Lease"). Under the terms of the Winter Street Lease, we also have the ability to sub-lease our corporate office and laboratory space. The original lease commenced in 2010 and was extended, at Alkermes' option, for approximately five years in 2020. The extension term commenced in March 2021 for approximately 163,000 square feet of space and in September 2021 for the remaining approximately 17,000 square feet of space. The Winter Street Lease expires in 2026 and includes a tenant option to extend the term of the Winter Street Lease for an additional

five-year period, which we are not reasonably certain to exercise. The Winter Street Lease was assigned to us in connection with the Separation and will be used solely for our operations. The Parent has been primarily obligated to the landlord for the Winter Street Lease, and, following the Separation, the Parent is jointly and severally liable with us for, and will continue to guarantee, all obligations under the Winter Street Lease. Furthermore, the Parent is the applicant with respect to the letter of credit security deposit that secures the obligations of the tenant under the Winter Street Lease. The Parent maintained a $1.9 million collateralized letter of credit related to such security deposit as of September 30, 2023. As we did not have legal ownership over any bank accounts as of September 30, 2023, there were no cash or cash equivalents balances specifically attributable to us for the historical periods presented and, accordingly, no amount is reflected in the unaudited condensed combined financial statements related to the letter of credit.

As of September 30, 2023, the remaining contractual operating lease liability associated with the Winter Street Lease was $16.5 million. For additional information on our operating lease, see Note 5, *Leases*, in the notes the unaudited condensed combined financial statements.

We enter into contracts in the normal course of business with CROs, clinical supply manufacturers and vendors for pre-clinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period. Payments due upon cancellation consist of payments for services provided or expenses incurred.

Critical Accounting Policies and Significant Judgments and Estimates

Our accompanying combined financial statements have been prepared on a standalone basis and are derived from Alkermes' consolidated financial statements and accounting records. Our management's discussion and analysis of our financial condition and results of operations is based on those combined financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, share-based compensation, leases, income taxes and the allocation of corporate expenses. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, in the notes to the unaudited condensed combined financial statements appearing elsewhere in this report, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Allocation of Expenses

Our combined financial statements include general corporate expenses for certain business and support functions that are provided on a centralized basis, such as senior management, legal, human resources, accounting and finance, facilities, information technology and other corporate services. In addition, our combined financial statements include an allocation of certain R&D costs not directly attributable to individual programs. These costs have been allocated to us for the purposes of preparing the combined financial statements based on proportional cost allocation methods using headcount, square footage or proportional hours worked supporting us and other organizational activities, as applicable, which are considered to be a reasonable reflection of the utilization of services provided or benefit received by us during the periods presented. Management considers that such allocations have been made on a reasonable basis; however, these allocations may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis for the periods presented and, therefore, may not reflect our results of operations, financial position and cash flows had we operated as a standalone entity during the periods presented. All such costs have been deemed to have been incurred and settled through net parent investment in the period when the costs were recorded.

Accrued Research and Development

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Share-Based Compensation Expense

Share-based compensation expense represents the cost of the grant date fair value of equity awards recognized that are expected to vest over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option awards using the Black-Scholes option pricing model. The fair value of time-vesting restricted stock unit awards is equal to the ordinary share price on the date of grant and the fair value of performance-vesting restricted stock unit awards is estimated using a Monte Carlo simulation model. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected share price volatility, the expected term of share options, the expected dividend yield and the fair value of the underlying ordinary shares on the date of grant. Forfeitures are estimated based on historical experience at the time of grant and are revised in subsequent periods if actual forfeitures differ from those estimates. Changes in the assumptions can materially affect the fair value and ultimately how much share-based compensation expense is recognized. The assumptions used were those of the Parent and the share-based compensation expense we recognized in our financial statements is an allocation of Alkermes' historical share-based compensation expense. These inputs are subjective and generally require significant analysis and judgment to develop.

Leases

We account for leases under Accounting Standards Update (“ASU”) 2016-02, *Leases* (“Topic 842”). At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the relevant facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. We do not have material financing leases.

Leases contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. We combine the lease and non-lease components in our lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded at the lease commencement date based on the present value of lease payments over the expected remaining lease term. Certain adjustments to right-of-use assets may be required for items such as prepaid or accrued lease payments as well as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize an incremental borrowing rate to discount lease payments, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate the incremental borrowing rate, a credit rating applicable to us is estimated using a synthetic credit rating analysis since we do not currently have a rating agency-based credit rating.

We have elected not to recognize leases with an original term of one year or less on the balance sheet. We typically only include an initial lease term in our assessment of a lease arrangement. Options to renew a lease are not included in our assessment unless there is reasonable certainty that we will renew.

Assumptions that we made at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Income Taxes

In preparing the combined financial statements for us, the Parent has determined the tax provision for those operations on a separate return basis. We recognize income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative losses in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized, including the amount of Irish and non-Irish pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying business.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements, if any, that may potentially impact our financial position and results of operations is disclosed in Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, in the notes to the audited combined financial statements included in the Form 10 and in the notes to the unaudited condensed combined financial statements included elsewhere in this Form 10-Q.

Transition From Alkermes and Costs to Operate as an Independent Company

The combined financial statements reflect our operating results and financial position as our business was operated by the Parent during the periods presented, rather than as an independent company. We have incurred and expect to continue to incur additional ongoing operating expenses to operate as an independent company. These costs include the cost of various corporate headquarters functions, incremental information technology-related costs and incremental costs to operate standalone accounting, legal and other administrative functions. We may also incur non-recurring expenses and non-recurring capital expenditures.

As an independent company, our information technology operating costs may be higher than the costs allocated in the historical combined financial statements. In addition, we will incur non-recurring expenses and capital expenditures to establish independent information technology systems.

We continued to build our administrative infrastructure through the date of the Separation. We entered into transition services agreements with the Parent that will provide us with certain services and resources for an initial term of two years following the Separation. Historically, the Parent has provided our business with significant corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, which we refer to collectively as the “Alkermes Services.” We pay the Parent fees for the Alkermes Services under the transition services agreements, which fees are based on the Parent’s cost of providing the Alkermes Services. These transition services agreements allow us to operate our business independently prior to establishing a standalone infrastructure. During the transition from the Parent, we will incur non-recurring expenses to establish and expand our infrastructure.

It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical financial statements for the functions described above. Actual costs that would have been incurred if we operated as a standalone company during these periods would have depended on various factors, including organizational design, outsourcing and other strategic decisions related to corporate functions, information technology and back-office infrastructure.

Transactions with Related and Certain Other Parties

Prior to the Distribution, we entered into certain agreements with the Parent relating to the Separation, including a separation agreement, transition services agreements, a tax matters agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in the section captioned “Certain Relationships and Related Person Transactions,” in our Form 10.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”) was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” may take advantage of the extended transition period provided in Section 7(a)(2)(B) of

the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of the exemption for the delayed adoption of certain accounting standards, and therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standards and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of our fiscal year following the fifth anniversary of the date of the Distribution.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies for so long as the market value of our ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter of the preceding fiscal year, or our annual revenues are less than $100.0 million during the most recently completed fiscal year and the market value of our ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter of the preceding fiscal year. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2023. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that our disclosure controls and procedures were effective as of September 30, 2023 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2023, there were no changes in our internal control over financial reporting 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.

None.

Item 1A. Risk Factors.

You should consider carefully the following risks and uncertainties, together with all the other information contained in this Quarterly Report, including our unaudited condensed combined financial statements and notes thereto, when evaluating our ordinary shares. The impact from these risks and uncertainties may be materially adverse to our business, prospects, financial condition and results of operations. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially harm our business, prospects, financial condition and results of operations. As a result, the trading price of our ordinary shares could decline, which could decrease the value of our ordinary shares that you hold.

Risks Related to Our Financial Position and Capital Needs

Because we have a very limited operating history as a standalone company, valuing our business and predicting our prospects is challenging.

Historically and through the date of our separation from Alkermes plc ("Alkermes"), our business was conducted by Alkermes and we have a very limited operating history as a standalone company. We are developing a pipeline of immunotherapies that may meaningfully improve the lives of patients with cancer and have progressed our lead product candidate, nemvaleukin alfa ("nemvaleukin"), into potentially registrational clinical trials. The conduct of our business by Alkermes prior to the separation and our operations to date have focused primarily on organizing and staffing our company, business planning, identifying potential product candidates, and conducting clinical trials and preclinical studies for our product candidates. We have not yet demonstrated an independent ability to successfully complete any registrational clinical trials, obtain regulatory approvals, manufacture a clinical- or commercial-scale product, or conduct the sales and marketing activities necessary for successful product commercialization. Following the separation, Alkermes will continue to provide some of these functions to us for a specified time period, as described in "Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes" in our Form 10, which was most recently filed with the Securities and Exchange Commission ("SEC") on October 26, 2023 (the "Form 10"). We will need to make investments to replicate or outsource from other providers certain manufacturing facilities, systems, infrastructure and personnel to which we will no longer have access after our separation from Alkermes. Any initiatives to develop an independent ability to operate without access to Alkermes' existing operational and administrative infrastructure will include implementation costs. We may not be able to operate our business efficiently or at comparable costs to our pre-separation operations. Consequently, any predictions made about our future success or viability in the development and commercialization of biopharmaceutical products may not be as accurate as they could have been if we had a history of successfully developing and commercializing biopharmaceutical products. We expect our operating and financial results to be subject to frequent fluctuations. We expect to encounter challenges frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully navigate such challenges independently. If we do not address the challenges we face successfully, our business, prospects, financial condition and results of operations may be materially harmed.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from our product candidates or product sales, we do not expect to generate any revenue from the sale of products for a number of years and we may never generate revenue from the sale of products. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical and clinical studies;
- successfully initiate and complete clinical trials for nemvaleukin and other product candidates;
- successfully enroll subjects in, and complete, our ongoing clinical trials and any future clinical trials;
- initiate and/or successfully complete the safety and efficacy studies required to obtain United States ("U.S.") and/or non-U.S. regulatory approvals for our product candidates;
- establish clinical and commercial manufacturing capabilities or make arrangements with third party manufacturers for clinical supply and commercial manufacturing;

•obtain and maintain regulatory approval for our product candidates;

•obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;

•launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;

•obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

•effectively compete with other therapies;

•obtain and maintain healthcare coverage and adequate reimbursement for any approved products;

•enforce and defend intellectual property rights and claims; and

•maintain an acceptable safety profile for our products following approval.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating product revenue. In addition, we may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our shareholders to lose all or part of their investment.

Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future.

Our business has incurred operating losses to date due to costs incurred in connection with our research and development activities and general and administrative expenses associated with our operations and we have not yet generated any revenue for the oncology business or as a standalone company. If our product candidates are not successfully developed and approved, we may never generate any product revenue from product sales. Our net losses for the nine months ended September 30, 2023 and the year ended December 31, 2022 were $147.9 million and $189.8 million, respectively. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as our product candidates advance through clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities and incur additional costs associated with operating as an independent public company. If we obtain marketing and regulatory approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.

Following the completion of the separation, our cash and cash equivalents were $275.0 million. Our management believes that our cash and cash equivalents at the time of the separation will be sufficient to fund our current operating plan into the fourth quarter of 2025.

