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Â UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549 Â FORM 10-Q Â (Mark One) â˜’ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2024 OR â˜ 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 Â Mural Oncology plc (Exact Name of Registrant as Specified in its Charter) Â Â Ireland 98-1748617 (State or other jurisdiction ofincorporation or organization) (I.R.S. EmployerIdentification No.) 10 Earlsfort TerraceDublin 2, D02 T380, Ireland Not Applicable (Address of principal executive offices) (Zip Code) +353-1-905-8020

(Registrantâ€™s telephone number, including area code) Â Securities registered pursuant to Section 12(b) of the Act: Â Title of each class Â TradingSymbol(s) Â Name of each exchange on which registered Ordinary shares, nominal value $0.01 per share Â MURA Â 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 â˜’ No â˜ 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 (Â§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 â˜’ No â˜ 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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act. Â Large accelerated filer â˜ Accelerated filer â˜ Non-accelerated filer â˜’ Smaller reporting company â˜’ Â Â Â Â Emerging growth company Â â˜’ Â 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. â˜ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes â˜ No â˜’ As of November 1, 2024, the registrant had 17,060,310 ordinary shares, nominal value $0.01 per share, outstanding. Â Â Â Table of Contents Â Â Â Page Â CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS 2 Â SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS 3 Â Â Â PART I. FINANCIAL INFORMATION 5 Â Â Â Item 1. Financial Statements (Unaudited) 5 Â Condensed Consolidated Balance Sheets 5 Â Condensed Consolidated Statements of Operations and Comprehensive Loss 6 Â Condensed Consolidated Statements of Equity (Deficit) 7 Â Condensed Consolidated Statements of Cash Flows 8 Â Notes to Unaudited Condensed Consolidated Financial Statements 9 Item 2. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations 19 Item 3. Quantitative and Qualitative Disclosures About Market Risk 28 Item 4. Controls and Procedures 28 Â Â Â PART II. OTHER INFORMATION 29 Â Â Â Item 1. Legal Proceedings 29 Item 1A. Risk Factors 29 Item 5. Other Information 76 Item 6. Exhibits 78 Â Â Signatures 79 Â Â 1 CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS This Quarterly Report on 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 risks and uncertainties. All statements contained 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 â€œmay,â€ â€œwill,â€ â€œwould,â€ â€œcould,â€ â€œshould,â€ â€œbelieves,â€ â€œestimates,â€ â€œprojects,â€ â€œpotential,â€ â€œexpects,â€ â€œplans,â€ â€œseeks,â€ â€œintends,â€ â€œevaluates,â€ â€œpursues,â€ â€œanticipates,â€ â€œcontinues,â€ â€œdesigns,â€ â€œimpacts,â€ â€œaffects,â€ â€œforecasts,â€ â€œtarget,â€ â€œoutlook,â€ â€œinitiative,â€ â€œobjective,â€ â€œdesigned,â€ â€œpriorities,â€ â€œgoalâ€ 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. Forward-looking statements in this Quarterly Report include statements about, among other things: â€¢our post-Separation (as defined below) relationships with Alkermes plc (the â€œFormer Parentâ€ or â€œAlkermesâ€), third parties, collaborators and our employees; â€¢our ability to operate as a standalone company and execute our strategic priorities; â€¢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 periods during which the results of the trials will become available, and our research and development programs; â€¢our ability to efficiently discover and develop product candidates; â€¢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; â€¢the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; â€¢our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates; â€¢our ability to obtain and maintain regulatory approval of our product candidates; â€¢the safety profile and related adverse events of our product candidates; â€¢our ability to commercialize our products, if approved; â€¢the pricing and reimbursement of our products, if approved; â€¢the implementation of our business model, and strategic plans for our business and product candidates; â€¢the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates; â€¢estimates of our future expenses, revenue, capital requirements, and our needs for additional financing; â€¢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; â€¢future agreements with third parties in connection with the commercialization of product candidates and any product, if approved; â€¢the size and growth potential of the markets for our product candidates, and our ability to serve those markets; â€¢our financial performance; â€¢the rate and degree of market acceptance of our product candidates; 2 â€¢regulatory developments in the U.S. and relevant non-U.S. countries and the impact of U.S. and non-U.S. laws and regulations; â€¢our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; â€¢our ability to manufacture, or have manufactured, our products or product candidates; â€¢the success of competing therapies that are or may become available; â€¢our ability to attract and retain key scientific or management personnel; â€¢potential indemnification liabilities that we may owe to the Former Parent following the separation of its oncology business, resulting in our being a standalone public company (the â€œSeparationâ€); â€¢the tax treatment of the Separation and the distribution of our ordinary shares to the Former Parentâ€™s shareholders (the â€œDistributionâ€) and the limitations imposed on us under the tax matters agreement that we have entered into with the Former Parent; â€¢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 â€¢other risks and uncertainties, including those under the caption â€œRisk Factors.â€ See Part II, Item 1A, â€œRisk Factorsâ€ for a further description of important factors that could cause actual results to differ materially from those in the forward-looking statements. 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. Â 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 â€œRisk Factorsâ€ section of this Quarterly Report. These risks include, but are not limited to, the following: â€¢Because we have a very limited operating history as a standalone company, valuing our business and predicting our prospects is challenging. â€¢We may not achieve some or all of the expected benefits of our Separation from the Former Parent in November 2023 pursuant to which we became an independent company following the Distribution. â€¢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. â€¢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. â€¢Our business is highly dependent on the success of our lead product candidate, nemvaleukin alfa, 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. 3 â€¢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. â€¢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. â€¢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. â€¢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 for our products, if approved, or result in significant negative consequences following any marketing approval. â€¢We may not be successful in our efforts to identify or discover additional product candidates. â€¢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. â€¢Manufacturing of biological products is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs. â€¢We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. â€¢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. â€¢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. â€¢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. â€¢If the Separation and the Distribution from the Former Parent, 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 the Former Parent and the Former Parentâ€™s shareholders could be subject to significant tax liabilities, and we could be required to indemnify the Former Parent or its subsidiaries for material taxes pursuant to indemnification obligations under the tax matters agreement which we entered into with the Former Parent in connection with the Separation. â€¢We are an â€œemerging growth companyâ€ and a â€œsmaller reporting companyâ€ and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors. â€¢The price of our ordinary shares is 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. â€¢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. 4 PART Iâ€”FINANCIAL INFORMATION Item 1. Financial Statements. Mural Oncology plc and Subsidiaries Condensed Consolidated Balance Sheets (Unaudited) Â Â September 30,2024 Â Â December 31,2023 Â Â (in thousands) Â ASSETS Â Â Â Â Â Â CURRENT ASSETS: Â Â Â Â Â Â Cash and cash equivalents Â $ 111,018 Â Â $ 270,852 Â Marketable securities Â Â 64,483 Â Â Â â€” Â Receivable from Former Parent Â Â 1,393 Â Â Â 5,548 Â Prepaid expenses Â Â 6,149 Â Â Â 150 Â Other current assets Â Â 751 Â Â Â 787 Â Total current assets Â Â 183,794 Â Â Â 277,337 Â Property and equipment, net Â Â 8,851 Â Â Â 11,403 Â Right-of-use assets Â Â 8,633 Â Â Â 12,747 Â Restricted cash Â Â 1,969 Â Â Â 258 Â Other assets Â Â 27 Â Â Â â€” Â TOTAL ASSETS Â $ 203,274 Â Â $ 301,745 Â LIABILITIES AND EQUITY Â Â Â Â Â Â CURRENT LIABILITIES: Â Â Â Â Â Â Accounts payable Â $ 2,241 Â Â $ 5,973 Â Accrued expenses Â Â 17,208 Â Â Â 16,946 Â Operating lease liabilitiesâ€”short-term Â Â 5,442 Â Â Â 6,098 Â Other current liabilities Â Â 23 Â Â Â â€” Â Total current liabilities Â Â 24,914 Â Â Â 29,017 Â Operating lease liabilitiesâ€”long-term Â Â 4,104 Â Â Â 8,911 Â Other liabilities Â Â 115 Â Â Â â€” Â Total liabilities Â Â 29,133 Â Â Â 37,928 Â Commitments and contingencies (Note 10) Â Â Â Â Â Â Preferred shares, nominal value $0.01; 50,000,000Â shares authorized at September30, 2024 and December 31, 2023; noÂ shares issued or outstanding at September 30, 2024 or December 31, 2023 Â Â â€” Â Â Â â€” Â Ordinary shares, nominal value $0.01; 450,000,000Â ordinary shares authorized atSeptember 30, 2024 and December 31, 2023; 17,038,950Â and 16,689,740Â shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively Â Â 170 Â Â Â 167 Â Additional paid-in capital Â Â 299,021 Â Â Â 294,507 Â Unrealized gain on marketable securities Â Â 47 Â Â Â â€” Â Accumulated deficit Â Â (125,097) Â Â (30,857) Total equity Â Â 174,141 Â Â Â 263,817 Â TOTAL LIABILITIES AND EQUITY Â $ 203,274 Â Â $ 301,745 Â Â See accompanying notes to the unaudited condensed consolidated financial statements. 5 Mural Oncology plc and Subsidiaries Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) Â Â Three Months Ended September 30, Â Â Nine Months Ended September 30, Â Â 2024 Â Â 2023 Â Â 2024 Â Â 2023 Â Â (in thousands except share and per share amounts) Â Operating expenses Â Â Â Â Â Â Â Â Â Â Â Â Research and development Â $ 27,585 Â Â $ 40,354 Â Â $ 81,997 Â Â $ 123,290 Â General and administrative Â Â 6,513 Â Â Â 5,959 Â Â Â 20,411 Â Â Â 14,436 Â Total operating expenses Â Â 34,098 Â Â Â 46,313 Â Â Â 102,408 Â Â Â 137,726 Â Operating loss Â Â (34,098) Â Â (46,313) Â Â (102,408) Â Â (137,726) Other income Â Â 2,339 Â Â Â â€” Â Â Â 8,168 Â Â Â â€” Â Income tax provision Â Â â€” Â Â Â (4,966) Â Â â€” Â Â Â (10,185) Net loss Â $ (31,759) Â $ (51,279) Â $ (94,240) Â $ (147,911) Other comprehensive gain: Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Unrealized gain on marketable securities Â $ 101 Â Â $ â€” Â Â $ 47 Â Â $ â€” Â Other comprehensive gain Â Â 101 Â Â Â â€” Â Â Â 47 Â Â Â â€” Â Comprehensive loss Â $ (31,658) Â $ (51,279) Â $ (94,193) Â $ (147,911) Net loss per ordinary share - basic and diluted Â $ (1.87) Â $ (3.07) Â $ (5.57) Â $ (8.86) Weighted average ordinary shares outstanding - basic and diluted Â Â 17,028,552 Â Â Â 16,689,740 Â Â Â 16,916,096 Â Â Â 16,689,740 Â Â See accompanying notes to the unaudited condensed consolidated financial statements. 6 Mural Oncology plc and Subsidiaries Condensed Consolidated Statements of Equity (Deficit) (Unaudited) Â Â Â Ordinary Shares Â Shares Â Â Amount Â Â Net Parent Investment Â Â AdditionalÂ Paid in Capital Â Â Accumulated Other Comprehensive(Loss)/Gain Â Â AccumulatedÂ Deficit Â Â Total Equity Â Â (in thousands, except share data) Â Balance, December 31, 2023 Â Â 16,689,740 Â Â $ 167 Â Â $ â€” Â Â $ 294,507 Â Â $ â€” Â Â $ (30,857) Â $ 263,817 Â Issuance of ordinary shares under employee share plans Â Â 232,810 Â Â Â 2 Â Â Â â€” Â Â Â (2) Â Â â€” Â Â Â â€” Â Â Â â€” Â Share-based compensation expense Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 2,101 Â Â Â â€” Â Â Â â€” Â Â Â 2,101 Â Unrealized loss on marketable securities Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (74) Â Â â€” Â Â Â (74) Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (30,917) Â Â (30,917) Balance, March 31, 2024 Â Â 16,922,550 Â Â $ 169 Â Â $ â€” Â Â $ 296,606 Â Â $ (74) Â $ (61,774) Â $ 234,927 Â Issuance of ordinary shares under employee share plans Â Â 4,560 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Share-based compensation expense Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 1,190 Â Â Â â€” Â Â Â â€” Â Â Â 1,190 Â Unrealized gain on marketable securities Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 20 Â Â Â â€” Â Â Â 20 Â Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (31,564) Â Â (31,564) Balance, June 30, 2024 Â Â 16,927,110 Â Â $ 169 Â Â $ â€” Â Â $ 297,796 Â Â $ (54) Â $ (93,338) Â $ 204,573 Â Issuance of ordinary shares under employee share plans Â Â 111,840 Â Â Â 1 Â Â Â â€” Â Â Â 195 Â Â Â â€” Â Â Â â€” Â Â Â 196 Â Share-based compensation expense Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 1,030 Â Â Â â€” Â Â Â â€” Â Â Â 1,030 Â Unrealized gain on marketable securities Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 101 Â Â Â â€” Â Â Â 101 Â Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (31,759) Â Â (31,759) Balance, September 30, 2024 Â Â 17,038,950 Â Â $ 170 Â Â $ â€” Â Â $ 299,021 Â Â $ 47 Â Â $ (125,097) Â $ 174,141 Â Â Â Â Ordinary Shares Â Shares Â Â Amount Â Â Net ParentInvestment Â Â AdditionalÂ Paid in Capital Â Â Accumulated Other Comprehensive(Loss)/Gain Â Â AccumulatedÂ Deficit Â Â Total Equity Â Â (in thousands, except share data) Â Balance, December 31, 2022 Â Â â€” Â Â $ â€” Â Â $ (21,656) Â $ â€” Â Â $ â€” Â Â $ â€” Â Â $ (21,656) Net transfers from Former Parent prior to Separation Â Â â€” Â Â Â Â â€” Â Â Â 56,512 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 56,512 Â Share-based compensation expense allocated from Former Parent Â Â â€” Â Â Â â€” Â Â Â 2,753 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 2,753 Â Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (46,844) Â Â â€” Â Â Â â€” Â Â Â (46,844) Balance, March 31, 2023 Â Â â€” Â Â $ â€” Â Â $ (9,235) Â $ â€” Â Â $ â€” Â Â $ (9,235) Net transfers from Former Parent prior to Separation Â Â â€” Â Â Â Â â€” Â Â Â 45,649 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 45,649 Â Share-based compensation expense allocated from Former Parent Â Â â€” Â Â Â â€” Â Â Â 3,141 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 3,141 Â Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (49,788) Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (49,788) Balance, June 30, 2023 Â Â â€” Â Â $ â€” Â Â $ (10,233) Â $ â€” Â Â $ â€” Â Â $ â€” Â Â $ (10,233) Net transfers from Former Parent prior to Separation Â Â â€” Â Â Â â€” Â Â Â 51,637 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 51,637 Â Share-based compensation expense allocated from Former Parent Â Â â€” Â Â Â â€” Â Â Â 2,983 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 2,983 Â Net loss Â Â â€” Â Â Â â€” Â Â Â (51,279) Â Â â€” Â Â Â â€” Â Â Â (51,279) Balance, September 30, 2023 Â Â â€” Â Â $ â€” Â Â $ (6,892) Â $ â€” Â Â $ â€” Â Â $ â€” Â Â $ (6,892) See accompanying notes to the unaudited condensed consolidated financial statements. 7 Mural Oncology plc and Subsidiaries Condensed Consolidated Statements of Cash Flows (Unaudited) Â Â Nine Months EndedSeptember 30, Â Â 2024 Â Â 2023 Â Â (in thousands) Â CASH FLOWS FROM OPERATING ACTIVITIES: Â Â Â Â Â Â Net loss Â $ (94,240) Â $ (147,911) Adjustments to reconcile net loss to cash flows from operating activities: Â Â Â Â Â Â Depreciation Â Â 2,644 Â Â Â 1,954 Â Share-based compensation expense Â Â 4,419 Â Â Â 8,877 Â Amortization of discount on marketable securities Â Â (2,961) Â Â â€” Â Changes in assets and liabilities: Â Â Â Â Â Â Receivable from Former Parent Â Â 4,155 Â Â Â â€” Â Prepaid expenses Â Â (5,999) Â Â 729 Â Other current assets Â Â 36 Â Â Â (1,054) Right-of-use assets Â Â 4,114 Â Â Â 5,648 Â Other assets Â Â (27) Â Â â€” Â Accounts payable and accrued expenses Â Â (3,591) Â Â (15,291) Operating lease liabilities Â Â (5,463) Â Â (4,391) Other liabilities Â Â 138 Â Â Â (85) Cash flows used in operating

