

---

---

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

---

**FORM 10**

---

**GENERAL FORM FOR REGISTRATION OF SECURITIES  
PURSUANT TO SECTION 12(b) OR 12(g) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

---

**Mural Oncology Limited\***

(Exact name of Registrant as specified in its charter)

---

**Ireland**  
(State or other jurisdiction of  
incorporation or organization)

**Not Applicable**  
(I.R.S. Employer  
Identification No.)

**10 Earlsfort Terrace**  
**Dublin 2, D02 T380, Ireland**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

**+353-1-905-8020**  
(Registrant's telephone number, including area code)

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

Title of each class  
to be so Registered  
**Ordinary shares, nominal value \$0.01**

Name of each exchange on which  
each class is to be registered  
**The Nasdaq Global Market**

**Securities to be registered pursuant to Section 12(g) of the Act: None**

---

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

---

\* Prior to completion of the separation and distribution, we intend to alter the legal status of Mural Oncology Limited under Irish law to that of a public limited company by re-registering it as a public limited company and changing its name to Mural Oncology Public Limited Company.

---

---

---

## EXPLANATORY NOTE

We are omitting our financial statements for each of the three months ended March 31, 2023 and March 31, 2022 because they relate to historical periods that we believe will not be required to be included in the registration statement at the time of the initial public filing of the registration statement. Mural Oncology Limited intends to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment, at least 15 days prior to the anticipated effective date of the registration statement for its listing on a national securities exchange. Operations for Mural Oncology Limited on a standalone basis have not yet commenced, and the organization has nominal assets and liabilities.

**MURAL ONCOLOGY LIMITED**

**INFORMATION REQUIRED IN REGISTRATION STATEMENT  
CROSS-REFERENCE SHEET BETWEEN INFORMATION STATEMENT  
AND ITEMS OF FORM 10**

Certain information required to be included in this Form 10 is incorporated by reference to specifically identified portions of the body of the information statement filed with this Form 10 as Exhibit 99.1. None of the information contained in the information statement shall be incorporated by reference in this Form 10 or deemed to be a part of this Form 10 unless such information is specifically incorporated by reference.

***Item 1. Business.***

The information required by this item is contained under the sections of the information statement entitled “Information Statement Summary,” “Risk Factors,” “Cautionary Statement Concerning Forward-Looking Statements,” “Unaudited Pro Forma Combined Financial Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” “Certain Relationships and Related Person Transactions,” “Where You Can Find More Information” and “Index to Combined Financial Statements” and in the financial statements referenced in the information statement. Those sections are incorporated herein by reference.

***Item 1A. Risk Factors.***

The information required by this item is contained under the section of the information statement entitled “Risk Factors.” That section is incorporated herein by reference.

***Item 2. Financial Information.***

The information required by this item is contained under the sections of the information statement entitled “Summary Historical and Unaudited Pro Forma Combined Financial Information,” “Unaudited Pro Forma Combined Financial Statements,” “Capitalization” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Those sections are incorporated herein by reference.

***Item 3. Properties.***

The information required by this item is contained under the section of the information statement entitled “Business—Facilities.” That section is incorporated herein by reference.

***Item 4. Security Ownership of Certain Beneficial Owners and Management.***

The information required by this item is contained under the section of the information statement entitled “Security Ownership by Certain Beneficial Owners and Management.” That section is incorporated herein by reference.

***Item 5. Directors and Executive Officers.***

The information required by this item is contained under the section of the information statement entitled “Management.” That section is incorporated herein by reference.

***Item 6. Executive Compensation.***

The information required by this item is contained under the section of the information statement entitled “Executive Compensation.” That section is incorporated herein by reference.

**Item 7. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is contained under the sections of the information statement entitled “Management,” “Executive Compensation” and “Certain Relationships and Related Person Transactions.” Those sections are incorporated herein by reference.

**Item 8. Legal Proceedings.**

The information required by this item is contained under the section of the information statement entitled “Business.” That section is incorporated herein by reference.

**Item 9. Market Price of and Dividends on the Registrant’s Common Equity and Related Shareholder Matters.**

The information required by this item is contained under the sections of the information statement entitled “Risk Factors,” “Dividend Policy,” “Capitalization,” “The Separation and Distribution” and “Description of Mural’s Share Capital.” Those sections are incorporated herein by reference.

**Item 10. Recent Sales of Unregistered Securities.**

The information required by this item is contained under the section of the information statement entitled “Description of Mural’s Share Capital—Sale of Unregistered Securities.” That section is incorporated herein by reference.

**Item 11. Description of Registrant’s Securities to be Registered.**

The information required by this item is contained under the sections of the information statement entitled “Risk Factors,” “Dividend Policy,” “Capitalization,” “The Separation and Distribution” and “Description of Mural’s Share Capital.” Those sections are incorporated herein by reference.