We will require significant additional funding to advance our product candidates as we continue to expend substantial resources developing and commercializing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing products, and establishing marketing and sales capabilities to commercialize our product candidates. Conducting preclinical studies and clinical trials is a time-consuming, expensive, and uncertain process that can take 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 may not be commercially available for several years, if ever. Accordingly, we will need to continue to rely on additional financing 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 product candidates. In addition, we cannot guarantee that financing will be available in

sufficient amounts or on terms acceptable to us, if at all. We may raise additional funds through public or private equity financings, debt financings, collaborative arrangements, licensing arrangements or other sources. Volatility in the financial markets due to unfavorable global economic conditions, including disruptions in the banking industry and inflationary pressures, has generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities by us, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back, or eliminate expenditures for some of our development programs, including restructuring our operations, refinancing or restructuring our debt, or granting rights to third parties to develop and market product candidates that we would otherwise prefer to internally develop and market. If we grant such rights, the ultimate value of these product candidates to us may be reduced. Regardless of the terms of any debt or equity financings we may enter into, our agreements and obligations under the tax matters agreement with Alkermes may limit our ability to issue ordinary shares to raise capital during the four-year period beginning two years before and ending two years after the distribution by Alkermes of our ordinary shares to Alkermes shareholders. See "—Risks Related to the Separation and Distribution."

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we anticipate, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs or the commercialization of any product candidates or 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.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the "Federal Reserve") and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve 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. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve 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.

We do not hold, and do not expect to hold, cash deposits or securities at SVB and have not experienced any adverse impact to our current and projected business operations, financial condition or results of operations as a result of the SVB closure. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we expect to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. 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 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, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread 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 U.S. federal or U.S. 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, one or more of our critical vendors, third party manufacturers, or other business partners could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

Risks Related to Discovery, Product Development and Regulatory Approval of Our Product Candidates

Biopharmaceutical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our business depends heavily on the successful execution of our clinical development plan, regulatory approvals and commercialization of nemvaleukin and other product candidates. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate through extensive preclinical studies and clinical trials that such product candidate is safe and effective for use in humans. Designing, conducting, and completing a clinical development program is complex and expensive and can take many years to complete, and its outcome is inherently uncertain. We have incurred, and will continue to incur, substantial expenses for preclinical testing, clinical trials, and other activities related to our clinical development programs.

We may be unable to establish clinical outcomes that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Our current product candidates, as well as any we may discover in the future, will require substantial additional development and testing, and regulatory approvals, prior to commercialization.

Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. In some instances, significant variability in safety or efficacy appear in different clinical studies of the same product candidate due to numerous factors, including changes in study protocols, differences in the number and characteristics of the enrolled subjects, variations in the dosing regimen and other clinical study parameters or the dropout rate among study participants. Product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite promising preclinical testing and earlier clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical studies. Most product candidates that begin clinical studies are never approved for commercialization by regulatory authorities.

Successful completion of clinical trials is a prerequisite to submitting a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”), a marketing authorization application to the European Medicines Agency (“EMA”) and similar marketing applications to comparable non-U.S. regulatory authorities for each product candidate, as applicable, and, consequently, the ultimate approval and commercial marketing of any product candidates.

Although we are currently conducting two potentially registrational clinical trials for nemvaleukin, we do not know whether these trials, our other current clinical trials or any future clinical trials will be successful, as completion of these trials and the outcomes of the trials could vary based on a multitude of factors, including study start up, country approvals, and overall regional differences in treatments and outcomes.

We may experience delays in initiating or completing clinical trials and preparing for regulatory submissions. We also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that could delay or prevent our ability to develop our product candidates or receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to obtain regulatory authorizations to commence a clinical trial;
- the FDA, EMA or comparable other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial or prior to commercialization;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

•we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs") or contract development and manufacturing organizations ("CDMOs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CDMOs and trial sites;

•clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;

•the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we expect;

•subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;

•subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;

•subjects may experience severe or unexpected drug-related adverse effects;

•clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;

•we may decide to, or regulators, IRBs or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;

•we may need to add new or additional clinical trial sites and may experience delays or interruptions in site initiations;

•our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or third-party contractors;

•we may experience manufacturing delays, and any changes to manufacturing processes or third party contractors that may be necessary or desired could result in other delays;

•we may not be able to raise funding necessary to initiate or continue a trial;

•the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;

•the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in clinical trials;

•reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates;

•our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regional regulators, IRBs or ethics committees to suspend or terminate the clinical trials;

•we may elect to, or regional regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical trials for various other reasons, including noncompliance with regulatory requirements; and

•regulators may revise the requirements, timelines or pathways for approval of our product candidates, or such requirements, timelines or pathways may not be as we anticipate.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such clinical trials are being conducted, or the FDA, EMA or comparable regulatory authorities, or recommended for suspension or termination by the Independent Data Monitoring Committee for such clinical trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable non-U.S. regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or changes in treatment standards that could impact the relevance of our clinical trial. Clinical trials of any product candidates may fail to show acceptable

safety or efficacy, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or comparable non-U.S. regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials. Regulatory authorities also may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials, including if subsequent changes in standard of care impact the appropriateness of the design of our clinical trials.

In addition, conducting clinical trials in non-U.S. countries, as we may do for our product candidates, may present additional risks that may delay completion of our clinical trials. These potential risks include the failure of enrolled patients in non-U.S. countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with non-U.S. regulatory schemes, as well as political and economic risks relevant to such non-U.S. countries.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Regulatory authorities, investors, and or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business.

Clinical trials are expensive, and our operational, development and research and development costs will increase if we experience delays in clinical testing or marketing approvals. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Delays or difficulties in the enrollment of patients in our clinical trials could cause our clinical development activities to be delayed or otherwise adversely affected, which could materially impact our business.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any other products that may be approved for the indications we are investigating;
- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- adverse events in our clinical trials and in third-party clinical trials of agents similar to our product candidates;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control that may limit the availability of patients, principal investigators or staff or clinical trial sites.

In addition, our clinical trials will compete with other clinical trials for product candidates and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

Our preclinical studies or early clinical trials of our product candidates, whether conducted by us or third parties, may not necessarily be predictive of the results of later clinical trials that we conduct. Similarly, even if we are able to complete our planned clinical trials of our product candidates, positive results from such clinical trials may not be replicated in our subsequent preclinical studies or clinical trials or in real-world results.

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 FDA, EMA or comparable non-U.S. regulatory authority approval. Furthermore, the approval policies or regulations of the FDA, EMA or comparable non-U.S. regulatory authorities may significantly change in a manner that may render our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable non-U.S. regulatory authorities delaying, limiting or denying approval of our product candidates.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available, are not necessarily predictive of the final results of the completed study or the results of other ongoing or future studies and are subject to audit and verification procedures that could result in material changes.

From time to time, we may announce, publish or report preliminary, topline or interim data from our clinical trials, including those in the ARTISTRY development program for nemvaleukin. Such data are subject to the risk that one or more of the clinical outcomes may materially change as patients continue progressing through the study (for example, in oncology studies, a patient may progress from a complete or partial response to progressive disease), as patient enrollment continues and/or as more patient data become available, and such data may not be indicative of final data from such trials, data from future trials or real-world results. In addition, such data may remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary, topline or interim data disclosed. As a result, all preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse differences between preliminary, topline or interim data and final data could significantly harm our business, financial condition, cash flows and results of operations.

We may seek approval of our product candidates, 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.

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 ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product that is granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw 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; and 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 generally requires 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 for nemvaleukin or other product candidates, we may not be able to obtain accelerated approval, and even if we do, that product may not experience a faster development or regulatory review or approval process. In addition, receiving accelerated approval does not assure the product's accelerated approval will eventually be converted to a traditional approval.

We are conducting, and intend in the future to conduct, clinical trials for certain of our product candidates at sites outside the U.S. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the U.S. could subject us to additional delays and expense.

We are conducting, and intend in the future to conduct, one or more of our clinical trials outside the U.S. For example, we currently conduct or plan to conduct clinical trials in Canada, Australia, South Korea, Poland, Spain, Taiwan, the United Kingdom ("UK"), Italy, Austria, Israel, Singapore, the Netherlands, Germany, Belgium, Lithuania, the Czech Republic, Norway, Denmark, and France. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice ("GCP"). The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the U.S. In addition, while these clinical trials are subject to applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the U.S. If the FDA does not accept the data from any trial that we conduct outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

In addition, the conduct of clinical trials outside the U.S. could have a significant adverse impact on us or the trial results. Risks inherent in conducting international clinical trials include clinical practice patterns and standards of care that vary widely among countries; non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials; administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority frameworks; non-U.S. exchange rate fluctuations; and diminished protection of intellectual property in some countries. In addition, global economic or political unrest could result in delays in our clinical trials, or the ability of third parties on whom we rely to conduct our clinical trials in a timely manner. Any such delay could have an adverse impact on our business, financial condition and results of operations.

Side effects, serious adverse events, or other undesirable properties could arise from the use of our product candidates and, in turn, could delay or halt clinical trials, delay or prevent regulatory approval, result in a restrictive label, if approved, or result in significant negative consequences following any marketing approval.

Undesirable side effects or serious adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable non-U.S. regulatory authorities. For example, in Part B (n=74) of ARTISTRY-1, as of March 27, 2023, the most frequent nemvaleukin-related serious adverse events observed across the following system organ classes were: blood and lymphatic system disorders (6.8%), hepatobiliary disorders (4.1%), general disorders and administration site conditions (2.7%), investigations (2.7%), and metabolism and nutrition disorders (2.7%). In Part C (n=166) of ARTISTRY-1, as of March 27, 2023, the most frequent nemvaleukin-related serious adverse events observed across the following system organ classes were: blood and lymphatic system disorders (3.6%), injury, poisoning and procedural complications (3.0%), and general disorders and administration site conditions (2.4%).

Any related drug side effects or serious adverse events, or unforeseen side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability or desire of enrolled patients to complete the clinical trial, could result in suspension or termination of our clinical trials, or potential product liability claims.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects or serious adverse events caused by such product, a number of potentially significant consequences could result, including:

- we may suspend or be forced to suspend marketing of such product;
- we may be obliged to conduct a product recall or product withdrawal;
- other regulatory authorities may suspend, vary, or withdraw their approvals of such product;
- regulatory authorities may order the seizure of such product;
- regulatory authorities may require additional warnings on the label or a risk evaluation and mitigation strategy ("REMS") that could diminish the usage or otherwise limit the commercial success of such product;
- we may be required to conduct post marketing studies for such product;
- we could be sued and held liable for harm caused to patients that are believed to be related to use of such product;

•we could be required to pay fines and face other administrative, civil, and criminal penalties; and

•our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of such product.

Preclinical development is uncertain. Our discovery-stage and preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Our interleukin-18 ("IL-18") and interleukin-12 ("IL-12") programs are still in the discovery stage of development, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug applications ("IND") in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our current or future preclinical programs on the timelines we expect, or at all, and we cannot be sure that submission of INDs or similar applications in other jurisdictions will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

•the research methodology used may not be successful in identifying potential indications and/or product candidates;

•potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

•it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

The regulatory approval process for our product candidates will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

We are not permitted to market any biological product in the U.S. until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable non-U.S. regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA is not guaranteed, and the review and approval process is expensive, uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

The FDA may also require a panel of experts, referred to as an advisory committee ("Advisory Committee"), to deliberate on the adequacy of the safety and efficacy data from our clinical studies to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval in the U.S. of any product candidate that we develop based on the completed clinical trials.

In addition, public concern regarding the safety or efficacy of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product as a standalone entity. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for any current or future product candidates.

Manufacturing of biological products is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.

The manufacturing of biologics is complex and difficult and we and the third parties upon whom we rely for manufacturing may experience production issues or interruptions for our product candidates, including raw material or starting material variability in terms of quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, growth media contamination, equipment malfunctions, operator errors, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, or "acts of God" that are beyond our control or the control of our third-party manufacturers and other third parties.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biological sources. Such raw materials may be difficult to procure and may be subject to contamination or recall.

Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical development of any product candidates we may develop. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality that meet FDA, EMA, or other comparable applicable non-U.S. standards or specifications with consistent and acceptable production yields and costs. Our ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficacy that we are currently manufacturing is yet to be established. If we or our third-party manufacturers are unable to scale our manufacturing at the same levels of quality and efficiency, we may not have sufficient supply for our clinical trials or commercial supply. A material shortage, contamination or manufacturing failure in the manufacture of any product candidates we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

We also face risks related to our reliance on our current and any future third-party manufacturers. For example, we and our third-party manufacturers are subject to significant regulation with respect to manufacturing our product candidates. All entities involved in the manufacturing of our biological product candidates for clinical trials and, if approved, for commercial sale, including any third-party manufacturers of any product candidates we may develop, are subject to extensive regulation, including that such product candidates must be manufactured in accordance with applicable current Good Manufacturing Practices ("cGMP"). These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our third-party manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current good laboratory practices and cGMP regulations, as applicable. Our facilities and quality systems and the facilities and quality systems of our third-party manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidates we may develop or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our third-party manufacturers' facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the

temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any third-party manufacturer with which we contract for manufacturing and supply fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product, or revoke an existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Currently, we depend on single source manufacturers for certain elements of the manufacturing processes for certain of our product candidates. We cannot ensure that these manufacturers will remain in business or have sufficient capacity or supply to meet our needs. If the third party manufacturers on whom we rely have insufficient capacity or experience supply, labor or other interruptions, or experience manufacturing challenges related to quality, failure relating to materials, the supply and quality of active pharmaceutical ingredients and other product components and any potential shortage of raw materials, safety issues, utility or transportation disruptions or other site-specific incidents, environmental incidents, and others, our development and commercialization plans for our product candidates may be disrupted. Our use of single source manufacturers exposes us to several other risks, including price increases or manufacturing delays beyond our control. Moreover, reliance on third-party manufacturers generally entails risks to which we would not be subject if we manufactured the product candidates or components of the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors;
- scheduling and supply risks as a result of using third-party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, public health crises or global conflicts;
- the inability to obtain components or materials from alternate sources at acceptable prices in a timely manner; and
- substantial delays or difficulties related to the establishment of replacement manufacturers who meet regulatory requirements.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

Additionally, if supply from one approved manufacturer is interrupted, such as could be the case with our current third-party manufacturer, there could be a significant disruption in supply. While we believe there are alternate manufacturers who can provide the manufacturing processes required to develop our product candidates, if we have to switch to a replacement manufacturer, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Furthermore, an alternative manufacturer would need to be pre-approved by the FDA through a BLA supplement which could result in further delay. The regulatory authorities may also require additional bridging studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

Our business is highly dependent on the success of our lead product candidate, nemvaleukin, as well as the other product candidates in our pipeline. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize our product candidates, or if we experience delays in doing so, our business will be materially harmed.

Our business and future success is highly dependent on our ability to obtain regulatory approval for, and if approved, successfully launch and commercialize, our current product candidates, including our most advanced product candidate, nemvaleukin. Additionally, we have a portfolio of programs that are in preclinical development and may never advance to clinical-stage development.

Commencing clinical trials in the U.S. is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be

delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. In addition, emerging data from other clinical trials and regulatory approvals of other product candidates could impact the acceptability of our clinical trial designs. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union ("EU").

While we have interacted with the FDA in the development of our study design and protocols for our ARTISTRY clinical development program, we may experience issues that require revisions to our trial design and trial protocols. We have had no interactions with the FDA or other regulatory authorities with respect to our IL-18 and IL-12 programs, and the FDA or other regulatory authorities may not agree with our development strategy or plans for such programs.

We also may experience difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

Even if we succeed in obtaining regulatory approval for a product candidate, we do not currently have an infrastructure for the sale, marketing, market access, patient service and distribution of pharmaceutical products. In order to market our product candidates, we must build our sales, marketing, managerial and other non-technical capabilities, or arrange with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product candidate launch. If commercialization is delayed or does not occur, we would have prematurely or unnecessarily incurred such expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or potential profitability from such product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may fail to enter into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, or if we are unable to do so on commercially reasonable terms, we will not be successful in commercializing our product candidates if approved and our business, prospects, financial condition and results of operations will be materially harmed.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our current and any future product candidates, which may never occur. It may be years before we are able to demonstrate clinical trial safety and efficacy data sufficient to warrant submission for approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

The FDA or other regulatory authorities may not agree with our regulatory approval strategies or components of our filings for our products and may not approve, or may delay approval of, our products.

We must obtain government approvals before marketing or selling our products. The FDA in the U.S., and comparable regulatory authorities in other jurisdictions, impose substantial and rigorous requirements for the development, manufacture and commercialization of biological products, the satisfaction of which can take a significant number of years and can vary substantially based upon the type, complexity and novelty of the product.

In addition, regulation is not static, and regulatory authorities, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our plans for product development, manufacture and/or commercialization. The approval procedure and the time required to obtain approval also varies among countries. Regulatory authorities may have varying interpretations of the same data, and approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. In addition, the FDA or other regulatory authorities may choose not to communicate with or update us during clinical testing and regulatory review periods and the ultimate decision by the FDA or other regulatory authorities regarding drug approval may not be consistent with prior communications.

Regulatory approval by the FDA or other regulatory authorities can be delayed, limited or not granted at all for many reasons, including because regulatory authorities may not agree with our regulatory approval strategies, plans for accelerated development timelines, components of our filings such as clinical trial designs, conduct and methodologies, or the sufficiency of our submitted data

to meet their requirements for product approval. Regulatory authorities might not approve our or our licensees' manufacturing processes or facilities, or those of the CROs and contract manufacturing organizations who conduct research or manufacturing work on our or our licensees' behalf. Regulatory authorities also may change their requirements for approval or post-approval marketing. For example, we expect that the data from Cohort 2 of ARTISTRY-6 will be sufficient for traditional approval of nemvaleukin for mucosal melanoma. However, FDA could grant accelerated approval for nemvaleukin pending clinical trial results, further understanding of the treatment landscape, and the rarity of the disease and timeframe needed to conduct a confirmatory trial. If the FDA grants accelerated approval to nemvaleukin for the treatment of mucosal melanoma, the FDA is permitted to require that one or more post-approval confirmatory studies be underway prior to approval or within a specified time period after accelerated approval is granted. The FDA may require us to conduct another clinical trial to convert accelerated approval to traditional approval for nemvaleukin for the treatment of mucosal melanoma. The treatment of cancer is a rapidly evolving field and will continue to evolve. By such time, if ever, as we may receive necessary regulatory approvals for our product candidates, the standard of care for the treatment of the relevant cancers may have evolved such that it would be necessary to modify our plans for regulatory approval, and the prospects for regulatory approval and commercial acceptance of our products may be limited by a change in the standard of care.

In addition, disruptions at the FDA and other regulatory authorities that are unrelated to our company or our products, including those relating to the COVID-19 pandemic or other political or economic conditions, could cause delays to the regulatory approval process for our products.

Any failure to obtain, or delay in obtaining, regulatory approval for our products will prevent or delay their commercialization and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, any failure to obtain, or delay in obtaining, approval for our products could have a material impact on our shareholders' confidence in the strength of our development capabilities and/or our ability to generate significant revenue from our development program and could result in a significant decline in our share price.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-marketing information, including both U.S. federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable non-U.S. regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product 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 product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable non-U.S. regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, 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 revisions to the approved labeling to add

new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product 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 license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable non-U.S. regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA or other regulatory authorities may impose limitations or post-approval requirements on approvals for our products.

Even if regulatory approval to market a product is granted by the FDA or other regulatory authorities, the approved label for the product may not be consistent with our initial expectations or commercial plans. For example, the FDA or other regulatory authorities may impose limitations on the clinical data that may be included in the label or grant narrower indications for use than we sought or add a limitation on us or may require us to engage in deferred pediatric studies where such studies may be required under the Pediatric Research Equity Act. The FDA or other regulatory authorities may also restrict the manner in which the product may be marketed, require labeling statements such as a boxed warning or contraindications, or impose additional post-approval requirements, such as a REMS, with which we would need to comply in order to maintain the approval of such product. Our business could be seriously harmed if we do not complete these post-approval requirements or if such post-approval requirements significantly restrict the marketing, sale or use of such product, impose costly requirements on our activities, or place us at a competitive disadvantage to other pharmaceutical and biotechnology companies.

In addition, legislation and regulatory policies relating to post-approval requirements and restrictions on promotional activities for pharmaceutical products, or FDA or other regulatory authority regulations, guidance or interpretations with respect to such legislation or regulatory policy, may change, which may impact the development and commercialization of our products.

Failure to comply with applicable legal and regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other enforcement action against our product candidates or us.

In addition, we are, or may become, subject to various U.S. federal, state, and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions, and civil and criminal penalties.

The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing, reimbursement and our ability to create meaningful value propositions for patients, prescribers and payors. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant

judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

We may seek certain designations for our product candidates, including Fast Track, Priority Review, and Breakthrough Therapy designations in the U.S. and Innovative Licensing and Access Pathway in the UK, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We have obtained Fast Track designations ("FTD") for nemvaleukin in mucosal melanoma and for nemvaleukin in combination with pembrolizumab for platinum-resistant ovarian cancer ("PROC"). The FDA may grant FTD to a product candidate if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition. For products granted FTD, sponsors may have greater interactions with the FDA, and a sponsor can submit completed sections of its BLA on a rolling basis for review by FDA rather than waiting until every section of the BLA is completed before the entire application can be reviewed.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. We may seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months after the 60-day filing date of an original application, rather than the standard review period of ten months after the 60-day filing date of an original application.

We may also seek Breakthrough Therapy designation for one or more of our product candidates. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product 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 products 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.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products 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 product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In January 2023, we announced that the UK's Medicines and Healthcare products Regulatory Agency (the "MHRA") had granted an Innovation Passport designation for nemvaleukin for the treatment of mucosal melanoma, under the UK's Innovative Licensing and Access Pathway (the "ILAP"). The ILAP aims to accelerate the time to market and facilitate patient access to certain types of medicinal products in development which target a life-threatening or seriously debilitating condition, or where there is a significant patient or public health need. To access the ILAP, an applicant applies for an Innovation Passport designation. Once an Innovation Passport designation is granted, the MHRA and its partner agencies (including The All Wales Therapeutics and Toxicology Centre, National Institute for Health and Care Excellence ("NICE") and the Scottish Medicines Consortium ("SMC")) work with the Innovation Passport designee to define a Target Development Profile ("TDP"). The TDP sets out a unique product-specific roadmap toward patient access in the UK, and provides access to a toolkit to support all stages of the design, development and approvals process, including continuous benefit-risk assessment, increased support for novel development approaches and enhanced patient engagement. Although the goal of the ILAP is to reduce the time to market and enable earlier patient access, access to the ILAP does not mean that the regulatory requirements are less stringent, nor does it ensure that a marketing authorization application will be approved within a particular timeframe or at all.

We have received Orphan Drug designation for nemvaleukin in mucosal melanoma and may seek additional Orphan Drug designations for other indications or for our other product candidates. However, we may be unsuccessful in obtaining, or may be unable to maintain the benefits associated with Orphan Drug designation including the potential for market exclusivity.

We have received Orphan Drug designation ("ODD") from the FDA for nemvaleukin for the treatment of mucosal melanoma and may seek additional ODD for additional indications or for our other product candidates. Even if we receive orphan drug exclusivity, the exclusivity may be revoked under certain circumstances, such as if the FDA later determines that the request for

designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. We will also be required to submit annual reports describing any changes that may affect the orphan drug status of the product. Further, even if we receive orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition during the exclusivity period because different drugs with different active moieties can be approved for the same condition, and the same product can be approved for different uses. Also, in the U.S., even after an orphan drug is approved and receives orphan drug exclusivity, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug, including because it has been shown to be clinically superior to the drug with exclusivity because it is safer, more effective or makes a major contribution to patient care. In the EU, a marketing authorization may be granted to a similar medicinal product to an authorized orphan product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the European Commission or comparable non-U.S. regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Risks Related to the Commercialization of Our Product Candidates

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success.