activities Â Â (96,775) Â Â (151,524) CASH FLOWS FROM INVESTING ACTIVITIES: Â Â Â Â Â Â Purchases of marketable securities Â Â (167,475) Â Â â€” Â Sales and maturities of marketable securities Â Â 106,000 Â Â Â â€” Â Additions of property and equipment Â Â (69) Â Â (2,274) Cash flows used in investing activities Â Â (61,544) Â Â (2,274) CASH FLOWS FROM FINANCING ACTIVITIES: Â Â Â Â Â Â Proceeds from issuance of ordinary shares under employee share plans Â Â 196 Â Â Â â€” Â Net transfers from Former Parent Â Â â€” Â Â Â 153,798 Â Cash flows provided by financing activities Â Â 196 Â Â Â 153,798 Â Net decrease in cash, cash equivalents and restricted cash Â Â (158,123) Â Â â€” Â Cash, cash equivalents and restricted cashâ€”beginning of period Â Â 271,110 Â Â Â â€” Â Cash, cash equivalents and restricted cashâ€”end of period Â $ 112,987 Â Â $ â€” Â SUPPLEMENTAL CASH FLOW DISCLOSURE: Â Â Â Â Â Â Non-cash investing and financing activities: Â Â Â Â Â Â Purchased capital expenditures included in accounts payable and accrued expenses Â $ 23 Â Â $ 345 Â RECONCILIATION OF BALANCE SHEET TO STATEMENT OF CASH FLOWS: Â Â Â Â Â Â Cash and cash equivalents Â $ 111,018 Â Â $ â€” Â Restricted cash Â Â 1,969 Â Â Â â€” Â Total cash, cash equivalents and restricted cash as shown in the statement of cash flows Â $ 112,987 Â Â $ â€” Â Â See accompanying notes to the unaudited condensed consolidated financial statements. 8 Mural Oncology plc and Subsidiaries Notes to Condensed Consolidated Financial Statements (Unaudited) 1. Organization and Description of Business Mural Oncology plc, an Irish public limited company, and its consolidated subsidiaries (â€œMuralâ€ or the â€œCompanyâ€) is a clinical-stage oncology business focused on discovering and developing immunotherapies that may meaningfully improve the lives of patients with cancer. By leveraging its core competencies in immune cell modulation and protein engineering, the Company has developed a portfolio of investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers. The Company was established as a shelf company in May 2017 as a private company limited by shares and was de-shelved in 2023 in connection with the Separation. In August 2023, the legal status of the Company under Irish law was altered to that of a public limited company.The accompanying financial statements include the combined, historical financial position, results of operations, net parent investment and cash flows of Alkermes plc, an Irish public limited company, and its consolidated subsidiariesâ€™ (the â€œFormer Parentâ€ or â€œAlkermesâ€) oncology business (the â€œoncology businessâ€) as it was historically managed as part of the Former Parent prior to the completion of the separation of the Former Parentâ€™s oncology business from the Former Parentâ€™s neuroscience business on November 15, 2023 (the â€œSeparationâ€), and the creation of the Company, as a result of the Distribution (as defined below), as an independent, publicly traded company, which holds the assets, liabilities, and operations associated with the oncology business.The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry. There can be no assurance that the Companyâ€™s research and development (â€œR&Dâ€) will be successfully completed, that any products developed will obtain necessary government regulatory approval or that any products, if approved, will be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnological companies. In addition, the Company is dependent upon the services of its employees, consultants and service providers. Even if the Companyâ€™s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant product revenue from product sales.The Separation On November 2, 2022, the Former Parent announced its intent, as approved by its board of directors, to explore the Separation. In connection with the Separation, on November 13, 2023, the Company entered into certain agreements with the Former Parent to provide a framework for the Companyâ€™s relationship with the Former Parent following the Separation. These agreements include:â€¢a separation agreement;â€¢a tax matters agreement;â€¢an employee matters agreement;â€¢a lease assumption agreement; andâ€¢transition services agreements.The separation agreement sets forth the Companyâ€™s agreements with the Former Parent regarding the principal actions to be taken by the Company and the Former Parent in connection with the Separation, including those related to the distribution of the Companyâ€™s ordinary shares to the Former Parentâ€™s shareholders (the â€œDistributionâ€). The separation agreement identifies the assets transferred to, liabilities assumed by and contracts assigned to the Company, including the Winter Street Lease (as defined in Note 7, Leases), as part of the Separation, and provides for when and how such transfers, assumptions and assignments occurred. Under the terms of the separation agreement, the Former Parent granted the Company a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to any intellectual property controlled by the Former Parent as of the date of the Distribution, allowing the Company to use such intellectual property for the oncology business, and the Company granted the Former Parent a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property transferred to the Company as part of the Separation for the Former Parentâ€™s use outside of the oncology business. Each of the Company and the Former Parent agreed to releases with respect to pre-Distribution claims, and cross-indemnities with respect to post-Distribution claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to the Company under the separation agreement with the Company, and financial responsibility for the obligations and liabilities allocated to the Former Parent under the separation agreement with the Former Parent.The tax matters agreement governs the Companyâ€™s and the Former Parentâ€™s respective rights, responsibilities, and obligations with respect to taxes (including taxes arising in the ordinary course of business and incurred as a result of any failure of the Distribution, together with certain related transactions, to qualify as tax-free for U.S. federal income tax purposes), tax attributes, the 9 preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect to tax matters.The employee matters agreement, as amended in December 2023, governs the Companyâ€™s and the Former Parentâ€™s rights, responsibilities, and obligations after the Separation with respect to employment, benefits and compensation matters relating to employees and former employees (and their respective dependents and beneficiaries) who are or were associated with the Former Parent, including those who became employees of the Company in connection with the Separation. The employee matters agreement also specifies the allocation of assets and liabilities generally relating to employees, employment or service-related matters and employee benefit plans; other human resources, employment and employee benefits matters; and the treatment of equity-based awards granted by the Former Parent prior to the Separation to employees who became employees of the Company in connection with the Separation.Under the terms of the lease assumption agreement, the Company assumed all of the Former Parentâ€™s obligations under the Winter Street Lease.The Company and the Former Parent entered into two transition services agreements, pursuant to one of which the Former Parent and its subsidiaries agreed to provide, on an interim, transitional basis, various services to the Company, and the second of which the Company and its subsidiaries agreed to provide certain services to the Former Parent, in each case for a term of two years following the Separation, unless earlier terminated in accordance with the terms of the applicable agreement. On November 14, 2023, in connection with the Separation, the Company received a cash contribution of $275.0 million from the Former Parent. The Former Parent effected the Separation through the Distribution on November 15, 2023. On the effective date of the Distribution, each Alkermes shareholder received one ordinary share of the Company for every ten ordinary shares of Alkermes held as of the close of business on November 6, 2023, the record date for the Distribution. Registered shareholders received cash in lieu of any fractional ordinary shares of the Company that they would have received as a result of the application of the distribution ratio. As a result of the Separation and the Distribution, the Company operates as an independent, publicly traded company and commenced trading under the symbol â€œMURAâ€ on the Nasdaq Global Market on November 16, 2023. LiquidityUnder Accounting Standards Update ("ASU") No. 2014-15, Presentation of Financial Statementsâ€”Going Concern (Subtopic 205-40), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. The Company has generated operating losses for all the historical periods presented and expects to continue to generate operating losses for the foreseeable future. The Company expects to fund its operations and capital needs through the funding received from the Former Parent through the date of the Separation, including the cash contribution of $275.0 million received from the Former Parent at the time of the Separation. The Companyâ€™s continued operations were dependent on the funding received from the Former Parent through the Separation and, going forward, will be dependent on its ability to generate cash from operating activities and to raise additional capital to finance its future operations subsequent to the Separation. The Company will need additional financing to support its continuing operations and further develop or commercialize any product candidates. If the Company 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 the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. For the four-year period beginning two years before and ending two years after the Distribution, the Company is prohibited under the tax matters agreement with the Former Parent from taking or failing to take actions that would prevent the Separation and the 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 Internal Revenue Code of 1986, as amended (the â€œCodeâ€), which may limit for a period of time the Companyâ€™s ability to pursue certain strategic transactions, equity issuances or repurchases or other transactions.The Company expects that, based on its current operating plans, the Companyâ€™s existing cash, cash equivalents and marketable securities will be sufficient to fund its current planned operations for at least the next twelve months from the issuance of these unaudited condensed consolidated financial statements. 2. Basis of Presentation and Summary of Significant Accounting Policies Basis of Presentation The accompanying unaudited condensed consolidated financial statements include the accounts of Mural Oncology plc and its wholly-owned subsidiaries. For the periods prior to the Separation, the accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a standalone basis and are derived from the Former Parentâ€™s consolidated financial

statements and accounting records. All intercompany transactions and accounts within the Company have been eliminated. 10 The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (â€œGAAPâ€) and, for the periods prior to the Separation, reflect the historical results of operations, financial position and cash flows of Mural, as included in the consolidated financial statements of the Former Parent and using the Former Parentâ€™s historical accounting policies. For the periods prior to the Separation, these unaudited condensed consolidated financial statements do not purport to reflect what the Companyâ€™s results of operations, financial position or cash flows would have been had the Company operated as a standalone public company prior to the Separation, nor are they necessarily indicative of the Companyâ€™s future results of operations, financial position, or cash flows. As the Companyâ€™s operations were not historically held by a single legal entity or separate legal entities, net parent investment is shown in lieu of stockholdersâ€™ equity in the historical combined financial statements for the periods prior to the Separation. Net parent investment represents the cumulative investment by the Former Parent in the Company through the dates presented, inclusive of operating results. All transactions between the Company and the Former Parent are considered to be effectively settled in the unaudited condensed consolidated financial statements at the time the transaction is recorded. The effects of the settlement of these transactions between the Company and the Former Parent are reflected in the unaudited condensed consolidated statements of cash flows as â€œNet transfers from Former Parentâ€ within financing activities and in the unaudited condensed consolidated statements of equity (deficit) as â€œNet parent investment.â€ Historically, the Company was dependent upon the Former Parent for all of its working capital and financing requirements, as the Former Parent used a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to the Company for the historical periods presented prior to the Separation. Financing transactions prior to the Separation related to the Former Parent are accounted for as a financing activity on the accompanying unaudited condensed consolidated statements of cash flows through the date of the Separation. In connection with the Separation, certain assets and liabilities that were included on the consolidated balance sheet prior to the Separation were retained by the Former Parent and were therefore adjusted through net parent investment in the Companyâ€™s consolidated financial statements. The unaudited condensed consolidated financial statements of the Company include, for the periods prior to the Separation, the assets, liabilities, and expenses of the Former Parent that management has determined are specifically identifiable to the Company, 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 the Company as a pre-revenue, development-stage biotechnology company, the unaudited condensed consolidated financial statements of the Company do not include any revenue or commercial expenses of the Former Parent. The unaudited condensed consolidated financial statements of the Company also include, for the periods prior to the Separation, an allocation of costs that were not directly attributable to the operations of the Company, including the costs of general and administrative support functions that were provided by the Former Parent, such as senior management, information technology, legal, accounting and finance, human resources, facility, and other corporate services. In addition, the Companyâ€™s unaudited condensed consolidated financial statements include, for the periods prior to the Separation, an allocation of certain R&D costs not directly attributable to individual programs. These costs have been allocated to the Company for the purposes of preparing the unaudited condensed consolidated financial statements based on proportional cost allocation methods using headcount, square footage or proportional hours worked supporting the Company and other organizational activities, as applicable, which are considered to be reasonable reflections of the utilization of services provided or benefit received by the Company 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 the Company had operated on a standalone basis for the periods presented and, therefore, may not reflect the Companyâ€™s results of operations, financial position, and cash flows had the Company operated as a standalone entity during the periods presented. See Note 12, Related Parties, for additional information regarding related-party transactions with the Former Parent. The Company has incurred, and expects to continue 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 the Company prior to the Separation by the Former Parent and will continue under a transition services agreement with the Former Parent or will be performed using the Companyâ€™s own resources. Unaudited Interim Financial Information The accompanying condensed consolidated financial statements of the Company for the three and nine months ended September 30, 2024 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2023. The condensed consolidated financial statements for the three and nine months ended September 30, 2023 were derived from the Former Parentâ€™s audited financial statements. The year-end condensed consolidated balance sheet data, which are presented for comparative purposes, were derived from audited financial statements but do not include all disclosures required by GAAP. In the opinion of management, the condensed consolidated financial statements include all adjustments of a normal recurring nature that are necessary to state fairly the results of operations for the reported periods. The 11 financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 are also unaudited. 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 Securities and Exchange Commission for interim financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited annual consolidated financial statements as of and for the year ended December 31, 2023 and the notes thereto, which are included in the Companyâ€™s Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the â€œAnnual Report on Form 10-Kâ€). The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. Use of Estimates The preparation of the Companyâ€™s unaudited condensed consolidated financial statements in accordance with GAAP requires the Company 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, the Company evaluates its estimates and judgments and methodologies, including but not limited to, those related to allocations of expenses, assets and liabilities from the Former Parentâ€™s historical financials to the Company, the impairment of long-lived assets, and measurement of share-based compensation, leases, and income taxes including the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience of the Former 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 consolidated financial statements as of and for the three and nine months ended September 30, 2024 and 2023 are consistent with those discussed herein and in Note 2, Basis of Presentation and Summary of Significant Accounting Policies, in the â€œNotes to Consolidated Financial Statementsâ€ accompanying the Companyâ€™s Annual Report on Form 10-K.Recently Issued Accounting Pronouncements From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the â€œFASBâ€) or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company 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 ASU No. 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures (â€œASU 280â€). ASU 280 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 ASU-280 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. The Company is evaluating the impact of the adoption of ASU-280 on its consolidated financial statements and related disclosures and does not expect the adoption of ASU-280 to have a material impact on the Companyâ€™s consolidated financial statements. In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (â€œASU-740â€). ASU-740 requires public entities to provide enhanced disclosure of specific categories of reconciling items included in the rate reconciliation; disclosure of the nature, effect and underlying causes of each reconciling item in the rate reconciliation and the judgment used in the categorization of such items; and enhanced disclosures for income taxes paid. The amendments in this ASU are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is evaluating the impact of the adoption of ASU-740 on its consolidated financial statements and disclosures. 3. Cash, Cash Equivalents and Marketable SecuritiesAs of September 30, 2024, the Company had cash and cash equivalents of $111.0 million and marketable securities of $64.5 million. As of December 31, 2023, the Company had cash and cash equivalents of $270.9 million and no marketable securities. In addition, the Company had a long-term restricted cash balance of $2.0 million and $0.3 million as of September 30, 2024 and December 31, 2023, respectively, which was restricted for a letter of credit and for use pertaining to corporate credit cards. See Note 7, Leases, for additional information regarding the letter of credit.Cash and cash equivalents are carried at cost, which approximates fair market value. Marketable securities are classified as available for sale and are recorded at fair value with the related unrealized gains and losses included in accumulated other 12 comprehensive gain (loss), a component of equity. All of the realized gains and losses on the sale of these marketable securities are determined using the specific identification method. There were no realized gains or losses as of September 30, 2024. Aggregated by investment