**Item 12. Indemnification of Directors and Officers.**

The information required by this item is contained under the section of the information statement entitled “Description of Mural’s Share Capital—Indemnification of Directors and Officers.” That section is incorporated herein by reference.

**Item 13. Financial Statements and Supplementary Data.**

The information required by this item is contained under the section of the information statement entitled “Index to Combined Financial Statements” and in the financial statements referenced therein. That section is incorporated herein by reference.

**Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 15. Financial Statements and Exhibits.**

(a) Financial Statements. The information required by this item is contained under the section of the information statement entitled “Index to Combined Financial Statements” and in the financial statements referenced therein. That section is incorporated herein by reference.

(b) Exhibits. The following documents are filed as exhibits hereto:

<b>Exhibit Number</b>	<b>Exhibit Description</b>
2.1*	Form of Separation Agreement by and between Alkermes plc and Mural Oncology plc
3.1*	Form of Amended and Restated Memorandum and Articles of Association of Mural Oncology plc
10.1*	Form of Transition Services Agreement by and between Alkermes, Inc. and Mural Oncology, Inc.
10.2*	Form of Transition Services Agreement by and between Mural Oncology, Inc. and Alkermes, Inc.
10.3*	Form of Tax Matters Agreement by and between Alkermes plc and Mural Oncology plc
10.4*	Form of Employee Matters Agreement by and between Alkermes plc and Mural Oncology plc
10.5*+	Form of Deed of Indemnification between Mural Oncology plc and individual directors, secretaries and officers
10.6*+	Form of Indemnification Agreement between Mural Oncology, Inc. and individual directors
10.7*+	Form of Indemnification Agreement between Mural Oncology, Inc. and individual officers
10.8*+	Form of Mural Oncology plc 2023 Stock Option and Incentive Plan, and forms of award certificates thereunder
10.9*+	Form of Mural Oncology, Inc. Employment Agreement with executive officers
99.1	Information Statement of Mural Oncology Limited, preliminary and subject to completion, dated August 1, 2023

\* To be filed by amendment.

+ Management contract or compensatory plan or arrangement.

**SIGNATURES**

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

MURAL ONCOLOGY LIMITED

By: \_\_\_\_\_  
Name:  
Title:

Date: \_\_\_\_\_, 2023

**Information contained herein is subject to completion or amendment. A Registration Statement on Form 10 relating to these securities has been filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.**

**Exhibit 99.1**

**PRELIMINARY AND SUBJECT TO COMPLETION, DATED AUGUST 1, 2023**

## **INFORMATION STATEMENT**

# **MURAL ONCOLOGY LIMITED**

This information statement is being furnished to you as a holder of ordinary shares of Alkermes plc (“Alkermes”), in connection with the distribution of ordinary shares of Mural Oncology Limited (“Mural”), to Alkermes shareholders. Following the separation and distribution, as each are described in this information statement, Mural will hold, directly or indirectly, certain assets and liabilities related to Alkermes’ oncology business.

You will receive \_\_\_\_\_ ordinary shares of Mural for every \_\_\_\_\_ ordinary shares of Alkermes that you own as of the close of business on \_\_\_\_\_, 2023, the record date for the distribution, and will receive cash in lieu of any fractional ordinary shares of Alkermes that you would have received after application of the above ratio. As discussed under the section of this information statement entitled, “The Separation and Distribution—Trading Between the Record Date and Distribution Date,” if you sell your ordinary shares of Alkermes in the “regular way” market after the record date and before the distribution, you will also be selling your right to receive ordinary shares of Mural in connection with the distribution. Mural expects the ordinary shares of Mural to be distributed to you on \_\_\_\_\_, 2023. This date of distribution of the Mural ordinary shares is referred to in this information statement as the “distribution date.”

The distribution is intended to be tax-free to Alkermes shareholders for United States (“U.S.”) federal income tax purposes, except for cash received in lieu of fractional ordinary shares. Consummation of the distribution is subject to certain conditions, including the receipt of a private letter ruling from the Internal Revenue Service (the “IRS”) and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes’ board of directors and each continuing to be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended (the “Code”), except for cash received in lieu of fractional ordinary shares.

The separation and distribution is intended to be tax-free to Alkermes shareholders for Irish tax purposes, except for cash received in lieu of fractional ordinary shares.

No vote of Alkermes shareholders is required for the distribution. Therefore, you are not being asked for a proxy, and you are requested not to send Alkermes any proxy, in connection with the distribution. You do not need to pay any consideration, exchange or surrender your existing Alkermes ordinary shares or take any other action to receive your ordinary shares of Mural in the distribution.