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. If our product candidates receive marketing approval but do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including:

- the product's efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product's convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;

•the recommendations with respect to the product in guidelines published by scientific organizations;

•the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;

•the strength of marketing, sales and distribution support;

•the effectiveness of our sales and marketing efforts;

•clinicians' and patients' perceptions of other similar immuno-oncology product candidates or products with a similar mechanism of action as ours;

•the approval of other new products for the same indications;

•our ability to offer the product for sale at competitive prices; and

•public perception of our company and the reputation of our business.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

We have no history of commercializing marketed products and we have not yet implemented our commercialization operations. There can be no assurance that we will successfully set up our commercialization capabilities.

We have never commercialized a product candidate and we currently have no sales, marketing or distribution capabilities. Historically and through the date of the separation, our business was conducted by Alkermes. Our operations to date have been limited to organizing and staffing our company, business planning, and undertaking preclinical studies and clinical trials of our product candidates. Establishing commercialization capabilities will require substantial investment of time and money and may divert significant management focus and resources. In addition, we would be competing with larger biopharmaceutical and biotechnology companies with established commercialization and marketing capabilities as we seek to recruit suitable personnel. Accordingly, there can be no assurance that our efforts to set up commercialization capabilities will be successful. We may pursue collaborative arrangements regarding the sales and marketing of our products, if approved, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. Further, if we enter into arrangements with third parties to perform sales and marketing services, our product revenues, if any, may be lower than if we were to market and sell any products that we develop ourselves. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the U.S., the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidate, we may have difficulties generating revenue from them.

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

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.

We have chosen to initially develop nemvaleukin for the treatment of mucosal melanoma and in combination with pembrolizumab for the treatment of PROC. Our development efforts are currently focused on certain cancer types and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable insurance coverage, adequate reimbursement levels and cost-effective pricing policies with third-party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the U.S., the EU or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, such products may not be considered cost-effective and/or the resulting reimbursement payment rates may be insufficient or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines 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 medicines from countries where they may be sold at lower prices than in the U.S. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the U.S., third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the U.S. for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. Moreover, increasing efforts by governmental and other third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted U.S. federal and U.S. 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 further discussed below. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. and coverage and reimbursement for products can therefore differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our ability to demonstrate to these third-party payors that any of our approved product candidates creates a meaningful value proposition for patients, prescribers and payors will be important to gaining market access and reimbursement and there is no guarantee that we will be successful in doing so. Furthermore, we expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval.

In the U.S. and non-U.S. jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"). In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act. Pursuant to subsequent legislation, this 2% reduction was suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction began April 1, 2022, lasting through June 30, 2022. The 2% payment reduction resumed on July 1, 2022. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and U.S. Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (the "TCJA"), which was signed by former President Trump on December 22, 2017, the U.S. Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing U.S. federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or U.S. Congressional challenges in the future. It is unclear how such other challenges to repeal or replace the ACA or the health reform measures of the Biden Administration will impact the ACA or our business.

Current and future legislative efforts may limit the prices for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and U.S. federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, former President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, Centers for Medicare and Medicaid Services ("CMS") issued a final rule to rescind it. With issuance of this rule, CMS stated

that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services ("HHS") and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP"), to import certain prescription drugs from Canada into the U.S. At least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The 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 recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022 ("IRA") further delayed implementation of this rule to January 1, 2032.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs HHS, to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the U.S. federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and are approved for only that rare disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it will not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general are not yet known.

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 and price disclosure and transparency measures. Some states have adopted measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations 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 healthcare programs. Further, if any of our products are approved, we would be required to calculate and report certain price reporting metrics to the government, such as average sales price, and best price. The calculations necessary to determine the prices reported are complex and penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for our products may be reduced by mandatory discounts or rebates required by government healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional U.S. state and U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that U.S. federal and U.S. state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Finally, outside the U.S., in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as, or similar to, our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. See “Business—Competition.”

We are developing our initial product candidates for the treatment of cancer and have not yet received marketing approval for any of our product candidates. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

We are aware of a number of companies that are developing interleukin-2 (“IL-2”)-based product candidates for the treatment of cancer, as well as different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Nemvaleukin, if approved, may face competition from other IL-2-based cancer therapies, or other therapies targeting our initial indications. For example, Proleukin (aldesleukin), a synthetic protein similar to IL-2, is approved and marketed for the treatment of metastatic renal cell carcinoma and melanoma. In addition, we are aware of several companies that have IL-2-based programs in development for the treatment of cancer.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to biosimilar competition.

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product

containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates.

We depend upon third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to negotiate budgets and contracts with such third parties, any delays in the negotiation of budgets and contracts with such third parties may result in delays to our development timelines and increased costs.

Historically and through the date of the separation, our business was conducted by Alkermes. Following the separation, we plan to continue to build our infrastructure and hire personnel necessary to execute our operational plans. We expect to rely especially heavily on third parties over the course of our clinical trials, and, as a result, may have limited control over the investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. 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 third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable non-U.S. regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable non-U.S. regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with investigational products produced under cGMP requirements and may require a large number of patients which may increase the costs and expenses related to our clinical development programs.

Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates U.S. federal or U.S. state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties 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 preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed or precluded entirely.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms or in a timely fashion.

Switching or adding additional CROs involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We have not yet manufactured on a commercial scale and expect to rely on third parties to produce and process commercial quantities of our product candidates, if approved.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for our product candidates. To the extent that we enter into future manufacturing arrangements with third parties for commercial supply of our product candidates, if approved, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance.

The facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the FDA, EMA or comparable non-U.S. regulatory authorities following inspections that will be conducted after we submit an application to the FDA, EMA or comparable non-U.S. regulatory authorities. We do not directly control the manufacturing process of, and will be substantially dependent on, our third-party manufacturing partners for compliance with cGMP requirements for the manufacture of our product candidates. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable non-U.S. regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable non-U.S. regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We are developing, and may develop in the future, certain of our product candidates in combination with third-party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.

We intend to develop nemvaleukin, and likely other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, in ARTISTRY-7, an ongoing Phase 3 clinical trial, we are evaluating nemvaleukin in combination with pembrolizumab, an anti-programmed cell death 1 agent, for the treatment of PROC. Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, when used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercial product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships for the supply of such third party investigational or approved medicinal products, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results, or prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our plans to evaluate nemvaleukin in combination with other agents may result in adverse events based on the combination therapy that may negatively impact the reported safety profile of nemvaleukin as a monotherapy in clinical trials. In addition, the FDA or comparable non-U.S. regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive trial results are attributable to the third-party drug and not our product candidate. Developments related to the third-party drug may also impact our clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

If we are able to obtain marketing approval, the FDA or comparable non-U.S. regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third-party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable non-U.S. regulatory authorities could revoke approval of the third-party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable non-U.S. regulatory authorities may require us to conduct additional clinical trials to

demonstrate the continued efficacy of the combination. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may seek third-party collaborators or licensors for the research, development and commercialization of certain of our current or future product candidates. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any potential collaboration.

Collaborations, licenses or similar arrangements involving our research programs or any product candidates pose numerous risks to us, including the following:

- collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements;
- collaborators or licensors may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators or licensors may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators or licensors could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators or licensors may be acquired by a third party having competitive products or different priorities;
- collaborators or licensors with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidate(s);
- collaborators or licensors may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators or licensors and us that result in the delay or termination of the research, development, or commercialization of our product candidates or any of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations or license grants may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration or license agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator or licensor of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations, licenses or similar transactions do not result in the successful development and commercialization of product candidates, or if one of our collaborators or licensors terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments, as applicable, under such agreement. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or licensor or for us to attract new collaborators or licensors, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our

ability to reach a definitive collaboration or license agreement will depend, among other things, upon our assessment of the resources and expertise of such third-party collaborator or licensor and the terms and conditions of the proposed collaboration or license. Further, if we license rights for use in any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

Risks Related to Our Intellectual Property

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates, or the scope of our patent protection could be insufficiently broad, which could result in competition and a decrease in the potential market share for our product candidates.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the U.S. and abroad related to our product candidates that are important to our business. If we are unable to secure or maintain patent protection with respect to our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that the scope of the currently-pending patent applications will not be altered before the U.S. Patent and Trademark Office ("USPTO"), or non-U.S. patent offices. The standards applied by the USPTO, and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. The patent positions of therapeutic polypeptide and antibody companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, patents may not issue from our pending patent applications, or the scope of the pending patent applications may change. As such, we cannot predict with certainty the degree of future protection that we will have on our proprietary products and technology.

Changes to patent laws in the U.S. or other jurisdictions may diminish the value of our patents, and patents in general, thereby impairing our ability to protect our products or product candidates.

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications, and the enforcement or defense of issued patents.

These changes may affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. The U.S. Supreme Court, and other U.S. courts, have 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 enforce our patents. 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. Legislation passed by U.S. Congress, for example, the IRA, could potentially impact drug pricing and rebates depending on the success of drug products and the marketplace.

Issued patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged in patent office proceedings or in court.

The validity or enforceability of our patents may be challenged in district court, before the USPTO, or in a non-U.S. jurisdiction by a competitor. Alternatively, if we or one of our partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace.

Grounds for a validity challenge could be an alleged failure to meet one or more statutory requirements for patentability, including, for example, lack of patent eligible subject matter, lack of novelty, obviousness, lack of written description, lack of definiteness, or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting.

While we are not aware of any such grounds, someone could allege that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Additionally, third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries, including the USPTO and the European Patent Office.

Despite the due diligence we have conducted regarding our patent portfolio strategy, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one of our products and product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

Filing, prosecuting, defending, and enforcing patents in all countries throughout the world would be prohibitively expensive, and the laws of non-U.S. countries may not protect our rights to the same extent as the laws of the U.S. In addition, our intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties 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 may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products and product candidates in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in non-U.S. intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain non-U.S. jurisdictions. The legal systems of some countries, including India, China, Russia, and other developing countries do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology products and/or intellectual property rights owned by U.S. entities, which could make it difficult for us to stop the infringement, misappropriation, or other violation of our patents or other intellectual property rights.

Claims that our product candidates or, if approved, the sale or use of any such approved products infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Despite the measures we take to obtain and maintain our patents, we cannot guarantee that our product candidates or, if approved, the use of any such approved products, will not infringe third-party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future.

It is also possible that we failed to identify relevant third-party patents or applications. Patent applications in the U.S. and elsewhere are published publicly approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products.

In order to avoid or settle potential claims with respect to any of the patent rights described above or any other patent rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on commercially acceptable terms, or at all. Even if we or our strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Furthermore, confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how, and proprietary information concerning our business strategy in order to protect our competitive position. In the course of our research, development and business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining our company. We take steps to protect our proprietary information, and we seek to carefully draft our confidentiality agreements to protect our proprietary interests.

Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

If we fail to comply with our obligations under any license, collaboration, or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our products or product candidates.

We rely, in part, on license, collaboration, and other agreements with our strategic partners relating to intellectual property, including know-how and trade secrets. Although we have contractual provisions in place, there may be circumstances wherein a strategic partner may violate an agreement, or conclude that a violation has occurred. Enforcing or defending against an alleged breach may result in legal actions that may ultimately be costly.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could modify 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.

Unfavorable outcomes in an intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products or product candidates.