category, there were no marketable securities in an unrealized loss position as of September 30, 2024.Marketable securities, all of which had maturities of less than one year, consisted of the following: Â September 30, 2024 Â (in thousands) Â Amortized Cost Â Â Gross Unrealized Gains Â Â Gross Unrealized Losses Â Â Estimated Fair Value Â Marketable securities: Â Â Â Â Â Â Â Â Â Â Â Â Â U.S. treasury securities Â $ 43,071 Â Â $ 32 Â Â $ â€” Â Â $ 43,103 Â U.S. government agency bonds Â Â 21,365 Â Â Â 15 Â Â Â â€” Â Â Â 21,380 Â Total marketable securities Â $ 64,436 Â Â $ 47 Â Â $ â€” Â Â $ 64,483 Â Â 4. Fair ValueThe following table presents information about the Companyâ€™s financial assets measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 30, 2024. The fair value of these financial assets was determined based on three levels of input as follows:â€¢Level 1 - Quoted prices in active markets for identical assets;â€¢Level 2 - Observable inputs other than quoted prices in active markets; andâ€¢Level 3 - Unobservable inputs. (in thousands) Â September 30, 2024 Â Â Level 1 Â Â Level 2 Â Â Level 3 Â Assets: Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Money market mutual funds in cash equivalents Â $ 110,518 Â Â $ 110,518 Â Â $ â€” Â Â $ â€” Â Â Â Â Â Â Â Marketable securities: Â U.S. treasury securities Â Â 43,103 Â Â Â Â â€” Â Â Â 43,103 Â Â Â â€” Â Â Â Â Â Â Â Â Â Â Â U.S. government agency bonds Â Â 21,380 Â Â Â â€” Â Â Â 21,380 Â Â Â â€” Â Total Â $ 175,001 Â Â $ 110,518 Â Â $ 64,483 Â Â $ â€” Â The following table presents information about the Companyâ€™s financial assets measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2023. (in thousands) Â December 31, 2023 Â Â Level 1 Â Â Level 2 Â Â Level 3 Â Assets: Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Money market mutual funds in cash equivalents Â $ 268,720 Â Â $ 268,720 Â Â $ â€” Â Â $ â€” Â Total Â $ 268,720 Â Â $ 268,720 Â Â $ â€” Â Â $ â€” Â Â 5. Property and Equipment, Net Property and equipment, net consisted of the following: Â September 30, Â Â December 31, Â (in thousands) Â 2024 Â Â 2023 Â Furniture, fixtures and equipment Â $ 21,845 Â Â $ 21,738 Â Leasehold improvements Â Â 23,333 Â Â Â 23,333 Â Construction in progress Â Â â€” Â Â Â 15 Â Subtotal Â Â 45,178 Â Â Â 45,086 Â Less: accumulated depreciation Â Â (36,327) Â Â (33,683) Total property and equipment, net Â $ 8,851 Â Â $ 11,403 Â Depreciation expense was $0.9 million and $2.6 million for the three and nine months ended September 30, 2024, respectively, and $0.8 million and $2.0 million for the three and nine months ended September 30, 2023, respectively. 13 6. Accrued Expenses Accrued expenses consisted of the following: Â September 30, Â Â December 31, Â (in thousands) Â 2024 Â Â 2023 Â Accrued external research and development services Â $ 10,547 Â Â $ 8,543 Â Accrued compensation Â Â 5,430 Â Â Â 5,858 Â Accrued general and administrative Â Â 1,170 Â Â Â 2,545 Â Accrued other Â Â 61 Â Â Â â€” Â Total accrued expenses Â $ 17,208 Â Â $ 16,946 Â Â 7. Leases The Companyâ€™s only lease as of September 30, 2024 and December 31, 2023 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 â€œWinter Street Leaseâ€). Under the terms of the Winter Street Lease, the Company also has the ability to sub-lease its corporate office and laboratory space. The original lease commenced in 2010 and was extended, at the Former Parentâ€™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 five-year period, which the Company is not reasonably certain to exercise.The Winter Street Lease was assigned to the Company in connection with the Separation and is used solely for operations of the Company. The Former Parent has been primarily obligated to the landlord for the Winter Street Lease, and, following the Separation, the Former Parent is jointly and severally liable with the Company for, and continues to guarantee, all obligations under the Winter Street Lease. As of December 31, 2023, the Former Parent was the applicant with respect to a letter of credit security deposit that secured the obligations of the tenant under the Winter Street Lease. The Former Parent maintained a $1.9 million collateralized letter of credit (the â€œFormer Parent Letter of Creditâ€) related to such security deposit as of December 31, 2023. As the Company did not have legal ownership over any bank accounts prior to the Separation, there were no cash or cash equivalents balances specifically attributable to the Company for the historical periods presented and, accordingly, no amount related to the Former Parent Letter of Credit was reflected in the consolidated financial statements prior to the Separation. On January 3, 2024, the Company entered into a $1.7 million collateralized letter of credit that secures the obligations of the tenant under the Winter Street Lease. This letter of credit replaced the $1.9 million Former Parent Letter of Credit.On August 16, 2024, the Company entered into a sub-lease pursuant to which the Company sub-leased to a third party approximately 5,155 square feet of office space and approximately 3,739 square feet of laboratory space that the Company leases under the Winter Street Lease and the Company also entered into a separate sub-lease pursuant to which the Company sub-leased to another third party (both sub-lessees together, the â€œAugust Sub-lesseesâ€) approximately 3,387 square feet of office space and approximately 2,690 square feet of laboratory space that the Company leases under the Winter Street Lease (both sub-leases together, the â€œAugust Sub-leasesâ€). The August Sub-leases commenced on August 20, 2024 and are expected to terminate on April 18, 2026. Under the August Sub-leases, the August Sub-lessees will pay to the Company a total annualized fixed base rent of $0.5 million beginning 30 days after the commencement date of the August Sub-leases, as well as compensate the Company for the August Sub-lesseesâ€™ proportionate share of operating and other expenses related to the August Sub-leases. The August Sub-lesseesâ€™ base rent and proportionate share of operating and other expenses are included as contra-expense in the Companyâ€™s unaudited condensed consolidated statements of operations and comprehensive loss.On October 11, 2024, the Company entered into a sub-lease (the â€œOctober Sub-leaseâ€) pursuant to which the Company sub-leased to an additional third party (the â€œOctober Sub-lesseeâ€) approximately 30,102 square feet of office space that the Company leases under the Winter Street Lease. Under the October Sub-lease, the October Sub-lessee will pay the Company an annualized fixed base rent of $0.7 million beginning on January 1, 2025, as well as compensate the Company for a proportionate share of operating and other expenses related to the October Sub-lease beginning with the commencement date of the October Sub-lease. The October Sub-lease commenced on November 1, 2024 and is expected to terminate on April 30, 2026.As of the nine months ended September 30, 2024 and 2023, the incremental borrowing rate for the Winter Street Lease was 3.52%. As of September 30, 2024, the remaining term for the Winter Street Lease was 2.1 years. Cash paid for amounts included in the measurement of lease liabilities is included within cash flows from operating activities. During the three and nine months ended September 30, 2024, cash paid by the Company for amounts included for the measurement of lease liabilities was $1.6 million and $4.9 million, respectively. During the three and nine months ended September 30, 2023, cash paid by the Former Parent for amounts included for the measurement of lease liabilities was $1.6 million and $4.8 million, respectively. 14 The following table summarizes the effect of lease costs in the Companyâ€™s unaudited condensed consolidated statements of operations and comprehensive loss: Â Three Months Ended Â Â Nine Months Ended Â Â September 30, Â Â September 30, Â (in thousands) Â 2024 Â Â 2023 Â Â 2024 Â Â 2023 Â Operating lease cost Â $ 1,398 Â Â $ 1,419 Â Â $ 4,211 Â Â $ 4,388 Â Variable lease cost Â Â 1,111 Â Â Â 1,158 Â Â Â 3,410 Â Â Â 3,741 Â Total lease cost Â $ 2,509 Â Â $ 2,577 Â Â $ 7,621 Â Â $ 8,129 Â Â Future lease payments under non-cancelable leases as of September 30, 2024 consisted of the following: (in thousands) Â September 30,2024 Â Remainder of 2024 Â $ 739 Â 2025 Â Â 6,642 Â 2026 Â Â 2,484 Â Total operating lease payments Â $ 9,865 Â Less: imputed interest Â Â (319) Total operating lease liabilities Â $ 9,546 Â Â 8. Share-Based Compensation 2023 Stock Option and Incentive PlanThe Companyâ€™s 2023 Stock Option and Incentive Plan (the â€œ2023 Planâ€), which became effective on October 30, 2023, provides for the grant of up to 5,000,000 of the Companyâ€™s ordinary shares. The 2023 Plan allows the Company to make equity-based and cash-based incentive awards such as stock options, share appreciation rights, RSUs, restricted share awards, unrestricted share awards, cash-based awards, and dividend equivalent rights to officers, employees, non-employee directors, and consultants, subject to the provisions of the 2023 Plan.The 2023 Plan provides that the number of shares reserved and available for issuance under the 2023 Plan will be automatically increased on January 1, 2025, and each January 1 thereafter, in an amount equal to (i) 5% of the outstanding number of the Companyâ€™s ordinary shares on the immediately preceding December 31, or (ii) such lesser number of shares as determined by the 2023 Plan Administrator. The ordinary shares underlying any awards under the 2023 Plan that are forfeited, cancelled or held back upon exercise of settlement of an award to satisfy the exercise price or any tax withholding obligation, or are otherwise terminated or forfeited (other than by exercise) will be added back to the ordinary shares available for issuance under the 2023 Plan. At September 30, 2024, 1,151,966 ordinary shares were reserved and available for issuance under the 2023 Plan.2023 Employee Stock Purchase PlanThe Companyâ€™s 2023 Employee Stock Purchase Plan (the â€œESPPâ€) became effective on October 30, 2023. The ESPP initially reserves and authorizes the issuance of up to a total of 100,000 of the Companyâ€™s ordinary shares to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2025 and each January 1 thereafter through January 1, 2034, by the least of (i) 100,000 ordinary shares, (ii) 1% of the outstanding number of ordinary shares on the immediately preceding December 31, or (iii) such lesser number of ordinary shares as determined by the administrator of the ESPP. 2024 Inducement Stock Option and Incentive PlanThe Companyâ€™s 2024 Inducement Stock Option and Incentive Plan (the â€œ2024 Planâ€), which became effective on January 12, 2024, provides for the grant of up to 300,000 of the Companyâ€™s ordinary shares. The 2024 Plan allows the Company to make equity-based incentive awards such as non-qualified stock options, share appreciation rights, RSUs, restricted share awards, unrestricted share awards, and dividend equivalent rights to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment with the Company, in either case as an inducement material to the individualâ€™s entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4), subject to the provisions of the 2024 Plan.The ordinary shares

underlying any awards under the 2024 Plan that are forfeited, cancelled or held back upon exercise of settlement of an award to satisfy the exercise price or any tax withholding obligation, or are otherwise terminated or forfeited (other than by exercise) will be added back to the ordinary shares available for issuance under the 2024 Plan. At September 30, 2024, 119,400 ordinary shares were reserved and available for issuance under the 2024 Plan. 15 Converted AwardsOn November 13, 2023, the Company entered into the employee matters agreement with the Former Parent under which the Company agreed to convert all outstanding Former Parent stock options and RSUs held by the Companyâ€™s employees under the Former Parentâ€™s share-based compensation plans into the Company stock options and RSUs under the 2023 Plan in accordance with the conversion ratio set forth in the agreement. On December 14, 2023, the Former Parent and the Company amended the employee matters agreement to adjust the conversion ratio used to calculate the number of the Companyâ€™s RSUs issuable to each employee in exchange for each RSU of the Former Parent. All outstanding equity awards held by the Companyâ€™s employees were converted and issued under the 2023 Plan in December 2023 in accordance with the amended employee matters agreement. Except for the number of underlying shares and the exercise price of the stock options, the converted awards retain substantially the same terms and conditions of the original awards, including their term and vesting conditions.Former Parent Share-based Compensation PlansThe Former Parent had share-based compensation plans which provided for granting equity awards, including non-qualified and incentive stock options, RSUs, RSU awards, cash-based awards, and performance shares to employees, officers and directors of, and consultants to, the Former Parent. Prior to the Separation, all share-based compensation plans were managed on a consolidated basis by the Former Parent and share-based compensation expense was allocated to the Company related to stock options, time-based RSU awards and performance-based RSU awards issued by the Former Parent. Accordingly, the amounts presented for periods prior to the Separation are not necessarily indicative of future share-based compensation and do not necessarily reflect the amount that the Company would have issued as an independent company for the periods presented. Stock Plan ActivityThe following average assumptions were used to estimate the fair value of stock options granted by the Company during the nine months ended September 30, 2024 using the Black-Scholes option pricing model: Â Â Nine Months Ended September 30, 2024 Risk-free interest rate Â 3.5% - 4.6% Dividend rate Â 0% Expected volatility Â 82% - 87% Expected life (years) Â 2.0Â - 6.2 A summary of stock option activity under the 2023 Plan and the 2024 Plan for the nine months ended September 30, 2024 is as follows: Â Â Number of Options Â Â Weighted-Average Exercise Price Â Options outstanding at December 31, 2023 Â Â 3,348,715 Â Â $ 4.53 Â Â Â Â Â Â Granted Â Â 535,881 Â Â $ 4.79 Â Â Â Â Â Â Cancelled/forfeited Â Â (1,003,997) Â $ 4.61 Â Â Â Â Â Â Exercised Â Â (61,762) Â $ 3.18 Â Options outstanding at September 30, 2024 Â Â 2,818,837 Â Â $ 4.58 Â Options exercisable at September 30, 2024 Â Â 1,087,411 Â Â $ 4.75 Â The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2024 was $3.26. At September 30, 2024, there were 2.7 million stock options vested or expected to vest, with a weighted average exercise price of $4.58 per share, a weighted average contractual remaining life of 7.7 years and an aggregate intrinsic value of $1 thousand. At September 30, 2024, the aggregate intrinsic value of stock options exercisable was less than $1 thousand with a weighted average remaining contractual term of 6.3 years. The number of stock options expected to vest was determined by applying the pre-vesting forfeiture rate to the total number of outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying shares exceeds the exercise price of the stock option.At September 30, 2024, there was $2.6 million of unrecognized share-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 1.5 years.A summary of RSU activity under the 2023 Plan and the 2024 Plan for the nine months ended September 30, 2024 is as follows: 16 Â Â Number of Shares Â Â Weighted-Average Grant Date Fair Value Per Share Â Unvested outstanding at December 31, 2023 Â Â 1,129,512 Â Â $ 4.45 Â Â Â Â Â Â Granted Â Â 253,386 Â Â $ 4.96 Â Â Â Â Â Â Vested Â Â (287,448) Â $ 4.48 Â Â Â Â Â Â Cancelled/forfeited Â Â (234,863) Â $ 4.63 Â Unvested outstanding at September 30, 2024 Â Â 860,587 Â Â $ 4.54 Â At September 30, 2024, there was $1.7 million of unrecognized share-based compensation expense related to unvested RSUs, which will be recognized over a weighted average remaining contractual term of 1.4 years.The following table represents share-based compensation expense included in the Companyâ€™s unaudited condensed consolidated statements of operations and comprehensive loss: Â Three Months EndedSeptember 30, Â Â Nine Months EndedSeptember 30, Â (in thousands) Â 2024 Â Â 2023 Â Â 2024 Â Â 2023 Â Research and development Â $ 368 Â Â $ 1,401 Â Â $ 1,835 Â Â $ 6,000 Â General and administrative Â Â 662 Â Â Â 1,582 Â Â Â 2,584 Â Â Â 2,877 Â Total share-based compensation expense Â $ 1,030 Â Â $ 2,983 Â Â $ 4,419 Â Â $ 8,877 Â Â 9. Income Taxes During each of the three and nine months ended September 30, 2024, the Company recorded no income tax provision. During the three and nine months ended September 30, 2023, the Company recorded an income tax provision of $5.0 million and $10.2 million, respectively, related to its U.S. entity. The income tax provision was primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Code. The provision was calculated on a separate return basis and is not necessarily representative of the tax provision that may arise in the future. Net operating losses previously reported by the Former Parent did not carry over to the Company 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 2024, the Company reassessed the valuation allowance and considered all positive and negative evidence, including its cumulative losses over the year ended December 31, 2023 and the nine months ended September 30, 2024 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, 2024. 