There is no current trading market for Mural ordinary shares. Mural expects that a limited market, commonly known as a “when issued” trading market, will develop on or shortly before the record date for the distribution, and that “regular way” trading of Mural ordinary shares will begin on the first trading day following the completion of the distribution. Mural has applied for listing of its ordinary shares on the Nasdaq Global Market under the symbol “MURA”. No assurance can be given that Mural’s listing application will be approved. Consummation of the distribution is subject to the satisfaction of certain conditions, including that the Mural ordinary shares to be delivered to the Alkermes shareholders in the distribution be approved for listing on the Nasdaq Global Market, but such condition may be waived by Alkermes in its sole discretion.

Mural is an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As an emerging growth company, Mural will be subject to reduced public company reporting requirements.

**In reviewing this information statement, you should carefully consider the matters described under the caption “[Risk Factors](#)” beginning on page 21.**

**Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this information statement is truthful or complete. Any representation to the contrary is a criminal offense.**

This information statement does not constitute an offer to sell or the solicitation of an offer to buy any securities.

This document is not a prospectus within the meaning of section 1348 of the Companies Act 2014 of Ireland (as amended) or the EU Prospectus Regulation (Regulation (EU) 2017/1129) of the European Parliament and of the Council. No offer of securities of Mural to the public is made, or will be made, in connection with the distribution or the separation, that requires the publication of a prospectus pursuant to Irish prospectus law within the meaning of section 1348 of the Companies Act 2014 of Ireland in general, or in particular pursuant to the EU Prospectus Regulation. This document has not been reviewed or approved by the Central Bank of Ireland or any other competent authority in the European Economic Area for the purposes of the EU Prospectus Regulation. This document does not constitute investment advice or the provision of investment services within the meaning of the European Union (Markets in Financial Instruments) Regulations 2017 of Ireland (S.I. No. 375 of 2017) (as amended) or otherwise or the Markets in Financial Instruments Directive (2014/65/EU) or otherwise. Neither Alkermes nor Mural is an authorized investment firm within the meaning of the European Union (Markets in Financial Instruments) Regulations 2017 of Ireland (S.I. No. 375 of 2017) (as amended) or the Markets in Financial Instruments Directive (2014/65/EU) and the recipients of this document should seek independent legal and financial advice in determining their actions in respect of, or pursuant to this document.

**This information statement is first being mailed to Alkermes shareholders on or about \_\_\_\_\_, 2023.**

**The date of this information statement is \_\_\_\_\_, 2023.**

**TABLE OF CONTENTS**

<a href="#">PRESENTATION OF INFORMATION</a>	1
<a href="#">QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION</a>	3
<a href="#">INFORMATION STATEMENT SUMMARY</a>	11
<a href="#">SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION</a>	20
<a href="#">RISK FACTORS</a>	21
<a href="#">CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS</a>	84
<a href="#">DIVIDEND POLICY</a>	86
<a href="#">CAPITALIZATION</a>	87
<a href="#">UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS</a>	88
<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a>	93
<a href="#">BUSINESS</a>	105
<a href="#">MANAGEMENT</a>	157
<a href="#">EXECUTIVE COMPENSATION</a>	162
<a href="#">CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS</a>	165
<a href="#">SECURITY OWNERSHIP BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</a>	169
<a href="#">THE SEPARATION AND DISTRIBUTION</a>	170
<a href="#">MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES</a>	176
<a href="#">MATERIAL IRISH TAX CONSEQUENCES</a>	185
<a href="#">DESCRIPTION OF MURAL'S SHARE CAPITAL</a>	189
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	202
<a href="#">INDEX TO COMBINED FINANCIAL STATEMENTS</a>	F-1



## PRESENTATION OF INFORMATION

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement about Mural assumes the completion of all of the transactions referred to in this information statement in connection with the separation and distribution.

Unless the context otherwise requires, references in this information statement to the following terms shall have the following respective meanings:

- “Alkermes” refers to Alkermes plc, an Irish public limited company, and its consolidated subsidiaries;
- “distribution” refers to the distribution of ordinary shares by Alkermes to Alkermes’ shareholders of record as of the record date that will be satisfied by Mural’s issuance of its ordinary shares to the persons entitled to receive the distribution, as further described in this information statement;
- “Mural,” “we,” “us,” “our,” “our company” and “the company” refer to (i) Mural Oncology Limited, an Irish limited company, together with its subsidiaries, as the context requires, prior to the re-registration of Mural Oncology Limited as a public limited company, and (ii) Mural Oncology Public Limited Company, an Irish public limited company, together with its subsidiaries, as the context requires, after the re-registration of Mural Oncology Limited as a public limited company, in each case as they will exist, assuming the completion of all the transactions referred to in this information statement in connection with the separation;
- “neuroscience business” refers to Alkermes’ neuroscience business;
- “oncology business” refers to Alkermes’ oncology business as it was historically managed as part of Alkermes prior to the completion of the separation;
- “product candidates” refers to our current and future product candidates; and
- “separation” refers to the planned separation of Alkermes’ oncology business from Alkermes’ neuroscience business and the creation, as a result of the distribution, of an independent, publicly traded company, Mural, which will hold the assets and liabilities associated with the oncology business, as further described in this information statement.