If third parties successfully assert intellectual property rights against us, we might be barred from developing and commercializing related products or product candidates. Prohibitions against commercializing specified product or product candidates, could be imposed by a court or by a settlement agreement between an adverse party and us.

In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed.

An unfavorable outcome could result in a loss of our current patent rights. This could require us to obtain a license from the patent owner in order to continue our research and development programs or our partnerships or, if approved, to market our

product(s). Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all.

An intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our ordinary shares to decline.

Given that we are a new standalone public company with a developing reputation, during the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our ordinary shares may decline.

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- others may identify compounds more quickly than we are able to, and might file their patent applications before us;
- we or our partners might not have been the first to make the inventions covered by our issued patent or pending patent application;
- we or our partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our pending patent applications might not lead to issued patents;
- our issued patents that we own or have exclusively licensed may not provide us with a competitive advantage; for example, our issued patents may not be broad enough to prevent the commercialization of competitive products, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our or our partners' existing or potential commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Risks Related to Our Business and Industry

A variety of risks associated with operating our business internationally could adversely affect our business.

We face risks associated with our international operations, including possible unfavorable political and tax conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- non-U.S. government taxes, regulations and permit requirements;
- U.S. and non-U.S. government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act ("FCPA");
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular non-U.S. countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities aboard; and
- changes in diplomatic and trade relationships.

Our business activities outside of the U.S. are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA and similar anti-corruption laws generally prohibit offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the U.S. Securities and Exchange Commission ("SEC") and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank"), private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

We are or may become subject to tax audits in Ireland, the U.S. or other countries into which we expand our operations, and such jurisdictions may assess additional income tax against us. The final determination of tax audits could be materially different from our recorded income tax provisions and accruals. The ultimate results of an audit could have a material adverse effect on our operating results or cash flows in the period or periods for which that determination is made and could result in increases to our overall tax expense in subsequent periods.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements for these individuals, could harm our business.

Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we intend to provide equity incentive awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at-will employees and may terminate their employment with us on short notice. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across our organization.

Our relationships with healthcare providers and 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, statutory or contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to

these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. See the section titled “Business – Government Regulation – Healthcare and Privacy Laws” in our Form 10.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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. U.S. federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company’s attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in U.S. federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management’s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

We are subject to certain U.S. and non-U.S. 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 non-U.S. anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations (collectively, “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. 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. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Our employees, independent contractors, CROs, consultants, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from

government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 1, 2023, we had approximately 110 full-time employees and no part-time employees and had engaged approximately 15 independent contractors. We may experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs, finance and, if any of our product candidates receive marketing approval, sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, and could give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media and social media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

•significant negative financial impact; and

•the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain product liability insurance coverage, we may be unable to secure such insurance, and any insurance coverage we obtain may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

If we or any third-party manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any third-party manufacturers and suppliers we engage are subject to numerous U.S. federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the responsible use of hazardous and flammable materials, including chemicals and biological and radioactive materials.

Compliance with applicable environmental, health and safety laws and regulations may be expensive, and current or future environmental, health and safety laws and regulations may impair our research and product development efforts.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, any third-party manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a catastrophic event, such as a terrorist attack, war or other armed conflict, geopolitical tensions or trade wars, pandemic or natural disaster.

We depend on our employees, consultants, third-party manufacturers, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including terrorist attacks, wars or other armed conflicts, geopolitical tensions or trade wars, pandemics or natural disasters, these events could result in significant disruptions to our research and development, manufacturing, preclinical studies, clinical trials, and, ultimately, if approved, the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, such as natural disasters, which are increasing in frequency due to the impacts of climate change, the outbreak of wars or other armed conflicts, the escalation of hostilities, geopolitical tensions or trade wars, acts of terrorism or “acts of God,” particularly involving geographies in which we or third parties on whom we depend have offices, manufacturing or clinical trial sites, could adversely affect our businesses. For example, the current military conflicts between Russia and Ukraine and in the Middle East could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. In particular, sanctions imposed by the U.S., the EU and other countries in response to the conflict between Russia and Ukraine and the potential response to such sanctions could adversely affect our business and/or our supply chain, our CROs, third-party manufacturers and other third parties with which we conduct business. While we do not currently conduct business in these geographies, we cannot be certain what the overall impact of these events will be on our business or on the business of any third parties on whom we depend. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us, our third-party manufacturers, our CROs, regulatory agencies or other parties with which we are engaged could have a material adverse effect on our operations and financial performance.

Disruptions at the FDA, SEC and other government agencies caused by funding shortages, changes in the federal administration or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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 and fundraising may rely, including those that fund research and development activities and regulate our access to the public markets, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the past decade, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. 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, following completion of the planned separation and distribution and in our operations as a public company, 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.

Compliance with state, national and international privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to a variety of harms, including significant fines and penalties, litigation and reputational damage, any of which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous U.S. federal and U.S. state laws and regulations, including state security breach notification laws, state health information privacy laws, and U.S. federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Most prominently, in California the California Consumer Protection Act (“CCPA”), as amended by the California Privacy Rights Act (“CPRA”), which went into effect on January 1, 2023, establishes a privacy framework for covered businesses by creating an expansive definition of personal information, establishing data privacy rights for consumers and employees in the State of California, imposing special rules on the collection of consumer data from minors, and creating a potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA and the CPRA. While clinical trial data is currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope.

Certain other U.S. state laws impose similar privacy obligations, and we also anticipate that more U.S. states will increasingly enact legislation similar to the CCPA. The CCPA has prompted a number of proposals for new U.S. federal and U.S. state-level privacy legislation and in some states efforts to pass comprehensive privacy laws have been successful. Laws similar to the CCPA are currently in effect in Virginia, Colorado, and Connecticut, and seven additional states have passed such laws, which will come into effect over the next few years.

Further, each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“HIPAA”).

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal information, including health information, in the EU are governed by the provisions of the EU General Data Protection Regulation (“EU GDPR”), as well as transposing and supplementary national data protection legislation in force in relevant Member States. While the UK is no longer a Member State of the EU, the EU GDPR forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (the “UK GDPR”, together with the EU GDPR the “GDPR”) and is supplemented by the Data Protection Act 2018 in the UK. The GDPR and relevant national laws impose a broad range of strict requirements on companies subject to them, such as including

requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area ("EEA") (or in the case of the UK GDPR, outside of the UK), providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates in certain circumstances, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

To enable the transfer of personal data outside of the EEA or the UK, safeguards must be implemented in compliance with European and UK data protection laws.

One such safeguard is reliance on a decision determining that a country outside the EEA or the UK provides an "adequate" level of protection for personal data. Although the UK is a third country under EU GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. This decision is subject to review and has an expiry date of 27 June 2025. If not renewed or revoked, transfers of personal data originating in the EEA to the UK would require a form of appropriate safeguard, such as those detailed below, to be put in place to allow transfers to continue in compliance with the EU GDPR, which could disrupt our business. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that it considers the EU as providing adequate protection for personal data so personal data transfers from the UK to the EEA remain free flowing.

In the absence of an adequacy decision, the most commonly used appropriate safeguard is the standard contractual clauses issued by the European Commission. On June 4, 2021, the European Commission issued new forms of standard contractual clauses ("SCCs") for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The SCCs are a contract between a data exporter and a data importer where the parties agree to the provision of specific protections for personal data and the terms cannot generally be amended by the parties. As of December 27, 2022, the new SCCs must be used for all transfers outside of the EEA in place of the SCCs that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission's new SCCs but has published the UK International Data Transfer Agreement (the "IDTA") and International Data Transfer Addendum to the new SCCs (the "UK Addendum"), which provides modifications to the European Commission's SCCs to enable transfers from the UK in compliance with UK GDPR. For new transfers, the IDTA or the UK Addendum needs to be in place. For any existing transfers relying on pre-Brexit EU SCCs, the IDTA or the UK Addendum must be in place for all transfers from the UK from March 21, 2024. In addition to SCCs, following a ruling from the Court of Justice of the EU, in Data Protection Commissioner v Facebook Ireland Limited and Maximillian Schrems, Case C-311/18 ("Schrems II"), companies relying on SCCs to govern transfers of personal data to third countries (in particular the U.S.) need to perform a transfer impact assessment ("TIA") to assess whether the data importer can ensure that personal data will be subject to an essentially equivalent level of protection as under the GDPR in the jurisdiction to which the data is imported. Where the TIA concludes that the level of protection will not be essentially equivalent, the data importer must consider whether it can implement additional guarantees to safeguard the personal data and ensure that the level of protection for the personal data is raised. The TIA includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. We are required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost.

If we are investigated by a European or UK data protection authority, we may face fines and other penalties, including bans on processing and transferring personal data. EU and UK data protection authorities have the power to impose administrative fines for violations of the GDPR of up to a maximum of €20 (£17.5) million or 4% of the data controller's or data processor's total worldwide global turnover for the preceding fiscal year, whichever is higher, and violations of the GDPR may also lead to damages claims by data controllers and data subjects. An investigation by a European or UK data protection authority could be triggered by the authority acting of its own volition or by a complaint made to the authority by an individual data subject. Administrative fines are in addition to other corrective powers that an authority may exercise, e.g., orders to bring processing operations into compliance in a specified manner and within a specified time period or a temporary or permanent ban on processing activities. Such penalties are in addition to any civil litigation claims by data controllers, clients, and data subjects. As such, we will need to take steps to cause our processes to continue to be compliant with the applicable portions of the GDPR, but we cannot assure you that we will be able to implement changes in a timely manner or without significant disruption to our business, or that such steps will be effective, and we may face the risk of liability under the GDPR.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. The UK has also now introduced a Data Protection and Digital Information Bill (the "UK Bill") into the UK legislative process with the intention for this bill to reform the UK's data protection regime following the UK's exit from the EU. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime and threaten the UK adequacy decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk. An additional consequence of amendment to the data protection legal framework in the UK is that the UK would no longer be considered to provide an "adequate" level of protection for personal data and the European Commission adequacy decision in favor of the UK would be revoked. Such an action would remove the ability for data to flow freely between the EEA and the UK and would require that another appropriate safeguard is put in place for data transfers to continue in compliance with the EU GDPR.

Many jurisdictions outside of Europe where we may do business or conduct trials in the future are also considering and/or have enacted comprehensive data protection legislation. In addition, we also continue to see jurisdictions imposing data localization laws. These and similar regulations may interfere with our intended business activities, inhibit our ability to expand into those markets, require modifications to our products or services or prohibit us from continuing to offer services or conduct trials in those markets without significant additional costs.

Our computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, which have a material adverse effect on our reputation, business, financial condition or results of operations.

Our computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. If we experience a material system failure, accident or security breach that causes interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in significant reputational, financial, legal, regulatory, business or operational harm. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing 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 or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Additionally, actual, potential or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants. Further, it is possible that unauthorized access to our data may be obtained through inadequate use of security controls by suppliers or other vendors. We rely on such third parties to implement effective security measures and identify and correct for any failures, deficiencies or breaches.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us. These events could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. Because the techniques used by computer programmers who may attempt to penetrate and sabotage our network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents. Additionally, in the event of material failures, security breaches, cyberattacks or other related breaches of our computer systems or the computer systems of third parties with access to our data, our liability insurance may not be sufficient in type or amount to cover us against related claims.

Risks Related to the Separation and Distribution

We may not achieve some or all of the expected benefits of the separation.

We may not be able to achieve the full operational, financial and strategic benefits expected to result from the separation, or such benefits may be delayed or not realized at all. The separation is expected to provide the following benefits, among others: (i) allowing us to focus exclusively on our business and distinct needs from those of Alkermes, and pursue our own operational and strategic priorities and respond to trends, developments and opportunities in our target markets; (ii) reduce competition for capital allocation and (iii) more direct potential access to the capital markets as a standalone company.