10. Commitments and Contingencies The Company, from time to time, may be involved with lawsuits arising in the ordinary course of business. the Company 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.In the normal course of business, the Company contracts with third parties for preclinical, clinical and other research and development services. These contracts generally do not contain minimum purchase commitments and are cancellable upon notice by the Company. The Company has, however, entered into agreements with contract manufacturing organizations that include noncancellable costs or that may be subject to cancellation fees. As of September 30, 2024, open purchase commitments for such noncancellable contract manufacturing costs totaled approximately $9.2 million.See Note 7, Leases, for information related to the Companyâ€™s lease obligations. See Note 1, Organization and Description of Business, for information related to the tax matters agreement, which governs the Companyâ€™s and the Former Parentâ€™s respective rights, responsibilities, and obligations with respect to taxes and which contains certain indemnifications. 11. Net Loss per ShareBasic net loss per share is computed by dividing the net loss in each period by the weighted average number of ordinary shares outstanding during such period. Diluted net loss per share is computed similarly to basic net loss per share except that the denominator is increased to include the number of additional ordinary shares that would have been outstanding if the potential ordinary shares had been issued and if the additional ordinary shares were dilutive. For the periods presented, ordinary share equivalents, consisting of share-based awards, were not included in the calculation of the diluted net loss per share because to do so would be anti-dilutive. There were no dilutive equity instruments as of September 30, 2023 as there were no equity awards of the Companyâ€™s ordinary shares prior to the Separation. 17 On November 15, 2023, the effective date of the Distribution, 16,689,740 of the Companyâ€™s ordinary shares were distributed to the Former Parentâ€™s shareholders of record as of November 6, 2023, the record date for the Distribution. This share amount was utilized for the calculation of basic and diluted earnings per share for periods prior to the Separation as there were no shares of the Company outstanding prior to the Separation.As of September 30, 2024 and 2023, the number of ordinary shares underlying potentially dilutive securities consist of: Â Â September 30, Â Â Â 2024 Â Â 2023 Â Options to purchase ordinary shares Â Â 2,818,837 Â Â Â â€” Â Restricted share units Â Â 860,587 Â Â Â â€” Â Total Â Â 3,679,424 Â Â Â â€” Â Â 12. Related Parties Corporate expenses prior to the Separation represent shared costs of the Former Parent that have been allocated to the Company based on a systematic and rational methodology and are reflected as expenses in these unaudited condensed consolidated financial statements. These amounts include, but are not limited to, items such as general management and executive oversight, costs to support the Companyâ€™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 Former Parent as a whole. Corporate expense allocations in the periods prior to the Separation were generally allocated to the Company based on proportional cost allocation methods using headcount, square footage, or proportional hours worked supporting the Company and other organizational activities, as applicable, which are considered to be reasonable reflections of the utilization of services provided or benefit received by the Company during the periods presented. Total corporate expense allocations from the Former Parent for the periods prior to the Separation in general and administrative expenses were $2.5 million and $8.8 million during the three and nine months ended September 30, 2023, respectively. Total corporate expense allocations from the Former Parent for the periods prior to the Separation in R&D expenses were $3.9 million and $12.9 million during the three and nine months ended September 30, 2023, respectively. The Former Parent assumed all of the outstanding accrued liabilities and accounts payable related to the oncology business as of the date of the Separation.Management considers the allocation methodologies used to be reasonable and appropriate reflections of the related expenses attributable to the Company prior to the Separation for purposes of the unaudited condensed consolidated financial statements; however, the expenses reflected in these unaudited condensed consolidated financial statements may not be indicative of the actual expenses that would have been incurred during the periods presented prior to the Separation if the Company had operated as a standalone entity. In addition, the expenses reflected in the unaudited condensed consolidated financial statements may not be indicative of expenses that will be incurred in the future by the Company. See Note 1, Organization and Description of Business, for details of the Companyâ€™s cash and financing

arrangements. As of the date these unaudited condensed consolidated financial statements were available for issuance, there were no existing intercompany debt or other financing agreements in place with the Former Parent. As of September 30, 2024, the Company had a receivable from the Former Parent of $1.4 million pursuant to the transition services agreements. During the three and nine months ended September 30, 2024, the Company received $1.0 million and $7.4 million, respectively, from the Former Parent and paid $0.4 million and $5.3 million, respectively, to the Former Parent pursuant to the transition services agreements.See Note 2, Basis of Presentation and Summary of Significant Accounting Policies, for additional information on the preparation and basis of presentation of these consolidated financial statements, including the treatment of certain R&D costs not directly attributable to individual programs, cash and cash equivalents, share-based compensation, and 401(k) Plan expenses. As of the date of the Separation, the Former Parent was no longer a related party to the Company. 18 Item 2. Managementâ€™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 consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the â€œAnnual Report on Form 10-Kâ€). This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, including those set forth under â€œRisk Factorsâ€ appearing elsewhere in this Quarterly 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 Securities and Exchange Commission (the â€œSECâ€), 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 (â€œnemvaleukinâ€), is an investigational, engineered interleukin-2 (â€œIL-2â€) 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, the ARTISTRY-6 (Cohort 2) trial for the treatment of mucosal melanoma as a monotherapy and the ARTISTRY-7 trial for the treatment of platinum-resistant ovarian cancer (â€œPROCâ€) in combination with pembrolizumab. We expect to report topline overall survival results for the interim analysis from our ARTISTRY-7 trial in PROC based on approximately 75% of events (approximately 215 of 286 total overall survival events) late in the first quarter of 2025 or early in the second quarter of 2025 and final results in the second quarter of 2026, subject to reaching the required number of events for the analysis, and topline results from Cohort 2 in our ARTISTRY-6 trial in mucosal melanoma in the second quarter of 2025. Data from the phase 1/2 ARTISTRY-3 trial which support the less frequent IV (â€œLFIVâ€) recommended phase 2 dose and schedule were presented at the American Society of Clinical Oncology annual meeting in June 2024.We are also testing the newly recommended phase 2 dose of LFIV nemvaleukin (infusions on days 1 and 8 per three-week dosing cycle) as a monotherapy in patients with cutaneous melanoma in Cohort 3 of the ARTISTRY-6 trial. We are also testing the same LFIV dosing regimen of nemvaleukin in combination with pembrolizumab in patients with cutaneous melanoma in Cohort 4 of the ARTISTRY-6 trial. We expect to report preliminary monotherapy data from Cohort 3 in the first half of 2025 and preliminary combination data from Cohort 4 in the second half of 2025. In addition to nemvaleukin, we are also developing engineered therapies targeting the interleukin-18 (â€œIL-18â€) and interleukin-12 (â€œIL-12â€) 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 before the end of 2024. We also plan to submit an Investigational New Drug application to the U.S Food and Drug Administration for our IL-18 program in the fourth quarter of 2025. The Separation On November 2, 2022, Alkermes plc (the â€œFormer Parentâ€ or â€œAlkermesâ€) announced its intent, as approved by its board of directors, to explore the separation of its neuroscience business and oncology business (the â€œSeparationâ€). In connection with the Separation, on November 13, 2023, we entered into certain agreements with the Former Parent to provide a framework for our relationship with the Former Parent following the Separation. These agreements include: â€¢a separation agreement, â€¢a tax matters agreement; â€¢an employee matters agreement; â€¢a lease assumption agreement; and â€¢transition services agreements. The separation agreement sets forth our agreements with the Former Parent regarding the principal actions to be taken by us and the Former Parent in connection with the Separation, including those related to the distribution of our ordinary shares to the Former Parentâ€™s shareholders (the â€œDistributionâ€). The separation agreement identifies the assets transferred to, liabilities assumed by and contracts assigned to us, including the lease for our primary office and laboratory space (the â€œWinter Street Leaseâ€), as part of the Separation, and provides for when and how such transfers, assumptions and assignments occurred. Under the terms of the separation 19 agreement, the Former Parent granted us a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to any intellectual property controlled by the Former Parent as of the date of the Distribution, allowing us to use such intellectual property for the oncology business, and we granted the Former Parent a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property transferred to us as part of the Separation for the Former Parentâ€™s use outside of the oncology business. Each of us and the Former Parent agreed to releases with respect to pre-Distribution claims, and cross-indemnities with respect to post-Distribution claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to us under the separation agreement with us, and financial responsibility for the obligations and liabilities allocated to the Former Parent under the separation agreement with the Former Parent. The tax matters agreement governs our and the Former Parentâ€™s respective rights, responsibilities, and obligations with respect to taxes (including taxes arising in the ordinary course of business and incurred as a result of any failure of the Distribution, together with certain related transactions, to qualify as tax-free for U.S. federal income tax purposes), tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect to tax matters. The employee matters agreement, as amended in December 2023, governs our and the Former Parentâ€™s rights, responsibilities, and obligations after the Separation with respect to employment, benefits and compensation matters relating to employees and former employees (and their respective dependents and beneficiaries) who are or were associated with the Former Parent, including those who became our employees in connection with the Separation. The employee matters agreement also specifies the allocation of assets and liabilities generally relating to employees, employment or service-related matters and employee benefit plans; other human resources, employment and employee benefits matters; and the treatment of equity-based awards granted by the Former Parent prior to the Separation to employees who became our employees in connection with the Separation. Under the terms of the lease assumption agreement, we assumed all of the Former Parentâ€™s obligations under the Winter Street Lease. We and the Former Parent entered into two transition services agreements, pursuant to one of which the Former Parent and its subsidiaries agreed to provide, on an interim, transitional basis, various services to us, and the second of which we and our subsidiaries agreed to provide certain services to the Former Parent, in each case for a term of two years following the Separation, unless earlier terminated in accordance with the terms of the applicable agreement. On November 14, 2023, in connection with the Separation, we received a cash contribution of $275.0 million from the Former Parent. The Former Parent effected the Separation through the Distribution on November 15, 2023. Liabilities incurred prior to the Separation remained obligations of the Former Parent unless otherwise specified in the separation agreement. On the effective date of the Distribution, each Alkermes shareholder received one of our ordinary shares for every ten ordinary shares of Alkermes held as of the close of business on November 6, 2023, the record date for the Distribution. Registered shareholders received cash in lieu of any of our fractional ordinary shares that they would have received as a result of the application of the distribution ratio. As a result of the Separation and the Distribution, we operate as an independent, publicly traded company and commenced trading under the symbol â€œMURAâ€ on the Nasdaq Global Market on November 16, 2023. Our historical combined financial statements for the periods prior to the date of the Separation have been prepared on a standalone basis and are derived from the Former Parentâ€™s consolidated financial statements and accounting records. Since the date of the Separation, we present our financial statements on a consolidated basis as a standalone publicly traded company. Our unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. (â€œGAAPâ€). See Note 2, Basis of Presentation and Summary of Significant Accounting Policies, in the notes to our unaudited condensed consolidated financial statements in this Quarterly Report and in the notes to the consolidated financial statements in our Annual Report on Form 10-K for additional information on the preparation and basis of presentation of our audited consolidated financial statements and unaudited condensed consolidated financial statements. Our financial position, results of operations and cash flows historically operated as part of the Former Parentâ€™s financial position, results of operations and cash flows prior to and until the Distribution. The unaudited condensed consolidated 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 prior to the Separation. Our operating structure and capitalization have changed as a result of the Separation, and we expect them to continue to change as we continue to establish operations as an independent company.

Components of Results of Operations Prior to the date of the Separation, our operations were managed in the normal course of business as part of the Former Parent. Accordingly, certain shared costs were allocated to us and reflected as expenses in the historical consolidated financial statements, as described in greater detail in the notes to the unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical 20 Former Parent expenses attributable to us for purposes of the standalone financial statements. The expenses reflected in the historical consolidated 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 consolidated financial statements. Revenue Through September 30, 2024, 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 (â€œR&Dâ€) 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 (â€œCROsâ€), consulting fees and costs related to laboratory services, the purchase of drug product materials and third-party manufacturing development activities. Internal R&D expenses include employee-related expenses, occupancy costs and depreciation. 