This information statement describes the business to be transferred to Mural by Alkermes in the separation as if the transferred business was Mural’s business for all historical periods described. References in this information statement to Mural’s historical assets, liabilities, products, business or activities of Mural’s business are generally intended to refer to the historical assets, liabilities, products, business or activities of the transferred business as such business was conducted as part of Alkermes prior to the separation.

You should not assume that the information contained in this information statement is accurate as of any date other than the date set forth on the cover. Changes to the information contained in this information statement may occur after that date, and we undertake no obligation to update the information, except in the normal course of our public disclosure obligations or as required by applicable law.

Websites described in this information statement and the content therein or connected thereto shall not be deemed incorporated into this information statement.

### Trademarks, Trade Names and Service Marks

Mural owns or has rights to use the trademarks, service marks and trade names that it uses in conjunction with the operation of its business, including \_\_\_\_\_, which may be registered or trademarked in the U.S. and other jurisdictions. Mural’s rights to its trademarks may be limited to select markets. Each trademark, trade name or service mark of any other company appearing in this information statement is, to Mural’s knowledge, owned by such other company.

## **Industry and Other Data**

We obtained the industry and market data in this information statement from our own internal estimates and from industry and general publications and research, surveys, studies and trials conducted by third parties. We believe that this third-party data is generally reliable; however, we have not independently verified data from third-party sources. In addition, while we believe our estimates are reliable, they have not been verified by any independent sources.

Estimates in this information statement of the patient populations for the diseases that we are targeting are based on published estimates of the rates of incidence of the diseases from scientific and general publications and research, surveys and studies conducted by third parties that we consider to be reliable, although such publications do not guarantee the accuracy or completeness of such information.

## QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION

***What is Mural and why is Alkermes separating Mural's business and distributing Mural's ordinary shares?***

Mural is an Irish incorporated limited company established in May 2017 as a shelf company and was recently de-shelved to hold Alkermes' oncology business in connection with the separation. Prior to the separation, the oncology business was held and conducted within Alkermes. The separation of Mural from Alkermes and the distribution of Mural ordinary shares to Alkermes shareholders are intended to provide you with equity investments in two separate, independent public companies, each of which will be able to focus on its respective business strategies. Alkermes and Mural believe the separation will enable each company to pursue focused growth and investment strategies in its respective therapeutic areas of expertise, with the goal of enhancing the long-term performance potential of each business, as discussed in "The Separation and Distribution—Overview" and "The Separation and Distribution—Reasons for the Separation."

***Why am I receiving this document?***

Alkermes is delivering this information statement to you because you are a holder of Alkermes ordinary shares. If you remain a holder of Alkermes ordinary shares as of the close of business on \_\_\_\_\_, 2023, you will be entitled to receive \_\_\_\_\_ ordinary shares of Mural for every \_\_\_\_\_ ordinary shares of Alkermes that you held of record at the close of business on such date. This information statement will help you understand how the separation will affect your investment in Alkermes and your investment in Mural after the distribution.

***How will the separation of Mural from Alkermes work?***

Currently, all of Mural's issued shares are held legally and beneficially by an Irish corporate services provider (which is not a subsidiary of Alkermes). Prior to the transfer by Alkermes to Mural of the oncology business, which will occur prior to the distribution, Mural will have no business operations. Alkermes will transfer its oncology business to Mural in return for which we will issue Mural ordinary shares to Alkermes shareholders, pro rata to their respective holdings in Alkermes. For the purposes of Irish law, this will be treated as Alkermes having made a dividend in specie, or a non-cash dividend, to its shareholders. In connection with these transactions, we will acquire by surrender all shares of Mural currently held by the Irish corporate services provider referred to above for no consideration, following which we will cancel all such shares. Immediately following the distribution, the persons entitled to receive Mural ordinary shares

***Why is the separation of Mural structured as a distribution?***

in the distribution will own all of the outstanding Mural ordinary shares. See “The Separation and Distribution—The Number of Mural Ordinary Shares You Will Receive” for more information.

***What is the record date for the distribution?***

Alkermes believes that a distribution of ordinary shares of Mural to the Alkermes shareholders that is tax-free for U.S. federal income tax and Irish tax purposes is an efficient way to separate its oncology business in a manner that is expected to create long-term value for Alkermes, Mural and their respective shareholders. For more information, see “The Separation and Distribution—Conditions to the Distribution.”

***When will the distribution occur?***

The record date for the distribution will be \_\_\_\_\_, 2023.

It is expected that the ordinary shares of Mural will be distributed on \_\_\_\_\_, 2023, to holders of record of Alkermes ordinary shares at the close of business on \_\_\_\_\_, 2023. We refer in this information statement to the date on which ordinary shares of Mural are distributed as the “distribution date.” However, the completion and timing of the distribution are dependent upon a number of conditions and no assurance can be provided as to the timing of the distribution or that all conditions to the distribution will be met (or otherwise waived by Alkermes) in order for the distribution to occur.