These anticipated benefits are based on a number of assumptions and uncertainties, which may prove to be incorrect or incomplete and we may not achieve these and other anticipated benefits for a variety of reasons. As a standalone company, we may be more susceptible to market fluctuations and other adverse events than if we were still a part of Alkermes; our business will be less diversified than Alkermes' business prior to completion of the separation and the actions that have been required to separate Alkermes' and our respective businesses could disrupt our operations. If we fail to achieve some or all of the benefits expected to result from the separation, or if such benefits are delayed, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

As an independent, publicly traded company, we may not enjoy the same benefits that we did as a part of the business of Alkermes.

As an integrated company with Alkermes, we were able to use Alkermes' size and purchasing power in procuring various goods and services related to the manufacture of our product candidates and to share economies of scope and scale in costs, employees, vendor relationships and customer relationships. Although Alkermes will provide certain of these services for a specified time period pursuant to the transition services agreements we have entered into with Alkermes, this arrangement may not fully capture the benefits that have resulted from being integrated with Alkermes and may result in us paying higher amounts than those allocated to us in the past for services provided on a centralized basis. As a separate, standalone company, we may be unable to obtain goods and services related to the manufacture of our product candidates at the prices and terms obtained prior to the separation, which could impact our overall profitability. This could have an adverse effect on our financial condition, results of operations and cash flows following the completion of the separation.

We have a very limited history of operating as a standalone company and we expect to incur increased administrative and other costs by virtue of our status as an independent public company. Our historical combined financial information included in this report is not necessarily representative of the results that we would have achieved and may achieve as a separate, publicly traded company and should not be relied upon as an indicator of our future results.

Historically and through the date of the separation, our business was conducted by Alkermes. Our historical information provided in this report refers to our business as operated by and integrated with Alkermes. Our historical combined financial information included in this report is derived from the consolidated financial statements and accounting records of Alkermes. Accordingly, the historical combined financial information included in this report may not reflect the operating results, financial condition or cash flows that we would have achieved as a separate, publicly traded company during the periods presented, or the financial results we will achieve in the future. In particular, our future financial results may vary from the historical combined financial information included in this report as a result of the following factors, among others:

- our historical combined financial data does not reflect the separation;
- our historical financial data reflects expense allocations for certain business and support functions that are provided on a centralized basis within Alkermes, such as expenses for clinical and preclinical activities, manufacturing, research and development expenses not directly attributable to individual oncology programs and corporate administrative services, including senior management, information technology, legal, accounting and finance, human resources, facilities and other corporate services that may be lower than the comparable expenses we would have actually incurred, or will incur in the future, as a standalone company;
- our capital structure will be different from that reflected in our historical combined financial statements;
- significant increases may occur in our cost structure as a result of becoming a standalone public company, including costs related to public company reporting, investor relations and compliance with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"); and
- the separation may have a material effect on our relationships with our suppliers, vendors, third-party manufacturers, collaborators and other business relationships.

Our financial condition and future results of operations, after giving effect to the separation, will be materially different from results reflected in our historical financial statements included elsewhere in this report. As a result of the separation, it may be difficult for investors to compare our future results to historical results or to evaluate our relative performance or trends in our business.

The separation may result in disruptions to, and harm our relationships with, our strategic business partners.

Uncertainty related to the separation may lead the suppliers, manufacturers, CROs, third-party manufacturers, and other parties with which we currently do business or may do business with in the future to terminate or attempt to negotiate material changes in our existing business relationships, or cause any of these parties to delay entering into business relationships with us or consider entering into business relationships with parties other than us. These disruptions could have a material and adverse effect on our business, prospects, financial condition and results of operations. The effect of such disruptions could be exacerbated by any delays in the completion of the separation.

Our agreements with Alkermes may not reflect terms that would have resulted from negotiations with unaffiliated third parties.

The agreements related to the separation, including, among others, the separation agreement, the transition services agreements, the tax matters agreement and the employee matters agreement were entered into in the context of the separation while we were still controlled by Alkermes. Prior to the distribution, Alkermes effectively had the sole and absolute discretion to determine and change the terms of the separation and distribution, including the terms of any agreements between Alkermes and us. As a result, our agreements with Alkermes may not reflect terms that would have resulted from negotiations between unaffiliated third parties in an arms-length transaction. For a more detailed description, see “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes” in our Form 10.

As we build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

We continue to install and implement information technology infrastructure to support our critical business functions, particularly in relation to areas outside the U.S., including collecting and storing proprietary and confidential data, including intellectual property, our proprietary business information, systems relating to accounting and reporting, manufacturing process control, inventory control and trial and research data. We may incur temporary interruptions in business operations if we cannot transition effectively from Alkermes’ existing transactional and operational systems and data centers and the transition services that support these functions as we replace these systems. We may not be successful in effectively and efficiently implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we implement the new systems and replace Alkermes’ information technology services, or our failure to implement the new systems and replace Alkermes’ services effectively and efficiently, could disrupt our business and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our ability to operate our business effectively may suffer if we do not, quickly and cost effectively, establish our own administrative and support functions necessary to operate as a standalone public company.

In connection with the separation, we are creating our own financial, administrative, corporate governance, and public company compliance and other support systems, including for the services Alkermes had historically provided to us, or we expect to contract with third parties to replace Alkermes systems that we are not establishing internally. We expect this process to be complex, time consuming and costly. In addition, we are also establishing or expanding our own tax, treasury, internal audit, investor relations, corporate governance, and publicly listed company compliance and other corporate functions. These corporate functions fall beyond the scope of the operational service domains formerly provided by Alkermes and will require us to develop new standalone corporate functions. We may need to make significant investments to replicate, or will need to outsource from other providers, these corporate functions to replace these additional corporate services that Alkermes historically provided to us prior to the separation. Alkermes may continue to provide support for certain of our business functions, including financial, corporate, administrative and other support systems, after the separation for a limited period of time, pursuant to the transition services agreements and certain other agreements we entered into with Alkermes. Any failure or significant downtime in our own financial, administrative or other support systems or in the Alkermes financial, administrative or other support systems during the transitional period in which Alkermes provides us with support could negatively impact our results of operations or prevent us from paying our suppliers and employees, executing business combinations and non-U.S. currency transactions, if required, or performing administrative or other services on a timely basis, which could negatively affect our results of operations.

Further, as a standalone public company, we will incur significant legal, accounting and other expenses that we did not independently incur as part of Alkermes. The provisions of the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq, have imposed various requirements on public companies. For example, the Sarbanes-Oxley Act requires, among other

things, that we maintain and periodically evaluate our internal control over financial reporting and disclosure controls and procedures. In particular, we and our management will have to perform system and process evaluation and testing of our and their internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act.

Although Alkermes has historically tested, and currently tests, its internal control over financial reporting on a regular basis, we have not previously done so as a standalone entity. Doing so for ourselves will require our management and other personnel to devote a substantial amount of time to establish these controls in order to comply with these requirements and will also increase our legal and financial compliance costs. In particular, compliance with Section 404 of the Sarbanes-Oxley Act will require a substantial accounting expense and significant management efforts. We cannot be certain at this time that all of our controls will be considered effective and our internal control over financial reporting may not satisfy the regulatory requirements when they become applicable to us.

Alkermes may fail to perform under various transaction agreements that were executed as part of the separation or we may fail to have necessary systems and services in place when certain of the transaction agreements expire.

In connection with the separation, we and Alkermes entered into a separation agreement and various other agreements, including transition services agreements, a tax matters agreement and an employee matters agreement. These agreements are discussed in greater detail in “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes” in our Form 10. Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after the separation. We will rely on Alkermes to satisfy its performance and payment obligations under these agreements. If Alkermes is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur operational difficulties or losses.

If we do not have in place our own systems and services, or if we do not have agreements with other providers of these services when the transaction or transitional agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We are in the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Alkermes currently provides to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Alkermes’ systems to our systems. These systems and services may also be more expensive or less efficient than the systems and services Alkermes is expected to provide during the transition period.

In connection with the separation, we have assumed and agreed to indemnify Alkermes for certain liabilities. If we are required to make payments pursuant to these indemnities to Alkermes, we may need to divert cash to meet those obligations and our financial results could be harmed.

Pursuant to the separation agreement and certain other agreements we entered into with Alkermes, we have assumed and agreed to indemnify Alkermes for certain liabilities for uncapped amounts, which may include, among other items, associated defense costs, settlement amounts and judgments, as discussed further in “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes” in our Form 10. Payments pursuant to these indemnities may be significant and could harm our business, particularly indemnities relating to our actions that could impact the tax-free nature of the separation and distribution and certain related transactions. Third parties could also seek to hold us responsible for liabilities of the Alkermes business. Alkermes has agreed to indemnify us for liabilities of the Alkermes business, but such indemnity from Alkermes may not be sufficient to protect us against the full amount of such liabilities, and Alkermes may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from Alkermes any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. In addition, pursuant to the separation agreement and certain other agreements we entered into with Alkermes, we have agreed to undertake certain obligations for the benefit of Alkermes and its former employees who became employees of ours following the Separation. If we fail to comply with such obligations, we may be liable to Alkermes. Each of these risks could harm our business, prospects, financial condition and results of operations.

The separation may impede our ability to attract and retain key personnel, which could materially harm our business.

Our success will depend in large part upon the leadership and performance of our management team and other key employees. Operating as an independent company will demand a significant amount of time and effort from our management and other employees and may give rise to increased employee turnover. If we lose the services of members of our management team or other key employees, we may not be able to successfully manage our business or achieve our business objectives. Following the separation, we will need to continue to attract and retain qualified key personnel in a highly competitive environment. Our ability to attract, recruit and retain such talent will depend on a number of factors, including the hiring practices of our competitors, the performance of our development programs, our compensation and benefits, work location and work environment and economic conditions affecting our industry generally. If we cannot effectively hire and retain qualified employees, our business, prospects, financial condition and results of operations could suffer.

Risks Related to Tax Matters

If the separation and distribution, in relevant part and together with certain related transactions, do not qualify as transactions that are tax-free for U.S. federal income tax purposes, certain U.S. subsidiaries of Alkermes and Alkermes' shareholders could be subject to significant tax liabilities, and we could be required to indemnify Alkermes or its subsidiaries for material taxes pursuant to indemnification obligations under the tax matters agreement.

It was a condition to the distribution that Alkermes receive a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. Alkermes has received a favorable private letter ruling from the IRS addressing the qualification of the distribution under Section 355 of the Code. However, the private letter ruling does not address all of the issues that are relevant to determining whether the separation and distribution, in relevant part and together with certain related transactions, qualify as transactions that are tax-free for U.S. federal income tax purposes. The IRS private letter ruling and the opinion of Goodwin Proctor LLP are based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings from Alkermes and us (including those relating to the past and future conduct of Alkermes and us) and are subject to certain caveats. If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or Alkermes breach any of our respective covenants relating to the separation, the IRS private letter ruling and any tax opinion may be invalid. Accordingly, notwithstanding receipt of the IRS private letter ruling and an opinion of Goodwin Procter LLP, the IRS could determine that the separation and distribution, in relevant part and together with certain related transactions, should be treated as taxable transactions for U.S. federal income tax purposes if it determines that any of the facts, assumptions, representations, statements or undertakings that were included in the request for such IRS private letter ruling or on which any such opinion was based are false or have been violated. In addition, an opinion of Goodwin Procter LLP represents the judgment of Goodwin Procter LLP, which is not binding on the IRS or any court. Accordingly, notwithstanding receipt by Alkermes of the tax opinion and the IRS private letter ruling referred to above, the IRS could assert that the separation and distribution and certain related transactions do not qualify for tax-free treatment for U.S. federal income tax purposes.