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 â€œRisk Factorsâ€”Risks Related to Discovery, Product Development and Regulatory Approval of Our Product Candidatesâ€ in this Quarterly Report. General and Administrative Expenses General and administrative (â€œG&Aâ€) expenses consist primarily of salaries and related costs for personnel, including share-based compensation and travel expenses for employees in executive, operational, finance, legal, business development, information technology, and human resource functions. Other G&A expenses include facility-related costs, professional fees for accounting, tax, legal and consulting services, directorsâ€™ fees and expenses associated with obtaining and maintaining patents. We recognize all G&A expenses as incurred. We expect G&A expenses to continue to be higher as we operate as a standalone public company than they had been prior to the Separation. Other Income Other income consists primarily of interest income. We earn interest income from interest-bearing cash accounts and money market mutual funds, which we classify as cash and cash equivalents. We also record in other income any gains and losses resulting from the revaluation of assets and liabilities denominated in foreign currencies due to changes in underlying exchange rates. Results of Operations Comparison of the Three Months Ended September 30, 2024 and 2023 Research and Development Expenses The following table sets forth our R&D expenses for the three months ended September 30, 2024 and 2023: 21 Â Three Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â External R&D expenses: Â Â Â Â Â Â Â Â Â Development programs: Â Â Â Â Â Â Â Â Â Nemvaleukin Â Â Â Â Â Â Â Â Â Â ARISTRY-1 Â $ 0.1 Â Â $ 1.0 Â Â $ (0.9) ARISTRY-2 Â Â 0.1 Â Â Â 1.6 Â Â Â (1.5) ARISTRY-3 Â Â 0.5 Â Â Â 1.1 Â Â Â (0.6) ARISTRY-6 Â Â 3.1 Â Â Â 2.5 Â Â Â 0.6 Â ARISTRY-7 Â Â 4.8 Â Â Â 8.3 Â Â Â (3.5) Other program spend Â Â 6.8 Â Â Â 6.1 Â Â Â 0.7 Â Early discovery programs Â Â 0.7 Â Â Â 0.9 Â Â Â (0.2) Other external R&D expenses Â Â 1.3 Â Â Â 2.9 Â Â Â (1.6) Total external R&D expenses Â Â 17.4 Â Â Â 24.4 Â Â Â (7.0) Internal R&D expenses: Â Â Â Â Â Â Â Â Â Employee-related Â Â 7.6 Â Â Â 12.9 Â Â Â (5.3) Occupancy Â Â 2.3 Â Â Â 2.5 Â Â Â (0.2) Depreciation Â Â 0.3 Â Â Â 0.6 Â Â Â (0.3) Total internal R&D expenses Â Â 10.2 Â Â Â 16.0 Â Â Â (5.8) Research and development expenses Â $ 27.6 Â Â $ 40.4 Â Â $ (12.8) The decrease in R&D expenses in the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily due to different team composition compared to the personnel previously allocated to us by the Former Parent prior to the Separation, as well as decreased spend on the ARISTRY-1 and ARISTRY-2 trials as activities related to these trials wound down in 2023, and decreased spend on the ARISTRY-7 trial due to the timing of patient enrollment. General and Administrative Expenses The following table sets forth our G&A expenses for the three months ended September 30, 2024 and 2023: Â Three Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â General and administrative expense Â $ 6.5 Â Â $ 6.0 Â Â $ 0.5 Â The increase in G&A expense in the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily due to costs associated with operating as a standalone company after the Separation. This includes professional fees as well as differences in costs of insurance and property taxes compared to amounts previously allocated to us by the Former Parent prior to the Separation. Other Income The following table sets forth our other income for the three months ended September 30, 2024 and 2023: Â Three Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â Other income Â $ 2.3 Â Â $ â€” Â Â $ 2.3 Â Other income in the three months ended September 30, 2024 was primarily due to interest income from interest-bearing cash accounts and money market mutual funds and from marketable securities. Income Tax Provision The following table sets forth our income tax provision expense for the three months ended September 30, 2024 and 2023: Â Three Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â Income tax provision Â $ â€” Â Â $ (5.0) Â $ 5.0 Â The income tax provision expense for the three months ended September 30, 2023 was primarily due to the capitalization and amortization of R&D expenses by the Former Parent in accordance with Section 174 of the Internal Revenue Code of 1986, as amended (the â€œCodeâ€). As noted in Note 9, Income Taxes, in the notes to our unaudited condensed consolidated financial statements 22 included elsewhere in this Quarterly Report, 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, 2024. Comparison of the Nine Months Ended September 30, 2024 and 2023 Research and Development Expenses The following table sets forth our R&D expenses for the nine months ended September 30, 2024 and 2023: Â Nine Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â External R&D expenses: Â Â Â Â Â Â Â Â Â Development programs: Â Â Â Â Â Â Â Â Â Nemvaleukin Â Â Â Â Â Â Â Â Â Â ARISTRY-1 Â $ 0.4 Â Â $ 7.5 Â Â $ (7.1) ARISTRY-2 Â Â 0.1 Â Â Â 3.8 Â Â Â (3.7) ARISTRY-3 Â Â 2.1 Â Â Â 2.7 Â Â Â (0.6) ARISTRY-6 Â Â 6.9 Â Â Â 6.1 Â Â Â 0.8 Â ARISTRY-7 Â Â 15.6 Â Â Â 20.5 Â Â Â (4.9) Other program spend Â Â 16.6 Â Â Â 19.0 Â Â Â (2.4) Early discovery programs Â Â 2.1 Â Â Â 3.3 Â Â Â (1.2) Other external R&D expenses Â Â 6.1 Â Â Â 9.3 Â Â Â (3.2) Total external R&D expenses Â Â 49.9 Â Â Â 72.2 Â Â Â (22.3) Internal R&D expenses: Â Â Â Â Â Â Â Â Â Employee-related Â Â 24.1 Â Â Â 41.6 Â Â Â (17.5) Occupancy Â Â 7.0 Â Â Â 8.0 Â Â Â (1.0) Depreciation Â Â 1.0 Â Â Â 1.5 Â Â Â (0.5) Total internal R&D expenses Â Â 32.1 Â Â Â 51.1 Â Â Â (19.0) Research and development expenses Â $ 82.0 Â Â $ 123.3 Â Â $ (41.3) The decrease in R&D expenses in the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily due to different team composition compared to the personnel previously allocated to us by the Former Parent prior to the Separation, as well as decreased spend on the ARISTRY-1 and ARISTRY-2 trials as activities related to these trials wound down in 2023 and decreased spend on the ARISTRY-7 trial due to the timing of patient enrollment. General and Administrative Expenses The following table sets forth our G&A expenses for the nine months ended September 30, 2024 and 2023: Â Nine Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â General and administrative expense Â $ 20.4 Â Â $ 14.4 Â Â $ 6.0 Â The increase in G&A expense in the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily due to costs associated with operating as a standalone company after the Separation. This includes employee-related expenses and professional fees as well as differences in costs of insurance and property taxes compared to amounts previously allocated to us by the Former Parent prior to the Separation. Other Income The following table sets forth our other income for the nine months ended September 30, 2024 and 2023: Â Nine Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â Other income Â $ 8.2 Â Â $ â€” Â Â $ 8.2 Â Â 23 Other income in the nine months ended September 30, 2024 was primarily due to interest income from interest-bearing cash accounts and money market mutual funds and from marketable securities. Income Tax Provision The following table sets forth our income tax provision expense for the nine months ended September 30, 2024 and 2023: Â Nine Months EndedSeptember 30, Â Â Â Â (in millions) Â 2024 Â Â 2023 Â Â Change Â Income tax provision Â $ â€” Â Â $ (10.2) Â $ 10.2 Â The income tax provision expense for the nine months ended September 30, 2023 was primarily due to the capitalization and amortization of R&D expenses by the Former Parent in accordance with Section 174 of the Code. As noted in Note 9, Income Taxes, in the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report, 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, 2024. Liquidity and Capital Resources We have historically participated in the Former Parentâ€™s centralized approach to cash management, and, therefore, there were no cash amounts specifically attributable to us prior to the Separation. Historically, the primary source of liquidity for our business was funding by the Former Parent of the expenses allocated to the oncology business from the Former Parent. Transfers of cash to and from the Former Parent prior to the Separation have been reflected in net parent investment in the unaudited condensed consolidated balance sheets, statements of cash flows and statements of equity (deficit). The Former 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 Former 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: â€¢leverage our programs to continue advancing our product candidates into preclinical and clinical development; â€¢seek regulatory approvals for any product candidates that successfully complete clinical trials; â€¢hire additional clinical, quality control and scientific personnel; â€¢build out commercial infrastructure, including medical affairs, manufacturing, and distribution, as needed, in the event our product candidates obtain marketing approval; â€¢advance our IL-18 and IL-12 programs towards clinical development; â€¢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 â€¢maintain, expand and protect our intellectual property portfolio. We believe, based on our operating plan, that our cash, cash equivalents and marketable securities as of September 30, 2024 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: â€¢the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials; â€¢the costs, timing and outcome of regulatory review of our product candidates; â€¢the costs of future activities, including medical affairs, manufacturing and distribution, if any of our product candidates receive marketing approval; â€¢the cost and timing of hiring new employees to support our continued growth; 24 â€¢the cost of establishing sales, marketing and distribution capabilities if any of our product candidates receive regulatory approval; â€¢the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and â€¢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 are restricted from entering into certain transactions pursuant to a tax matters agreement we entered into with the Former Parent. 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 the 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 â€œRisk Factorsâ€” Risks Related to Tax Mattersâ€ in this Quarterly Report. 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 â€œRisk Factorsâ€”Risks Related to Our Financial Position and Capital Needsâ€ in this Quarterly Report. 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. Cash Flows As the Former Parent managed our cash and financing arrangements prior to the Separation, excess cash generated, if any, was deemed remitted to the Former Parent and all sources of cash were deemed funded by the Former Parent. The following table summarizes our cash flow activity: Â Nine Months EndedSeptember 30, Â (in millions) Â 2024 Â Â 2023 Â Cash, cash equivalents and restricted cash, beginning of period Â $ 271.1 Â Â $ â€” Â Cash flows used in operating activities Â $ (96.8) Â $ (151.5) Cash flows used in investing activities Â $ (61.5) Â $ (2.3) Cash flows provided by financing activities Â $ 0.2 Â Â $ 153.8 Â Cash, cash equivalents and restricted cash, end of period Â $ 113.0 Â Â $ â€” Â Â 25 Operating Activities Net cash used in operating activities for the nine months ended September 30, 2024 was $96.8 million which was primarily the result of our net loss of $94.2 million and an increase of $6.0 million in prepaid expenses, partially offset by non-cash charges of $4.1 million. The most significant non-cash charge we incurred was share-based compensation of $4.4 million. We used $6.6 million in cash from working capital, primarily related to a $6.0 million increase in prepaid expenses, a $3.7 million decrease in accounts payable, accrued expenses and other current liabilities, and a $5.5 million decrease in operating lease liabilities, partially offset by a $4.2 million decrease in our receivable from the Former Parent and a $4.1 million decrease in our right-of-use assets. 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. Investing Activities Net cash used in investing activities was $61.5 million for the nine months ended September 30, 2024, which was primarily due to the purchase of marketable securities, partially offset by the sales and maturities of marketable securities. Net cash used in investing activities was $2.3 million for the nine months ended September 30, 2023, which was attributed to the purchase of property and equipment. Financing Activities Net cash provided by financing activities for the nine months ended September 30, 2024 was due to proceeds received from the issuance of ordinary shares of the Company for the exercise of stock options under employee share plans. As the Former Parent managed our cash and financing arrangements until the Separation, all sources of cash prior to the Separation were deemed funded by the Former Parent. Net cash provided by financing activities for the nine months ended September 30, 2023 was due to the funding of our operating and investing activities by the Former Parent. Contractual Obligations and Commitments Our only lease as of September 30, 2024 and December 31, 2023 was the Winter Street Lease, 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. 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 the Former Parentâ€™s 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 is used solely for our operations. The Former Parent has been primarily obligated to the landlord for the Winter Street Lease, and, following the Separation, the Former Parent is jointly and severally liable with us for, and continues to guarantee, all obligations under the Winter Street Lease. Furthermore, prior to the Separation, the Former Parent was the applicant with respect to a letter of credit security deposit that secured the obligations of the tenant under the Winter Street Lease. The Former Parent maintained a $1.9 million collateralized letter of credit (the â€œFormer Parent Letter of Creditâ€) related to such security deposit as of December 31, 2023. As we did not have legal ownership over any bank accounts prior to the Separation, there were no cash or cash equivalents balances specifically attributable to us for the periods prior to the Separation and, accordingly, no amount is reflected in the consolidated financial statements for the periods prior to the Separation related to the Former Parent Letter of Credit. On January 3, 2024, we entered into a $1.7 million collateralized letter of credit that secures the obligations under the Winter Street Lease to replace the Former Parent Letter of Credit. On August 16, 2024, we entered into a sub-lease pursuant to which we sub-leased to a third party approximately 5,155 square feet of office space and approximately 3,739 square feet of laboratory space that we lease under the Winter Street Lease and we also entered into a separate sub-lease pursuant to which we sub-leased to

another third party (both sub-lessees together, the â€œAugust Sub-lesseesâ€) approximately 3,387 square feet of office space and approximately 2,690 square feet of laboratory space that we lease under the Winter Street Lease (both sub-leases together, the â€œAugust Sub-leasesâ€). The August Sub-leases commenced on August 20, 2024 and are expected to terminate on April 18, 2026. Under the August Sub-leases, the August Sub-lessees will pay to us a total annualized fixed base rent of $0.5 million beginning 30 days after the commencement date of the August Sub-leases, as well as compensate us for the August Sub-lesseesâ€™ proportionate share of operating and other expenses related to the August Sub-leases. The 26 August Sub-lesseesâ€™ base rent and proportionate share of operating and other expenses are included as contra-expense in our condensed consolidated statements of operations and comprehensive loss. On October 11, 2024, we entered into a sub-lease (the â€œOctober Sub-leaseâ€) pursuant to which we sub-leased to an additional third party (the â€œOctober Sub-lesseeâ€) approximately 30,102 square feet of office space that we lease under the Winter Street Lease. Under the October Sub-lease, the October Sub-lessee will pay us an annualized fixed base rent of $0.7 million beginning on January 1, 2025, as well as compensating us for a proportionate share of operating and other expenses related to the October Sub-lease beginning with the commencement date of the October Sub-lease. The October Sub-lease commenced on November 1, 2024 and is expected to terminate on April 30, 2026. As of September 30, 2024, the remaining contractual operating lease liability associated with the Winter Street Lease was $9.5 million. For additional information on our operating lease, see Note 7, Leases, in the notes to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. 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 unaudited condensed consolidated financial statements have been prepared on a standalone basis and are derived from the Former Parentâ€™s consolidated financial statements and accounting records for the periods prior to the Separation. Our managementâ€™s discussion and analysis of our financial condition and results of operations is based on those unaudited condensed consolidated 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 unaudited condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to allocation of corporate expenses, accrued research and development expenses, share-based compensation expense, leases and income taxes. 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. There have been no significant changes to our critical accounting policies or estimates from those described in the â€œCritical Accounting Policies and Significant Judgments and Estimatesâ€ section in Part II, Item 7 - â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ in our Annual Report on Form 10-K. Please refer to such section for a discussion of the accounting policies and estimates we deem to be most critical to the preparation of our consolidated financial statements. 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 unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. Transition From the Former Parent and Costs to Operate as an Independent Company The historical consolidated financial statements reflect our operating results and financial position as our business was operated by the Former Parent, rather than as an independent company, through the date of the Separation. 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 continue to build our administrative infrastructure following the date of the Separation. We entered into transition services agreements with the Former Parent that will provide us with certain services and resources for an initial term of two years following the Separation. Historically, the Former Parent 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 â€œAlkermes Services.â€ We pay the Former Parent fees for the Alkermes Services under the transition services agreements, which fees are based on the Former Parentâ€™s cost of providing the Alkermes Services. These transition services agreements have allowed us to operate our business independently prior to establishing a 27 standalone infrastructure. During the transition from the Former Parent, we have incurred, and expect to continue to 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 combined 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. Emerging Growth Company and Smaller Reporting Company Status In April 2012, the Jumpstart Our Business Startups Act of 2012 (â€œJOBS Actâ€) was enacted. Section 107 of the JOBS Act provides that an â€œemerging growth companyâ€ 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 â€œopt outâ€ 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 â€œopt outâ€ of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our consolidated 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 â€œlarge accelerated filer,â€ 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 â€œsmaller reporting companyâ€ 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, we 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 Securities Exchange Act of 1934, as amended) as of September 30, 2024. 