***What do Alkermes shareholders need to do to participate in the distribution?***

Nothing. **Shareholders of Alkermes as of the record date will not be required to take any action to receive Mural ordinary shares in connection with the distribution, but are urged to read this entire information statement carefully.** No approval of the distribution by Alkermes’ shareholders is required or sought. **Therefore, you are not being asked for a proxy to vote on the distribution, and you are requested not to send Alkermes any proxy.** You will neither be required to pay anything for the Mural ordinary shares nor be required to surrender any Alkermes ordinary shares in order to participate in the distribution.

***How will Mural ordinary shares be distributed in the distribution?***

The distribution will not affect the number of Alkermes ordinary shares outstanding or any rights of Alkermes shareholders, although it may affect the market value of each outstanding Alkermes ordinary share. See “Questions and Answers about the Separation and Distribution—Will the distribution affect the market price of my Alkermes ordinary shares?” for more information.

**Shareholders of Record:** If you are a shareholder of record (meaning your Alkermes ordinary shares are registered in your name (and not in the name of a bank, broker or other nominee) with Alkermes’ transfer agent, Computershare Trust Company, N.A. (“Computershare”), then the distribution

agent, \_\_\_\_\_, will credit the number of whole ordinary shares of Mural you receive in the distribution to your book-entry account on or shortly after the distribution date, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive.

*“Street name” or Beneficial Owners:* If you own Alkermes ordinary shares beneficially through a bank, broker or other nominee, your bank, broker or other nominee will credit your account with the number of Mural whole ordinary shares you receive in the distribution on or shortly after the distribution date. Please contact your bank, broker or other nominee for further information about your account. We will not issue any physical share certificates to any shareholders receiving Mural ordinary shares in the distribution, even if requested. See “The Separation and Distribution—When and How You Will Receive the Distribution” for more information.

***How many Mural ordinary shares will I receive in the distribution and how many are expected to be distributed in total?***

You will receive \_\_\_\_\_ Mural ordinary shares for every Alkermes ordinary shares you hold as of the close of business on \_\_\_\_\_, 2023, the record date. Based on approximately Alkermes ordinary shares outstanding as of \_\_\_\_\_, 2023, a total of approximately \_\_\_\_\_ Mural ordinary shares will be distributed. For more information, see “The Separation and Distribution—The Number of Mural Ordinary Shares You Will Receive.”

***Will Mural issue fractional ordinary shares in the distribution?***

Mural will not issue fractional ordinary shares in the distribution. Instead, all fractional ordinary shares that Alkermes shareholders would otherwise have been entitled to receive will be aggregated into whole shares and sold in the open market by the distribution agent. We expect the distribution agent to take about \_\_\_\_\_ after the distribution date to fully distribute the aggregate net cash proceeds of these sales on a pro rata basis (based on the fractional share such holder would otherwise be entitled to receive) to those Alkermes shareholders who would otherwise have been entitled to receive fractional ordinary shares. Recipients of cash in lieu of fractional ordinary shares will not be entitled to any interest on the amounts of payment made in lieu of fractional ordinary shares. For more information, see “The Separation and Distribution—The Number of Mural Ordinary Shares You Will Receive.”

***What are the conditions to the distribution?***

The distribution is subject to the satisfaction (or waiver by Alkermes in its sole discretion) of a number of conditions to be set forth in the separation agreement, including, among others, that Alkermes will have received a private letter ruling from the Internal Revenue Service (“IRS”) and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes’ board of directors and each continuing to

be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended (the “Code”), except for cash received in lieu of fractional ordinary shares, that the internal restructuring transactions and transfers of assets and liabilities to Mural contemplated by the separation agreement to be completed prior to the distribution shall have been completed, and that the Mural ordinary shares to be delivered to the Alkermes shareholders in the distribution be approved for listing on the Nasdaq Global Market, subject to official notice of issuance. For more information, see “The Separation and Distribution—Conditions to the Distribution.”

Alkermes and Mural cannot assure you that any or all of these conditions will be met, and Alkermes may waive any of these conditions to the distribution. In addition, Alkermes can determine, at any time, not to proceed with the distribution. If Alkermes were to waive certain conditions to the distribution that are not required to be satisfied by applicable law, such waiver may have an adverse effect on Alkermes and Mural and their respective shareholders. See “Risk Factors—Risks Related to the Separation and Distribution—The Distribution is subject to conditions, including certain conditions that may be waived.”

***Can Alkermes decide to cancel the distribution of Mural ordinary shares even if all of the conditions have been met?***

Yes, until the distribution has occurred, Alkermes has the right to terminate the distribution, even if all of the conditions are satisfied, if at any time the board of directors of Alkermes determines that the distribution is not in the best interests of Alkermes, that another strategic alternative is in the best interests of Alkermes or that it is not advisable at that time to separate the oncology business from Alkermes’ neuroscience business. See “The Separation and Distribution—Conditions to the Distribution” for more information.