If the separation and distribution, in relevant part and together with certain related transactions, fail to qualify as transactions that are tax-free under Sections 355 and 368(a)(1)(D) of the Code, in general, for U.S. federal income tax purposes, certain U.S. subsidiaries of Alkermes would recognize taxable gain and Alkermes shareholders who receive our ordinary shares in the distribution would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares. For more information, see "Material U.S. Federal Income Tax Consequences—Material U.S. Federal Income Tax Consequences of the Distribution" in our Form 10.

In connection with the distribution, we and Alkermes entered into a tax matters agreement pursuant to which we are responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the separation and distribution, in relevant part and together with certain related transactions, fail to qualify as transactions that are tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, and if and to the extent that such failure results from certain actions, omissions or failures to act by Alkermes, including a prohibited change of control in Alkermes under Section 355(e) of the Code or an acquisition of Alkermes shares or assets, then Alkermes will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from certain actions, omissions or failures to act by us, including a prohibited change of control in Mural under Section 355(e) of the Code or an acquisition of our shares or assets, then we will indemnify Alkermes for any resulting taxes, interest, penalties and other costs. If such failure does not result from a prohibited change of control in Alkermes or Mural under Section 355(e) of the Code and both we and Alkermes are responsible for such failure, liability will be shared according to relative fault. If neither we nor Alkermes is responsible for such failure, Alkermes will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see "Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes—Tax Matters Agreement" in our Form 10. Our indemnification obligations to Alkermes under the tax matters agreement are not limited in amount or subject to any cap. If we are required to pay any taxes or indemnify Alkermes and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, we may be subject to substantial liabilities.

We may not be able to engage in attractive strategic or capital-raising transactions following the separation.

To preserve the tax-free treatment of the separation and distribution for U.S. federal income tax purposes, for the four-year period beginning two years before and ending two years after the distribution, we are prohibited under the tax matters agreement, except in specific circumstances, from certain actions, including: (i) entering into or approving any transaction involving the acquisition of outstanding or newly issued Mural equity that, when combined with other non-excepted changes in ownership of our ordinary shares, results in a change in ownership of more than a specified percentage; (ii) liquidating or partially liquidating, or merging or consolidating (unless we are the survivor); (iii) making or changing any entity classification election; (iv) ceasing to be engaged in an active trade or business, or selling, transferring or disposing of more than a specified percentage of the assets of any

active trade or business or reducing the number of full-time employees engaged in any active trade or business by more than a specified percentage; (v) amending any of our organizational documents or taking any action affecting the voting rights of our ordinary shares; (vi) redeeming or otherwise repurchasing any of our outstanding shares or options; or (vii) taking or failing to take any other action that would prevent the separation and distribution, in relevant part and together with certain related transactions, from qualifying as transactions that are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. These restrictions may limit for a period of time our ability to pursue certain strategic transactions, equity issuances or repurchases or other transactions that we may believe to be in the best interests of our shareholders or that might increase the value of our business. For more information, see "Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes—Tax Matters Agreement" in our Form 10.

If we are a passive foreign investment company, there could be material adverse U.S. federal income tax consequences to U.S. holders.

Under the Code, we will be a passive foreign investment company (a "PFIC") for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U.S. holder holds our ordinary shares, the U.S. holder may be subject to material adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements.

It is uncertain whether we or any of our subsidiaries will be treated as a PFIC for U.S. federal income tax purposes for the year that includes the distribution or any subsequent tax year. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test described above, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering and the cash we have on our balance sheet as of immediately after the distribution. Because PFIC status is based on our income, assets, and activities for the entire taxable year, we cannot make a final determination at this time as to whether we will be a PFIC for the current taxable year and our PFIC status may change from year to year.

In certain circumstances, a U.S. holder of shares in a PFIC may alleviate some of the adverse tax consequences described above by making either a "qualified electing fund" election under Section 1295 of the Code (a "QEF Election") or a mark-to-market election (if our ordinary shares constitute "marketable" securities under the Code). However, a U.S. holder may make a QEF Election with respect to our ordinary shares only if we agree to furnish such U.S. holder annually with required information. We have not made a determination as to whether we would provide the information necessary for U.S. holders to make a QEF Election. There is also no assurance that we will have timely knowledge of our status as a PFIC in the future or of the required information to be provided.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section entitled "Material U.S. Federal Income Tax Consequences—Material U.S. Federal Income Tax Consequences of the Ownership and Disposition of Our Ordinary Shares—Passive Foreign Investment Company Rules" in our Form 10. U.S. holders should consult their tax advisors with respect to the potential material adverse U.S. tax consequences if we or any of our subsidiaries are or were to become a PFIC.

Risks Related to Ownership of Our Ordinary Shares

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors.

We qualify as an "emerging growth company", as defined in the JOBS Act. We may remain an emerging growth company until December 31, 2028, although if the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1.0 billion of non-convertible debt over a three-year period. For so long as we remain an emerging growth company,

we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

In addition, the JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of the exemption for the delayed adoption of certain accounting standards, and therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standards and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

The price of our ordinary shares could be subject to volatility related or unrelated to our operations.

Our share price is volatile. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ordinary shares at an attractive price or at all. The market price for our ordinary shares may be influenced by many factors, including:

- adverse results from preclinical studies or clinical trials of our product candidates or our competitors' product candidates or products;
- the commencement, enrollment, completion or results of any ongoing or future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated safety concerns related to the use of our product candidates;
- adverse regulatory decisions, including failure by us or one of our competitors to receive regulatory approval of product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- lower than expected market acceptance of our or our competitors' products following approval for commercialization;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- introduction of new products or services by our competitors;

•changes in financial estimates by us or by any securities analysts who might cover our shares;

•conditions or trends in our industry;

•our cash position;

•sales of our ordinary shares by us or our shareholders in the future;

•adoption of new accounting standards;

•ineffectiveness of our internal controls;

•changes in the market valuations of similar companies;

•stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry and those developing immuno-oncology products;

•publication of research reports or other media articles about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

•announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;

•announcements of investigations or regulatory scrutiny of our operations or lawsuits that may be filed against us;

•investors' general perception of our company and the reputation of our business;

•recruitment or departure of key personnel;

•overall performance of the equity markets;

•trading volume of our ordinary shares;

•disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;

•significant lawsuits, including patent or shareholder litigation;

•proposed changes to healthcare laws or pharmaceutical pricing in the U.S. or non-U.S. jurisdictions, or speculation regarding such changes;

•developments with respect to the COVID-19 pandemic;

•general political and economic conditions, including disruptions in the banking industry; and

•other events or factors, many of which are beyond our control.

In addition, in the past, shareholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' shares. This risk is especially relevant for us because biopharmaceutical companies have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If securities or industry analysts do not publish research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, our share price and trading volume could decline.

The trading market for our ordinary shares relies, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts or their research. There can be no assurance that analysts will begin to cover us. There is also no assurance that any covering analysts will provide favorable coverage, and unfavorable coverage, or lack of favorable coverage, could cause our share price and trading volume to decline.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in the manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in one or more transaction(s), investors may be

materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

We have adopted an equity incentive plan pursuant to which we may grant stock options, restricted stock unit awards and other equity-based awards to our employees, directors and consultants. Any increase in the number of shares outstanding as a result of the exercise of outstanding options or the vesting or settlement of outstanding equity awards will cause our shareholders to experience additional dilution, which could cause our share price to fall.

Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests and other actions by activist shareholders have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest or other activist shareholder action, we may not be able to respond successfully to the contest or action, which could be disruptive to our business. Even if we are successful, our business could be adversely affected by any proxy contest or activist shareholder action involving us because:

- responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, can disrupt operations and divert the attention of management and employees, and can lead to uncertainty;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our shareholders.

These actions could cause the market price of our ordinary shares to experience periods of volatility.

We do not intend to pay dividends on our ordinary shares so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the sole discretion of our board of directors. In addition, the terms of any future debt agreements that we may enter into may preclude us from paying dividends. Any return to our shareholders will therefore likely be limited in the foreseeable future to the appreciation of their shares.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. Our financial results historically were included within the consolidated results of Alkermes, and prior to the separation, we were not directly subject to reporting and other requirements of the Exchange Act and Section 404 of the Sarbanes-Oxley Act. For so long as we remain an emerging growth company, we will be exempt from Section 404(b) of the Sarbanes-Oxley Act, which requires auditor attestation to the effectiveness of internal control over financial reporting. We cannot predict if investors will find our ordinary shares less attractive because we may rely on the exemptions available to us as an emerging growth company. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We will be subject to Section 404(a) of the Sarbanes-Oxley Act requiring annual management assessment of the effectiveness of our internal control over financial reporting beginning with our second Annual Report on Form 10-K that we file with the SEC, and, as of the expiration of our emerging growth company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. These and other obligations will place significant demands on our management, administrative and operational resources, including accounting and information technology resources. To comply with these requirements, we anticipate that we will need to further upgrade our systems, including duplicating computer hardware infrastructure, implement additional financial and management controls, reporting systems and procedures and hire additional accounting, finance and information technology staff. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. If we are unable to do this in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired and our business, prospects, financial condition and results of operations could be harmed.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

An active trading market for our ordinary shares may not develop or be sustained and our shareholders may not be able to resell their shares of our ordinary shares.

Prior to the distribution, there was no public market for our ordinary shares. We cannot predict the extent to which an active market for our ordinary shares will develop or be sustained, or how the development of such a market might affect the market price for our ordinary shares. As a result, it may be difficult for our shareholders to sell their ordinary shares at an attractive price or at all.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, Dodd-Frank, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be materially adversely effected.

Pursuant to Section 404, in our second annual report due to be filed with the SEC, after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company with less than $100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are 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, including through hiring additional financial and accounting personnel, 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 we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

As a public company, 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 control over financial reporting, 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.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our ordinary shares, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may not be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize any or all potential benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Furthermore, for the four-year period beginning two years before and ending two years after the distribution, we will be restricted from entering into certain transactions pursuant to the tax matters agreement. For more information, see “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes—Tax Matters Agreement” in our Form 10.

Risks Related to Our Jurisdiction of Incorporation in Ireland

Irish law differs from the laws in effect in the U.S. and might afford less protection to the holders of our securities, and any actual or potential takeover offer for us will be subject to the Irish Takeover Rules.

Holders of our securities could have more difficulty protecting their interests than would the shareholders of a corporation incorporated in a jurisdiction of the U.S. As an Irish-incorporated company, we are governed by Irish law, including the Irish Companies Act 2014 and the Irish Takeover Rules, which differs in some significant, and possibly material, respects from provisions set forth in various U.S. state laws applicable to U.S. corporations and their shareholders, including provisions relating to interested directors, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. The duties of directors and officers of an Irish company are generally owed to the company only. Therefore, under Irish law, shareholders of Irish companies do not generally have a right to commence a legal action against directors or officers and may only do so in limited circumstances. Directors of an Irish company must act with due care and skill, honestly and in good faith with a view to the best interests of the company. Directors must not put themselves in a position in which their duties to the company and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the company or any of our subsidiaries. A director or officer can be held personally liable to the company in respect of a breach of duty to the company.

In addition, our Constitution provides that the Irish courts have exclusive jurisdiction to determine any and all derivative actions in which a holder of our ordinary shares asserts a claim in the name of the company, actions asserting a claim of breach of a fiduciary duty of any of the company’s directors and actions asserting a claim arising pursuant to any provision of Irish law or our Constitution. Under Irish law, the proper claimant for wrongs committed against a company, including by the company’s directors, is considered to be the company itself. Irish law permits a shareholder to initiate a lawsuit on behalf of a company such as us only in limited circumstances and requires court permission to do so, meaning there is limited ability for any potential shareholder to bring a claim directly to the Irish courts and the requirement for court permission may discourage potential shareholders from bringing a claim.