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, 2024 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SECâ€™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 three months ended September 30, 2024, 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. 28 PART IIâ€“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 consolidated 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 (the â€œFormer Parentâ€ or â€œAlkermesâ€), our business was conducted by the Former Parent. As a result, 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 (â€œnemvaleukinâ€), into potentially registrational clinical trials. The conduct of our business by the Former Parent 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, the Former Parent will continue to provide some of these functions to us for a specified time period, as described in Note 1, Organization and Description of Business, in the notes to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. We have made and will need to continue to make investments to replicate or outsource from other providers certain manufacturing facilities, systems, infrastructure and personnel to which we no longer have access following our Separation from the Former Parent. Any initiatives to develop an independent ability to operate without access to the Former Parentâ€™s 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: â€¢successfully complete our ongoing and planned preclinical and clinical studies; â€¢successfully initiate and complete clinical trials for nemvaleukin and other product candidates; â€¢successfully enroll subjects in, and complete, our ongoing clinical trials and any future clinical trials; â€¢initiate and/or successfully complete the safety and efficacy studies required to obtain United States (â€œU.S.â€) and/or non-U.S. regulatory approvals for our product candidates; â€¢establish clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing; â€¢obtain and maintain regulatory approval for our product candidates; 29 â€¢obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; â€¢launch commercial sales of our products, if and when approved, whether alone or in collaboration with others; â€¢obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third-party payors; â€¢effectively compete with other therapies; â€¢obtain and maintain healthcare coverage and adequate reimbursement for any approved products; â€¢enforce and defend intellectual property rights and claims; and â€¢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 as a standalone company, nor did our business when operated by the Former Parent generate any revenue. 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, 2024 and 2023 were $94.2 million and $147.9 million, respectively. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase 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. As of September 30, 2024, our cash, cash equivalents and marketable securities were $175.5 million. Our management believes that our existing cash, cash equivalents and marketable securities 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. 30 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 the Former Parent 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 the Former Parent of our ordinary shares to the Former Parentâ€™s shareholders. For more information, see â€œâ€”Risks Related to the Separation and the Distributionâ€ in this Quarterly Report. 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. Although we 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. 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 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. 31 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 (â€œBLAâ€) to the U.S. Food and Drug Administration (â€œFDAâ€), a marketing authorization application to the European Medicines Agency (â€œEMAâ€) 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: â€¢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; â€¢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; â€¢we may experience issues in reaching a consensus with regulatory authorities on trial design; â€¢regulators, institutional review boards (â€œIRBsâ€) 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; â€¢we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (â€œCROsâ€) or contract development and manufacturing organizations (â€œCDMOsâ€), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CDMOs and trial sites; â€¢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; â€¢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; â€¢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; â€¢subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials; â€¢subjects may experience severe or unexpected drug-related adverse effects; â€¢clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results; â€¢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; â€¢we may need to add new or additional clinical trial sites and may experience delays or interruptions in site initiations; â€¢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; 32 â€¢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; â€¢we may not be able to raise funding necessary to initiate or continue a trial; â€¢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; â€¢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; â€¢reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates; â€¢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; â€¢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 â€¢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. Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. However, it is uncertain as to whether the regulation will achieve those goals and as to how it will be interpreted and implemented. 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. Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDAâ€™s approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a Risk Evaluation and Mitigation Strategy (â€œREMSâ€). In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the U.S. Among other determinations, the district court held that plaintiffs were likely to prevail in their claim that the FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court 33 as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that the FDAâ€™s drug approval decision effectively compelled the plaintiffs to provide care for patients suffering adverse events caused by a given drug. In June 2024, the U.S. Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, and if it continues, and the regulatory uncertainty it has engendered, our ability to develop new drug product candidates and to maintain approval of existing drug products and measures adopted under a REMS is at risk and could be delayed, undermined or subject to protracted litigation. 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: â€¢cliniciansâ€™ and patientsâ€™ 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; â€¢the severity of the disease under investigation; â€¢the patient eligibility and the inclusion and exclusion criteria defined in the protocol; â€¢adverse events in our clinical trials and in third-party clinical trials of agents similar to our product candidates; â€¢the size and health of the patient population required for analysis of the trialâ€™s primary endpoints; â€¢the proximity of patients to trial sites; â€¢the design of the trial; â€¢our ability to recruit clinical trial investigators with the appropriate competencies and experience; â€¢our ability to obtain and maintain patient consents; â€¢our ability to monitor patients adequately during and after treatment; â€¢the risk that patients enrolled in clinical trials will drop out of the trials before completion; and â€¢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. 34 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. For example, our results in our ARTISTRY-1 trial are not necessarily indicative of results we may achieve in our ARTISTRY-6 and ARTISTRY-7 trials. We additionally intend to pursue development of nemvaleukin for other indications or with different dosing regimens, and results from our trials to date are not necessarily predictive of results in those potential future trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain 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, â€œtoplineâ€ 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 FDAâ€™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 (â€œIMMâ€), that is reasonably likely to predict an effect on IMM or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 (â€œFDORAâ€), 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 drugâ€™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. Prior to seeking accelerated approval of any of our product candidates, we would expect to seek feedback from the FDA and to otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue accelerated approval or any other form of expedited development, review or approval or that we will continue to pursue or apply for accelerated approval even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. 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 35 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 ensure the productâ€™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, our clinical trials globally, including at sites 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 (â€œUKâ€), Italy, Austria, Israel, Singapore, 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. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice (â€œGCPâ€) regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study satisfies certain conditions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with 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 for our products, 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 for any approved products or the delay or denial of regulatory approval by the FDA or other comparable non-U.S. regulatory authorities. 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: â€¢we may suspend or be forced to suspend marketing of such product; â€¢we may be obliged to conduct a product recall or product withdrawal; â€¢other regulatory authorities may suspend, vary, or withdraw their approvals of such product; â€¢regulatory authorities may order the seizure of such product; â€¢regulatory authorities may require additional warnings on the label or a REMS that could diminish the usage or otherwise limit the commercial success of such product; 36 â€¢we may be required to conduct post marketing studies for such product; â€¢we could be sued and held liable for harm caused to patients that are believed to be related to use of such product; â€¢we could be required to pay fines and face other administrative, civil, and criminal penalties; and â€¢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 (â€œIL-18â€) and interleukin-12 (â€œIL-12â€) 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 (â€œINDâ€) 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: â€¢the research methodology used may not be successful in identifying potential indications and/or product candidates; â€¢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 â€¢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. The FDAâ€™s 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 (â€œAdvisory Committeeâ€),

to deliberate on the adequacy of the safety and efficacy data from our clinical studies to support approval. The opinion of the Advisory Committee, 37 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. Our applications for our product candidates could fail to receive regulatory approval for many reasons, including the following: â€¢the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials; â€¢the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; â€¢the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; â€¢the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; â€¢we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidatesâ€™ risk-benefit ratios for their proposed indications are acceptable; â€¢the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and â€¢the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. 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 â€œacts of Godâ€ 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 38 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 (â€œcGMPâ€). 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 FDAâ€™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. In addition, certain Chinese biotechnology companies and contract manufacturers that may in the future supply us with drug product may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations. Regulatory authorities also may, at any time following approval of a product for sale, audit our third-party manufacturersâ€™ 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: â€¢the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors; â€¢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; â€¢termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; â€¢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; â€¢the inability to obtain components or materials from alternate sources at acceptable prices in a timely manner; and â€¢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. 39 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 (â€œEUâ€). 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. 40 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. Additionally, changes in laws or regulations, particularly if there are changes in or the enactment of additional statutes, promulgation of regulations or issuance of guidance during preclinical or clinical development, may require us to change our trial designs or conduct additional trials. For example, in December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other â€œpivotal studyâ€ of a new drug or biological product. 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 licenseesâ€™ manufacturing processes or facilities, or those of the CROs and contract manufacturing organizations who conduct research or manufacturing work on our or our licenseesâ€™ behalf. Regulatory authorities also may change their requirements for approval or post-approval marketing. For example, if the data from the ARTISTRY-6 cohort are positive, the FDA may 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. We will need to reach agreement with the FDA on a confirmatory data plan prior to receiving such approval, and there is no guarantee that the FDA will agree to any confirmatory data plan that we propose. 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. 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 shareholdersâ€™ 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. Inadequate funding for the FDA, the Securities and Exchange Commission (the â€œSECâ€) and other U.S. government agencies or the EMA or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA, EMA or comparable foreign regulatory authorities 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 FDA and other regulators have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, disruptions may result in events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDAâ€™s 41 inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities. Accordingly, if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. 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. 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 manufacturersâ€™ 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. 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. Even if any of our product candidates receive regulatory approval from 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. 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: â€¢restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; â€¢fines, warning letters or holds on clinical trials; â€¢refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; 42 â€¢product seizure or detention or refusal to permit the import or export of our product candidates; and â€¢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, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted in the U.S. for uses that are not approved by the FDA as reflected in the productâ€™s approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off-label uses, the FDA, EMA and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companiesâ€™ sales force with respect to off-label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agencyâ€™s non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDAâ€™s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. 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. 43 We may seek certain designations for our product candidates, including Fast Track, Priority Review, and Breakthrough Therapy designations in the U.S., Innovative Licensing and Access Pathway in the UK, and PRIME Designation in the EU, 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 (â€œFTDâ€) for nemvaleukin in mucosal melanoma and for nemvaleukin in combination with pembrolizumab for platinum-resistant ovarian cancer (â€œPROCâ€). 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 the 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, the UKâ€™s Medicines and Healthcare products Regulatory Agency (the â€œMHRAâ€) granted an Innovation Passport designation for nemvaleukin for the treatment of mucosal melanoma, under the UKâ€™s Innovative Licensing and Access Pathway (the â€œILAPâ€). 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 and the Scottish Medicines Consortium) work with the Innovation Passport designee to define a Target Development Profile (â€œTDPâ€). 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. Finally, in the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMAâ€™s role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The PRIME program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur of the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the 44 designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMAâ€™s grant of a marketing authorization. 