***What if I want to sell my Alkermes ordinary shares or my Mural ordinary shares?***

You should consult with your advisors, such as your broker, bank or tax advisors.

***What is “regular way” and “ex-distribution” trading of Alkermes ordinary shares?***

Beginning on or shortly before the record date and continuing up to and including the distribution date, it is expected that there will be two markets in ordinary shares of Alkermes: a “regular way” market and an “ex-distribution” market. Alkermes ordinary shares that trade in the “regular way” market will trade with an entitlement to Mural ordinary shares distributed pursuant to the distribution. Shares that trade in the “ex-distribution” market will trade without an entitlement to Mural ordinary shares distributed pursuant to the distribution. If you hold Alkermes ordinary shares on the record date and you decide to

***Where will I be able to trade Mural ordinary shares?***

sell any Alkermes ordinary shares before the distribution date, you should make sure your broker, bank or other nominee understands whether you want to sell your Alkermes ordinary shares with or without your entitlement to receive Mural ordinary shares pursuant to the distribution. See “The Separation and Distribution—Trading Between the Record Date and Distribution Date” for more information.

Currently, there is no public market for Mural ordinary shares. Mural has applied to have its ordinary shares authorized for listing on the Nasdaq Global Market under the symbol “MURA.” No assurance can be given that Mural’s listing application will be approved. Additionally, consummation of the distribution is subject to the satisfaction of certain conditions, including that the Mural ordinary shares to be delivered to the Alkermes shareholders in the distribution be approved for listing on the Nasdaq Global Market, but such condition may be waived by Alkermes in its sole discretion.

Mural anticipates that trading in its ordinary shares will begin on a “when issued” basis on or shortly before the record date for the distribution and will continue up to and including the distribution date. “When issued” trading in the context of the separation refers to a sale or purchase made conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. “When issued” trades generally settle within two weeks after the distribution date. On the first trading day following the distribution date, any “when issued” trading of our ordinary shares will end and “regular way” trading will begin. “Regular way” trading in respect of the securities of the separated entity refers to trading after the security has been distributed and typically involves a trade that settles on the second full trading day following the date of the trade. See “The Separation and Distribution—Trading Between the Record Date and Distribution Date” for more information. We cannot predict the trading prices for our ordinary shares before, on or after the distribution date.

***What will happen to the listing of Alkermes ordinary shares?***

Alkermes’ ordinary shares will continue to trade on the Nasdaq Global Select Market after the distribution.

***Will the number of Alkermes ordinary shares that I own change as a result of the distribution?***

No. The number of Alkermes ordinary shares that you own will not change as a result of the distribution.

***Will the distribution affect the market price of my Alkermes ordinary shares?***

Yes. As a result of the distribution, the trading price of Alkermes ordinary shares immediately following the distribution may be lower than the “regular way” trading price of such shares immediately prior to the distribution because the trading price will no longer reflect the value of the oncology business. Furthermore, as the market assesses Alkermes

***What are the material U.S. federal income tax consequences of the distribution?***

following the separation, the trading price of Alkermes ordinary shares may fluctuate. There can be no assurance that, following the distribution, the combined trading prices of Alkermes ordinary shares and Mural ordinary shares will equal or exceed what the trading price of Alkermes ordinary shares would have been in the absence of the separation and distribution, and it is possible that the post-distribution combined equity value of Alkermes and Mural will be less than Alkermes' equity value prior to the separation and distribution.

It is a condition to the distribution that Alkermes receives a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes' board of directors and each continuing to be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. If, as is expected and in accordance with the private letter ruling and opinion described above, the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, so qualify as a transaction that is tax-free under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, subject to the discussion below regarding cash in lieu of fractional ordinary shares, no gain or loss will be recognized by you and no amount will be included in your income upon receipt of Mural ordinary shares pursuant to the distribution. You will, however, recognize a gain or loss for U.S. federal income tax purposes with respect to cash received in lieu of a fractional ordinary share of Mural. You should consult your tax advisor as to the particular consequences of the distribution to you, including the applicability and effect of any U.S. federal, state and local tax laws, as well as non-U.S. tax laws. For more information regarding the material U.S. federal income tax consequences of the distribution, see "Material U.S. Federal Income Tax Consequences."