Our Constitution however also provides that unless we consent in writing to the selection of an alternative forum, the U.S. federal district courts of the U.S. shall be the sole and exclusive forum for resolving any dispute asserting a cause of action arising under the Securities Act of 1933, as amended (the “Securities Act”), and the Exchange Act, or the respective rules and regulations

promulgated thereunder. However, there is some uncertainty as to whether a court would enforce such a provision and, in any event, our shareholders will not be deemed to have waived our compliance with U.S. federal securities laws and the rules and regulations thereunder. Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for U.S. federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These provisions may limit, or increase the difficulty of, shareholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors and officers under the Securities Act and Exchange Act, or may result in increased costs to bring a claim.

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of U.S. federal or U.S. state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of U.S. federal or U.S. state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or U.S. state court based on civil liability, whether or not based solely on U.S. federal or U.S. state securities laws, would not automatically be enforceable in Ireland.

In addition, any actual or potential takeover offer for our company will be subject to the Irish Takeover Rules. Under the Irish Takeover Rules, during the course of an offer or at any earlier time during which our board of directors has reason to believe that an offer for our company may be imminent, our board of directors will not be permitted to take any action, other than seeking alternative offers, which might frustrate the making of an offer for our ordinary shares unless we obtain approval from our shareholders or from the Irish Takeover Panel for such action. Potentially frustrating actions that are prohibited during the course of an offer, or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent, include (i) the issuance of shares, options or convertible securities or the redemption or purchase of own shares, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer. Accordingly, if these restrictions become applicable to us, we may be unable to take, or may be delayed in taking, certain actions, in connection with a financing, commercial or strategic transaction or otherwise, that we believe are in the best interest of the company.

Transfers of our ordinary shares may be subject to Irish stamp duty.

Transfers of our ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company ("DTC") will not be subject to Irish stamp duty. However, if you hold your ordinary shares directly, rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee.

We may, in our absolute discretion, pay (or cause one of our affiliates to pay) any stamp duty. Our articles of association will provide that, in the event of any such payment, we (i) may seek reimbursement from the buyer, (ii) will have a lien against the shares acquired by such buyer and any dividends paid on such shares and (iii) may set-off the amount of the stamp duty against future dividends on such shares.

We might not meet the conditions for reconstruction relief on separation and distribution.

The separation and distribution fall within the charge to Irish stamp duty (at a rate of 1%) as the transfer relates to Irish property (i.e., the shares in an Irish company issued in consideration) unless a stamp duty exemption applies. An exemption is expected to be available in Ireland which applies to qualifying reconstructions which satisfy certain criteria. While it is expected that the conditions for the exemption should be met, there is a requirement that the relief is claimed by filing an electronic stamp duty return with Irish Revenue Commission ("Irish Revenue"). As a filing is made to Irish Revenue, Irish Revenue are notified of a claim and there is a risk that the availability of restructuring relief could be challenged.

If the conditions for stamp duty reconstruction relief are not met, the separation and distribution may also be unlikely to meet the conditions for the reconstruction relief for capital gains tax purposes. As a result, Alkermes shareholders may be subject to Irish tax on capital (or chargeable) gains, dividend withholding tax and income tax on dividends as a result of the separation and distribution. For further details, see "Material Irish Tax Consequences" in our Form 10.

Our ability to obtain financing may be limited by the terms of our future financing arrangements and the provisions of Irish law.

Restrictions in future financing arrangements and mandatory provisions of Irish law may adversely affect our ability to obtain financing. Future debt agreements or other financing arrangements may include covenants that limit our ability to engage in specified transactions, including prohibiting us from incurring additional secured or unsecured debt, paying dividends or redeeming equity

securities. In addition, Irish law requires that our directors must have specific authority from shareholders to allot and issue new shares generally, or to issue new shares for cash to new shareholders without offering such shares to existing shareholders pro-rata to their existing holdings (including, in each case, rights to subscribe for or otherwise acquire any shares), even where such shares form part of our authorized but unissued share capital. Irish law also provides that, in the event of an actual or potential takeover offer being made for us, various actions, including issuing shares, options or convertible securities, material acquisitions or disposals, entering into contracts other than in the ordinary course of business or any action, other than seeking alternative offers, may be prohibited unless approved by our shareholders or the Irish Takeover Panel. These restrictions may prevent or delay us from taking actions that we believe are in our best interest or from obtaining financing on favorable terms, in adequate amounts or at all, which may adversely impact our results of operations and financial condition.

There is no guarantee that the High Court of Ireland's approval of the creation of distributable reserves will be forthcoming.

While we currently do not intend for the foreseeable future to pay dividends, we may determine to pay dividends in the future, subject to applicable law. Under Irish law, dividends must be paid (and share repurchases must generally be funded) out of "distributable reserves," which we will not have immediately following the distribution. Immediately after the distribution, we will not have any "distributable reserves" but will have a significant amount of share premium. To create "distributable reserves," we would need to undertake an Irish legal process pursuant to which we will convert up to our entire share premium account to "distributable reserves." This process will require the approval of the High Court of Ireland. Although we are not aware of any reason why the High Court of Ireland would not approve the creation of distributable reserves in this manner, the issuance of the required order is a matter for the discretion of the High Court of Ireland and there is no guarantee that such approval will be forthcoming. In the event that "distributable reserves" are not created, no distributions by way of dividends, share repurchases or otherwise will be permitted under Irish law until such time as we have created sufficient distributable reserves from our operating activities.

Irish law imposes restrictions on certain aspects of capital management.

Irish law allows our shareholders to pre-authorize shares to be issued by our board of directors without further shareholder approval for up to a maximum of five years. This authorization was contained in our Constitution at the time of the distribution and will therefore lapse approximately five years after the distribution unless renewed by shareholders and we cannot guarantee that such renewal will be approved. Additionally, subject to specified exceptions, including the opt-out that is included in our articles of association, Irish law grants statutory pre-emptive rights to existing shareholders to subscribe for new issuances of shares for cash. This opt-out also expires approximately five years after the distribution unless renewed by further shareholder approval and we cannot guarantee that such renewal of the opt-out from pre-emptive rights will be approved. We cannot assure you that these Irish legal restrictions will not interfere with our capital management.

If a quorum is not present at a general meeting, decisions may be taken at an adjourned meeting by those shareholders in attendance, irrespective of their number.

Our Constitution provides that no business shall be transacted at any general meeting unless a quorum is present. Two or more shareholders present in person or by proxy holding not less than a majority of our issued and outstanding shares entitled to vote at the meeting in question constitute a quorum for such meeting. If a quorum is not present within an hour from the time appointed for the meeting, the meeting shall (i) if convened by the shareholders, be dissolved, and (ii) if otherwise convened, be adjourned for one week and held at the same time and place (or such other place as the board of directors determines). If a quorum is not present within an hour of the time appointed for the adjourned meeting, the shareholders present shall constitute a quorum.

Our Constitution provides that our board of directors or the chairperson of our board of directors may determine the manner in which the poll is to be taken at each meeting and the manner in which the votes are to be counted.

A poll in respect of the election of the chairperson or on a question of adjournment shall be taken immediately. A poll in respect of any other question shall be taken within 10 days from the date of the meeting at which the vote was taken, as the chairperson of the meeting directs. Any business other than that on which a poll has been demanded may proceed. No notice is required in respect of a poll not taken immediately. The result of the poll shall be deemed to be the resolution of the general meeting at which the poll was demanded. On a poll, a shareholder entitled to more than one vote need not use all their votes in the same way.

While there is no requirement for a poll to be conducted in writing under Irish law, it is standard practice that polling papers are provided by a company. The proxy form issued with notice of the general meeting may include the option to cast a vote on a poll. If supplied at the general meeting, polling papers are completed and put in a ballot box. The board of directors may also permit electronic or telephonic voting. If voting lists are used, generally three lists labeled "For", "Against" and "Abstain" (or "Withheld") are presented to the meeting and each shareholder signs the relevant list, and prints their name, whether they are voting as shareholder or proxy, and the number of votes cast.

General Risks

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and, in recent years, the COVID-19 pandemic has caused significant volatility and uncertainty in the U.S. and international markets. In addition, the current military conflicts between Russia and Ukraine and in the Middle East could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that may be initiated by nations including the U.S., the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, third-party manufacturers and other third parties with which we conduct business. A severe or prolonged economic downturn, global conflict or political unrest could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Changes in tax law could adversely affect our business and financial condition.

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 IRS and the U.S. Department of Treasury. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ordinary shares. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

In addition, non-U.S. governments may enact tax laws in response to the changes in the rules dealing with U.S. federal, state and local income taxation or otherwise that could result in further changes to global taxation and materially affect our financial position and results of operations or holders of our ordinary shares. The uncertainty surrounding the effect of the reforms on our financial results and business or on holders of our ordinary shares could also weaken confidence among investors.

We have broad discretion regarding use of our cash and cash equivalents, and we may use them in ways that do not enhance our operating results or the market price of our ordinary shares.

Our management has broad discretion in the application of our cash and cash equivalents. We could utilize our cash and cash equivalents in ways our shareholders may not agree with or that do not yield a favorable return, if any, and our management might not apply our cash and cash equivalents in ways that ultimately increase the value of our shareholders' investments. If we do not utilize our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause our share price to decline.

Item 6. Exhibits.

Exhibit Number	Description
2.1†	Separation Agreement, dated as of November 13, 2023, by and between Alkermes plc and Mural Oncology plc (incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.1†	Tax Matters Agreement, dated as of November 13, 2023, by and between Alkermes plc and Mural Oncology plc (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.2	Employee Matters Agreement, dated as of November 13, 2023, by and between Alkermes plc and Mural Oncology plc (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.3†	Transition Services Agreement, dated as of November 13, 2023, by and between Alkermes, Inc. and Mural Oncology, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.4†	Transition Services Agreement, dated as of November 13, 2023, by and between Mural Oncology, Inc. and Alkermes, Inc. (incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.5†	Employment Agreement, effective as of November 15, 2023, by and between Mural Oncology, Inc. and Adam Cutler (incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.6†	Employment Agreement, effective as of November 15, 2023, by and among Mural Oncology plc, Mural Oncology, Inc. and Dr. Caroline Loew (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form 10 filed with the SEC on October 10, 2023 (File No. 001-41837)).
10.7†	Employment Agreement, effective as of November 15, 2023, by and between Mural Oncology, Inc. and Vicki L. Goodman (incorporated by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.8	Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009, as amended (incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
10.9	Assignment and Assumption of Lease, dated as of November 13, 2023, by and between Alkermes, Inc. and Mural Oncology, Inc. (incorporated by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K filed with the SEC on November 15, 2023 (File No. 001-41837)).
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 – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ The certifications furnished in Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications are not to be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.

† Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Mural hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

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.

Mural Oncology plc

Date: December 14, 2023

By: /s/ Adam Cutler
Adam Cutler
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Caroline Loew, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Mural Oncology plc;

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)) for the registrant and have:

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

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

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

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

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

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

Date: December 14, 2023

By: /s/ Caroline Loew
Caroline Loew, Ph.D.
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, Adam Cutler, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Mural Oncology plc;

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)) for the registrant and have:

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

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

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

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

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

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

Date: December 14, 2023

By: /s/ Adam Cutler
Adam Cutler
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Mural Oncology plc (the "Company") on Form 10-Q for the period ended September 30, 2023 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, to the best of my knowledge:

(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: December 14, 2023

By: /s/ Caroline Loew
Caroline Loew, Ph.D.
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 Mural Oncology plc (the "Company") on Form 10-Q for the period ended September 30, 2023 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, to the best of my knowledge:

(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: December 14, 2023

By: /s/ Adam Cutler
Adam Cutler
Chief Financial Officer
(Principal Financial and Accounting Officer)