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 (â€œODDâ€) 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: â€¢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; â€¢the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or â€¢the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product. The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term â€œsame disease or conditionâ€ means the designated â€œrare disease or conditionâ€ and could not be interpreted by the FDA to mean the â€œindication or use.â€ Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that courtâ€™s order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. 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. 45 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: â€¢the productâ€™s efficacy, safety and potential advantages compared to alternative treatments; â€¢the prevalence and severity of any side effects; â€¢the productâ€™s convenience and ease of administration compared to alternative treatments; â€¢the clinical indications for which the product is approved; â€¢the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments; â€¢the recommendations with respect to the product in guidelines published by scientific organizations; â€¢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; â€¢the strength of marketing, sales and distribution support; â€¢the effectiveness of our sales and marketing efforts; â€¢cliniciansâ€™ and patientsâ€™ perceptions of other similar immuno-oncology product candidates or products with a similar mechanism of action as ours; â€¢the approval of other new products for the same indications; â€¢our ability to offer the product for sale at competitive prices; and â€¢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 products approved for marketing, and we have not yet implemented any commercialization operations. There can be no assurance that we will successfully establish our commercialization capabilities if any of our product candidates are approved. 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 the Former Parent. 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 46 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. 47 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 â€œACAâ€). 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 legislationâ€™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. 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 U.S. Congress repealed the â€œindividual mandate.â€ The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. 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 48 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 (â€œCMSâ€) 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 beneficiariesâ€™ access to evidence-based care. In addition, in October 2020, the U.S. Department of Health and Human Services (â€œHHSâ€) and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, to import certain prescription drugs from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America (â€œPhRMAâ€) but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2023, the FDA approved Floridaâ€™s plan for Canadian drug importation. 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 (â€œIRAâ€) 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 â€œexcessive 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.â€ 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. On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRAâ€™s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce (the â€œChamberâ€), Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. 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 49 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. For more information, see â€œBusinessâ€”Competitionâ€ in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the â€œAnnual Report on Form 10-Kâ€). 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 (â€œIL-2â€)-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 50 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 (â€œBPCIAâ€) 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 sponsorâ€™s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other companyâ€™s product. In December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA. 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 the Former Parent. 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. 51 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 managementâ€™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 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 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 52 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 drugâ€™s safety or efficacy profile, changes to the availability of the third-party drug, or 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 collaboratorsâ€™ 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: â€¢collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements; â€¢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 partyâ€™s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; â€¢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; â€¢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; â€¢collaborators or licensors may be acquired by a third party having competitive products or different priorities; â€¢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); â€¢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; â€¢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; â€¢we may lose certain valuable rights under certain circumstances, including if we undergo a change of control; â€¢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 â€¢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. 53 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 (â€œUSPTOâ€), 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 54 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 may be issued 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. 55 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 56 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. If such events were to occur, 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: â€¢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; â€¢others may identify compounds more quickly than we are able to, and might file their patent applications before us; â€¢we or our partners might not have been the first to make the inventions covered by our issued patent or pending patent application; â€¢we or our partners might not have been the first to file patent applications covering certain of our inventions; â€¢others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; â€¢our pending patent applications might not lead to issued patents; â€¢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; â€¢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 partnersâ€™ existing or potential commercial markets; â€¢we may not develop additional proprietary technologies that are patentable; and â€¢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: â€¢non-U.S. government taxes, regulations and permit requirements; â€¢U.S. and non-U.S. government tariffs, trade restrictions, price and exchange controls and other regulatory requirements; â€¢anti-corruption laws, including the Foreign Corrupt Practices Act of 1977, as amended (â€œFCPAâ€); â€¢economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular non-U.S. countries; â€¢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; â€¢production shortages resulting from any events affecting raw material supply or manufacturing capabilities aboard; and â€¢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, 57 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 SEC and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Doddâ€“Frank Wall Street Reform and Consumer Protection Act (â€œDodd-Frankâ€), 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 â€œBusiness â€“ Government Regulation â€“ Healthcare and Privacy Lawsâ€ in our Annual Report on Form 10-K. 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. 58 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 companyâ€™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 managementâ€™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, â€œTrade Lawsâ€) 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. 59 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 November 1, 2024, we had approximately 109 employees. 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: â€¢delay or termination of clinical trials; â€¢decreased demand for any product candidates or products that we may develop; â€¢injury to our reputation and significant negative media and social media attention; â€¢withdrawal of clinical trial participants or difficulties in recruiting new trial participants; â€¢initiation of investigations by regulators; â€¢costs to defend or settle the related litigation; â€¢a diversion of managementâ€™s time and our resources; â€¢substantial monetary awards to trial participants or patients; â€¢product recalls, withdrawals or labeling, marketing or promotional restrictions; â€¢significant negative financial impact; and â€¢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. 60 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 â€œacts of God,â€ 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. 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 (â€œCCPAâ€), as amended by the California Privacy Rights Act (â€œCPRAâ€), 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 61 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. For example, in addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of â€œsensitiveâ€ data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data and additional states (including Vermont) are considering such legislation for 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. 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 (â€œHIPAAâ€). 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 (â€œEU GDPRâ€), 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 â€œUK GDPRâ€, together with the EU GDPR the â€œGDPRâ€) 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 (â€œEEAâ€) (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 individualsâ€™ 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 â€œadequateâ€ 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 (â€œSCCsâ€) 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 62 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 Commissionâ€™s new SCCs but has published the UK International Data Transfer Agreement (the â€œIDTAâ€) and International Data Transfer Addendum to the new SCCs (the â€œUK Addendumâ€), which provides modifications to the European Commissionâ€™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, 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 (â€œTIAâ€) 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 â‚¬20 (Â£17.5) million or 4% of the data controllerâ€™s or data processorâ€™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 â€œUK Billâ€) into the UK legislative process with the intention for this bill to reform the UKâ€™s data protection regime following the UKâ€™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 â€œadequateâ€ 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, have in the past and may in the future suffer security breaches or fail, which may 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 have in the past and may in the future suffer security breaches or 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 63 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 any failures, deficiencies or breaches, and they may not always be successful in doing so. For example, we have been advised by one of our vendors that certain of our clinical data held by the vendor may have been accessed during a ransomware attack on the vendorâ€™s systems. 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 the Former Parent, 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 the Former Parent; our business will be less diversified than the Former Parentâ€™s business prior to completion of the Separation and the actions that have been required to separate the Former Parentâ€™s 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 the Former Parent. As an integrated company with the Former Parent, we were able to use the Former Parentâ€™s 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 the Former Parent will provide certain of these services for a specified time period pursuant to the transition services agreements we have entered into with the Former Parent, this arrangement may not fully capture the benefits that

have resulted from being integrated with the Former Parent 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. 64 We have a very limited history of operating as a standalone company and we expect to continue to incur increased administrative and other costs, as compared to prior to the Separation, by virtue of our status as an independent public company. Our historical combined financial information prior to the Separation included in this Quarterly Report is not necessarily representative of the results that we would have achieved for the periods presented 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 the Former Parent. Our historical information provided in this Quarterly Report includes references to our business as operated by and integrated with the Former Parent prior to the Separation. Our historical combined financial information through the date of the Separation included in this Quarterly Report is derived from the consolidated financial statements and accounting records of the Former Parent. Accordingly, the historical combined financial information included in this Quarterly 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 Quarterly Report as a result of the following factors, among others: â€¢our historical financial data reflects expense allocations for certain business and support functions that were provided on a centralized basis within the Former Parent, 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; â€¢our capital structure will be different from that reflected in our historical combined financial statements for periods prior to the Separation; â€¢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 â€œSarbanes-Oxley Actâ€); and â€¢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, will be different from results reflected in our historical financial statements included elsewhere in this Quarterly Report for periods prior to the Separation. 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 the Former Parent 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 the Former Parent. Prior to the Distribution, the Former Parent effectively had the sole and absolute discretion to determine and change the terms of the Separation and the Distribution, including the terms of any agreements between the Former Parent and us. As a result, our agreements with the Former Parent 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 Note 1, Organization and Description of Business, in the notes to the consolidated financial statements in our Annual Report on Form 10-K. 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 have substantially completed the installation and implementation of 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, 65 manufacturing process control, inventory control and trial and research data. Despite this, we may incur temporary interruptions in business operations as part of our initial standalone operation of transactional and operational systems and data centers. While we have substantially completed the process of implementing our new systems and transitioning our data, we may incur substantially higher costs for the ongoing management of these systems than currently anticipated. Our failure to implement the new systems successfully and replace the Former Parentâ€™s 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 maintain the administrative and support functions necessary to operate as a standalone public company. In connection with the Separation, we established our own financial, administrative, corporate governance, and public company compliance and other support systems, including for the services the Former Parent had historically provided to us, and we have contracted with third parties to replace certain of the Former Parentâ€™s systems that we did not establish internally. This process has been, and we expect that it will continue 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 the Former Parent and will require us to develop new standalone corporate functions. We have made significant investments to replicate, or to outsource from other providers, these corporate functions to replace these additional corporate services that the Former Parent historically provided to us prior to the Separation. In certain rare instances, the Former Parent 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 the Former Parent. Any failure or significant downtime in our own financial, administrative or other support systems or in the Former Parentâ€™s financial, administrative or other support systems during the transitional period in which the Former Parent 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 the Former Parent. 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 the Former Parent has historically tested 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. The Former Parent 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 the Former Parent 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 Note 1, Organization and Description of Business, in the notes to the consolidated financial statements in our Annual Report on Form 10-K. 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 the Former Parent to satisfy its performance and payment obligations under these agreements. If the Former Parent 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 have created our own, or engaged third parties to provide, systems and services to replace many of the systems and services the Former Parent currently provides or previously provided to us, but these new systems and services may not work as well, or we may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from the Former Parentâ€™s systems to our systems. These systems and services may also be more expensive or less efficient than the systems and services the Former Parent is expected to provide during the