***How will I determine my tax basis for U.S. federal income tax purposes in the Mural ordinary shares I receive in the distribution?***

For U.S. federal income tax purposes, generally, your aggregate basis in the ordinary shares that you hold in Alkermes and the new Mural ordinary shares received in the distribution (including any fractional interest in Mural ordinary shares for which cash is received) will equal the aggregate basis in the Alkermes ordinary shares held by you immediately before the distribution, allocated between your Alkermes ordinary shares and Mural ordinary shares (including any fractional interest in Mural ordinary shares for which cash is received) you receive in the distribution in proportion to the relative fair market value of each on the distribution date. You should



***How will I determine my tax basis for Irish tax purposes?***

consult your tax advisor as to the particular consequences of the distribution to you, including the application of the tax basis allocation rules and the application of state, local and non-U.S. tax laws. For more information regarding the material U.S. federal income tax consequences of the distribution, see “Material U.S. Federal Income Tax Consequences.”

For Irish tax purposes, Alkermes shareholders will be treated as having acquired their shares in Mural at the same time and for the appropriate portion of the original base cost as they acquired their original shares in Alkermes.

You should consult your tax advisor as to the particular consequences of the separation and distribution to you, including the application of the tax basis allocation rules and the application of Irish tax law. For more information regarding the material Irish tax consequences of the distribution, see “Material Irish Tax Consequences.”

***What are the material Irish tax consequences of the separation and distribution?***

The separation and distribution will not give rise to Irish taxes for Alkermes shareholders (except with respect to any cash received in lieu of fractional shares of Mural ordinary shares). Irish stamp duty may, depending on the manner in which the Mural ordinary shares are held, be payable in respect of transfers of Mural ordinary shares after the distribution. You should consult your tax advisor as to the particular tax consequences to you. For more information regarding the material Irish tax consequences of the separation and distribution, see “Material Irish Tax Consequences.”

***What will Mural’s relationship be with Alkermes following the separation?***

To effect a decisive and efficient separation into two separate companies, Mural intends to enter into a separation agreement with Alkermes. Additionally, Mural and Alkermes, or their respective subsidiaries, also intend to enter into various other agreements, including a transition services agreement under which we will temporarily receive certain services from Alkermes, a second transition services agreement under which we will temporarily provide certain services to Alkermes, a tax matters agreement and an employee matters agreement. These agreements will effectuate the separation and distribution and will provide for the allocation between Alkermes and Mural, or their respective subsidiaries, of Alkermes’ assets, employees, liabilities and obligations (including employee benefits, intellectual property and tax-related assets and liabilities) attributable to periods prior to, at and after Mural’s separation from Alkermes. These agreements will also govern certain relationships between Alkermes and Mural, or their respective subsidiaries, after the separation. For additional information regarding the separation agreement and other transaction agreements, see “Risk Factors—Risks Related to the Separation and Distribution” and “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes.”

## Table of Contents

### ***Who will manage Mural after the separation?***

Mural's management team is expected to include Dr. Caroline Loew, who will serve as Mural's chief executive officer after the separation. Mural is in the process of identifying other individuals who will serve on its management team following the separation and will update this information statement to include information about such individuals in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part. For more information regarding our expected management team and leadership structure, see "Management."

### ***Are there risks associated with owning Mural ordinary shares?***

Yes. Ownership of Mural ordinary shares is subject to both general and specific risks related to Mural's business, the industry in which it operates, its ongoing relationships with Alkermes and its status as a new, independent, publicly traded company. Ownership of Mural ordinary shares is also subject to risks related to the separation. These risks are described in the "Risk Factors" section of this information statement beginning on page 21. You are encouraged to read that section carefully.

### ***Does Mural plan to pay dividends?***

Mural does not expect to pay a regular cash dividend following the separation and distribution. The payment of any dividends in the future, and the timing and amount thereof, is within the discretion of Mural's board of directors. See "Dividend Policy."

### ***Who will be the distribution agent, transfer agent and registrar for the Mural ordinary shares?***

The distribution agent, transfer agent and registrar for Mural ordinary shares will be . Alkermes shareholders who have questions relating to the transfer or mechanics of the distribution should contact:

Address:

Tel:

E-mail:

### ***How can I contact Alkermes or Mural with any questions?***

Before the distribution, if you have any questions relating to Alkermes or Mural or the transactions described herein, you should contact:

Alkermes plc

Investor Relations

E-mail: [investor\\_relations@alkermes.com](mailto:investor_relations@alkermes.com)

After the distribution, Mural shareholders who have any questions relating to Mural or its business should contact Mural at:

Mural Oncology Limited

Address:

Tel:

E-mail:

## INFORMATION STATEMENT SUMMARY

The following is a summary of material information discussed in this information statement. This summary may not contain all the details concerning the separation and distribution or other information that may be important to you. To better understand the separation and distribution and Mural’s business and financial position, you should carefully review this entire information statement, including the risks discussed under “Risk Factors.”

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement assumes the completion of all of the transactions referred to in this information statement in connection with the separation. Some of the statements in this summary constitute forward-looking statements. See “Cautionary Statement Concerning Forward-Looking Statements” below in this information statement.