transition period. 66 In connection with the separation, we have assumed and agreed to indemnify the Former Parent for certain liabilities. If we are required to make payments pursuant to these indemnities to the Former Parent, 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 the Former Parent, we have assumed and agreed to indemnify the Former Parent for certain liabilities for uncapped amounts, which may include, among other items, associated defense costs, settlement amounts and judgments, as discussed further in Note 1, Organization and Description of Business, in the notes to the consolidated financial statements in our Annual Report on Form 10-K. 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 the Distribution and certain related transactions. Third parties could also seek to hold us responsible for liabilities of the Former Parentâ€™s business. The Former Parent has agreed to indemnify us for liabilities of the Former Parentâ€™s business, but such indemnity from the Former Parent may not be sufficient to protect us against the full amount of such liabilities, and the Former Parent may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from the Former Parent 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 the Former Parent, we have agreed to undertake certain obligations for the benefit of the Former Parent 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 the Former Parent. 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. 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 the Distribution from the Former Parent, 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 the Former Parent and the Former Parentâ€™s shareholders could be subject to significant tax liabilities, and we could be required to indemnify the Former Parent or its subsidiaries for material taxes pursuant to indemnification obligations under the tax matters agreement which we entered into with the Former Parent in connection with the Separation. It was a condition to the Distribution that the Former Parent receive a private letter ruling from the Internal Revenue Service (the â€œIRSâ€) and an opinion from Goodwin Procter LLP, together confirming that the Separation and the 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 Internal Revenue Code of 1986, as amended (the â€œCodeâ€), except for cash received in lieu of fractional ordinary shares. The Former Parent 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 the 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 the Former Parent and us (including those relating to the past and future conduct of the Former Parent 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 the Former Parent 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 the 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 the Former Parent of the tax opinion and the IRS private letter ruling referred to above, the IRS could assert that the Separation and the Distribution and certain related transactions do not qualify for tax-free treatment for U.S. federal income tax purposes. 67 If the Separation and the 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 the Former Parent would recognize taxable gain and the Former Parentâ€™s shareholders who received 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. In connection with the Distribution, we and the Former Parent 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 the 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 the Former Parent, including a prohibited change of control in the Former Parent under Section 355(e) of the Code or an acquisition of the Former Parentâ€™s shares or assets, then the Former Parent 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 the Former Parent for any resulting taxes, interest, penalties and other costs. If such failure does not result from a prohibited change of control in the Former Parent or Mural under Section 355(e) of the Code and both we and the Former Parent are responsible for such failure, liability will be shared according to relative fault. If neither we nor the Former Parent is responsible for such failure, the Former Parent will bear any resulting taxes, interest, penalties and other costs. Our indemnification obligations to the Former Parent 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 the Former Parent 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 the 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 the 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 Note 1, Organization and Description of Business, in the notes to the consolidated financial statements in our Annual Report on Form 10-K. 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 â€œPFICâ€) 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. Our PFIC status for our current and subsequent taxable years may also depend on whether we qualify for the PFIC 68 start-up exception. Depending on the particular circumstances, the application of the start-up exception may be subject to uncertainty, and there cannot be any assurance that we qualify for the start-up exception. Absent the start-up exception, we believe it is likely that PFIC status could arise for the prior year tax period, in which case certain elections may be desired, as discussed herein, after consultation with your personal tax advisor or tax professional. 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 â€œqualified electing fundâ€ election under Section 1295 of the Code (a â€œQEF Electionâ€) or a mark-to-market election (if our ordinary shares constitute â€œmarketableâ€ 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. If we determine we are a PFIC for any taxable year, upon written request by a U.S. Holder, we will endeavor to provide to a U.S. Holder such information as the IRS may require in order to enable the U.S. Holder to make and maintain a QEF Election, but there can be no assurance that we will timely provide such required information. 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. We urge U.S. holders to consult their tax advisors regarding the possible application of the PFIC rules, elections and consequences in the event we are a PFIC and/or the start-up exception is determined not to apply in a later year. Risks Related to Ownership of Our Ordinary Shares We are an â€œemerging growth companyâ€ and a â€œsmaller reporting companyâ€ 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 â€œemerging growth companyâ€, as defined in the Jumpstart Our Business Startups Act of 2012 (the â€œJOBS Actâ€). 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: â€¢being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ disclosure; â€¢not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; â€¢reduced disclosure obligations regarding executive compensation; and â€¢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 â€œopt outâ€ 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 â€œopt outâ€ of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our consolidated 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. 69 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: â€¢adverse results from preclinical studies or clinical trials of our product candidates or our competitorsâ€™ product candidates or products; â€¢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; â€¢adverse results from, delays in initiating or completing, or termination of clinical trials; â€¢unanticipated safety concerns related to the use of our product candidates; â€¢adverse regulatory decisions, including failure by us or one of our competitors to receive regulatory approval of product candidates; â€¢any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authorityâ€™s review of such filings, including without limitation the FDAâ€™s issuance of a â€œrefusal to fileâ€ letter or a request for additional information; â€¢lower than expected market acceptance of our or our competitorsâ€™ products following approval for commercialization; â€¢adverse developments concerning our manufacturers; â€¢our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; â€¢introduction of new products or services by our competitors; â€¢changes in financial estimates by us or by any securities analysts who might cover our shares; â€¢conditions or trends in our industry; â€¢our cash position; â€¢sales of our ordinary shares by us or our shareholders in the future; â€¢adoption of new accounting standards; â€¢ineffectiveness of our internal controls; â€¢changes in the market valuations of similar companies; â€¢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; â€¢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; â€¢announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; â€¢announcements of investigations or regulatory scrutiny of our operations or lawsuits that may be filed against us; â€¢investorsâ€™ general perception of our company and the reputation of our business; â€¢recruitment or departure of key personnel; â€¢overall performance of the equity markets; â€¢trading volume of our ordinary shares; â€¢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; â€¢significant lawsuits, including patent or shareholder litigation; â€¢proposed changes to healthcare laws or pharmaceutical pricing in the U.S. or non-U.S. jurisdictions, or speculation regarding such changes; 70 â€¢general political and economic conditions, including disruptions in the banking industry; and â€¢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 companiesâ€™ 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 managementâ€™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: â€¢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; â€¢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 â€¢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. 71 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 â€œExchange Actâ€), the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. Our financial results historically were included within the consolidated results of the Former Parent, 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 systemâ€™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 our ordinary shares that they hold. 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, compared to prior to the Separation, 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 72 standards, and this investment may result in increased general and administrative expenses and a diversion of managementâ€™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 affected. 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 are restricted from entering into certain transactions pursuant to the tax matters agreement. For more information, see Note 1, Organization and Description of Business, in the notes to the consolidated financial statements in our Annual Report on Form 10-K. 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 73 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 companyâ€™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 companyâ€™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 â€œSecurities Actâ€), 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, shareholdersâ€™ 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 (â€œDTCâ€) 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 Constitution provides 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. 74 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 we will seek or be able to create the distributable reserves needed to pay dividends. 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 â€œdistributable reserves,â€ which we do not have. However, we do have a significant amount of share premium. To create â€œdistributable reserves,â€ we would need to undertake an Irish legal process pursuant to which we will convert up to our entire share premium account to â€œdistributable reserves.â€ This process would require the approval of the High Court of Ireland and the approval of our shareholders. Although we do not currently plan to seek to create distributable reserves, if we later determine to do so, there can be no assurance that the High Court of Ireland would approve the creation of distributable reserves, as the issuance of the required order is a matter for the discretion of the High Court of Ireland, or that our shareholders would approve the creation of distributable reserves in the manner required. In the event that â€œdistributable reservesâ€ 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 75 electronic or telephonic voting. If voting lists are used, generally three lists labeled â€œFor,â€ â€œAgainstâ€ and â€œAbstainâ€ (or â€œWithheldâ€) 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 shareholdersâ€™ 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, cash equivalents and marketable securities, 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, cash equivalents and marketable securities. We could utilize our cash, cash equivalents and marketable securities 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 shareholdersâ€™ investments. If we do not utilize our cash, cash equivalents and marketable securities in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause our share price to decline. Item 5. Other Information. Director and Officer Trading Arrangements A portion of the compensation of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) is in the form of equity awards and, from time to time, directors and officers may engage in open-market transactions with respect to the securities acquired pursuant to such equity awards or other of our securities, including to satisfy tax withholding obligations when equity awards vest or are exercised, and for diversification or other personal reasons. Transactions in our securities by directors and officers are required to be made in accordance with our insider trading policy, which requires that the transactions be in accordance with applicable U.S. federal securities laws that prohibit trading while in possession of material nonpublic information. Rule 10b5-1 under the Exchange Act provides an affirmative defense that enables directors and officers to prearrange transactions in our securities in a manner that avoids concerns about initiating transactions while in possession of material nonpublic information. 76 During the three months ended September 30, 2024, the following officers adopted contracts, instructions, or written plans for the purchase or sale of our securities that were intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act (each, a â€œRule 10b5-1 Trading Arrangementâ€). On September 13, 2024, Caroline Loew, our Chief Executive Officer, adopted a Rule 10b5-1 Trading Arrangement providing for the potential sale of up to 124,204 of our ordinary shares obtained from the exercise of vested stock options or the vesting of restricted stock unit awards in accordance with the prices and formulas set forth in the plan. The number of ordinary shares that may be sold under this Rule 10b5-1 Trading Arrangement is not currently determinable as the number will vary based on the market price of our ordinary shares. This Rule 10b5-1 Trading Arrangement is scheduled to expire on August 15, 2025. On September 20, 2024, Maiken Keson-Brookes, our Chief Legal Officer, adopted a Rule 10b5-1 Trading Arrangement providing for the potential sale of up to 31,886 of our ordinary shares obtained from the exercise of vested stock options or the vesting of restricted stock unit awards in accordance with the prices and formulas set forth in the plan. The number of ordinary shares that may be sold under this Rule 10b5-1 Trading Arrangement is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the market price of our ordinary shares at the time of future RSU vesting. This Rule 10b5-1 Trading Arrangement is scheduled to expire on September 5, 2025. On September 23, 2024, Adam Cutler, our Chief Financial Officer adopted a Rule 10b5-1 Trading Arrangement providing for the potential sale of up to 28,767 our ordinary shares obtained from the exercise of vested stock options or the vesting of restricted stock unit awards in accordance with the prices and formulas set forth in the plan. The number of ordinary shares that may be sold under this Rule 10b5-1 Trading Arrangement is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the market price of our ordinary shares at the time of future RSU vesting. This Rule 10b5-1 Trading Arrangement is scheduled to expire on August 18, 2025. No other officers or directors adopted a Rule 10b5-1 Trading Arrangement during the three months ended September 30, 2024. None of our directors or officers modified or terminated a Rule 10b5-1 Trading Arrangement or adopted, modified, or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended September 30, 2024. 77 Item 6. Exhibits. Â ExhibitNumber Description 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 â€“ the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. 101.SCH Â Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents 104 Â Cover Page Interactive Data File (embedded within the Inline XBRL document) Â * Filed herewith. + The certifications furnished in Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed â€œfiledâ€ 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. 78 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. Â Mural Oncology plc Date: November 13, 2024 By: /s/ Adam Cutler Adam Cutler Chief Financial Officer Â Â Â (Principal Financial and Accounting Officer) Â 79 EX-31.1 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. Â Date: November 13, 2024 By: /s/ Caroline Loew Caroline Loew, Ph.D. Â Â Â Chief Executive Officer (Principal Executive Officer) Â Â EX-31.2 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. Â Date: November 13, 2024 By: /s/ Adam Cutler Adam Cutler Â Â Â Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) Â Â EX-32.1 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 â€œCompanyâ€) on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 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. Â Date: November 13, 2024 By: /s/ Caroline Loew Caroline Loew, Ph.D. Â Â Â Chief Executive Officer (Principal Executive Officer) Â Â EX-32.2 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 â€œCompanyâ€) on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 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. Â Date: November 13, 2024 By: /s/ Adam Cutler Adam Cutler Â Â Â Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) Â Â