### 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 novel, investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers. Our lead product candidate, nemvaleukin alfa (“nemvaleukin”), is an investigational, engineered interleukin-2 (“IL-2”) cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human IL-2 (“rhIL-2”), while mitigating its hallmark toxicities. In our clinical proof of concept study, nemvaleukin generated durable responses as a single agent and in combination with pembrolizumab across a range of tumor types. Nemvaleukin is currently in two potentially registrational studies, one for the treatment of mucosal melanoma as a monotherapy and one for the treatment of platinum-resistant ovarian cancer (“PROC”) in combination with pembrolizumab. We plan to report topline results in mucosal melanoma and interim results in PROC in . In addition to nemvaleukin, we are also developing engineered therapies targeting the interleukin-18 (“IL-18”) and interleukin-12 (“IL-12”) pathways, which have demonstrated therapeutic potential in third-party preclinical and clinical studies. We are currently conducting discovery-phase activities for our IL-18 and IL-12 programs, and we plan to nominate a product candidate in each program in 2024.

### Our Programs

We are developing a portfolio of immunotherapies currently focused on proinflammatory cytokines that leverages our significant immune cell modulation expertise and protein engineering capabilities. When developing product candidates, we apply a consistent analytical framework to focus on targets with sound biologic rationale and what we believe to be a surmountable technical challenge (e.g., overexpansion of regulatory T cells (“T<sub>regs</sub>”)) that has limited the mechanism to date. Once a target is identified, we apply our protein engineering capabilities to design a molecule that we believe can address the technical challenge. Our multi-faceted approach to cytokine engineering is aimed at maximizing the utility of identified cytokines and includes binding selectivity, tumor-targeting, half-life modification and *in-vivo* assembly. As shown in the figure below, our approach has yielded three distinct investigational immuno-oncology programs, each based on unique design approaches that we believe are potentially best suited for each cytokine:

#### Multi-Faceted Immuno-Oncology Approach to Molecular Design Grounded in Strong Scientific Rationale

	 Nemvaleukin alfa <sup>1</sup> (IL-2)	 Engineered IL-18	 Tumor-targeted split IL-12
<b>Technical challenge</b>	<ul style="list-style-type: none"> <li>Systemic toxicities due to overexpansion of T<sub>regs</sub> related to high-affinity IL-2R binding</li> </ul>	<ul style="list-style-type: none"> <li>Limited clinical efficacy due to IL-18Rβ tightly binding to IL-18, neutralizing IL-18 receptor activation</li> </ul>	<ul style="list-style-type: none"> <li>Limited rhIL-12 clinical utility due to severe toxicities where tolerable systemic dosing regimens are not efficacious</li> </ul>
<b>Protein engineering solution</b>	<ul style="list-style-type: none"> <li>Fusion of circularly permuted IL-2 with the IL-2Rα subunit resulting in only activating intermediate-affinity IL-2R</li> </ul>	<ul style="list-style-type: none"> <li>Engineered IL-18 designed with a half-life extension and to be resistant to IL-18Rβ neutralization, while retaining and optimizing the activity of IL-18</li> </ul>	<ul style="list-style-type: none"> <li>Separate inactive tumor-targeted IL-12 subunits assemble and activate in the tumor</li> </ul>

1. Intrinsically active stable, not degraded fusion protein, sterically occluded from binding to the high-affinity IL-2R

### *Nemvaleukin Alfa*

We used our protein engineering approach to design the molecular structure of nemvaleukin, our lead product candidate. Nemvaleukin is engineered to selectively bind to the intermediate-affinity IL-2 receptor complex and preferentially expand tumor-killing immune cells, such as CD8+ T cells and natural killer cells, with minimal expansion of immunosuppressive T<sub>regs</sub>. Nemvaleukin is an intrinsically active, stable fusion protein and, once administered, does not degrade to unmodified IL-2, which we believe contributes to its potential for enhanced tolerability.

*Objective Criteria to Assess Change in Tumor Burden.* We assessed clinical response in ARTISTRY-1, our Phase 1/2 clinical proof of concept study for nemvaleukin, using the Response Evaluation Criteria in Solid Tumors guidelines version 1.1 (“RECIST 1.1”), which are widely accepted, published criteria for assessing tumor burden and disease progression in oncology clinical trials. Under RECIST 1.1, (a) a partial response (“PR”) requires at least a 30% decrease in the sum of diameters of target lesions compared to the baseline sum diameters, (b) progressive disease (“PD”), requires at least a 20% increase in the sum of diameters of target lesions, (c) stable disease (“SD”) is defined as neither sufficient lesion shrinkage to qualify as a PR nor sufficient lesion increase to qualify as PD, and (d) a complete response (“CR”) means the disappearance of all target lesions and reduction in short axis of any pathological lymph nodes to <10mm.

Objective response rate (“ORR”) often used in oncology clinical trials, is the percentage of evaluable patients who had a CR or PR, and disease control rate (“DCR”) is the percentage of evaluable patients who had a CR, PR, or SD.

*ARTISTRY-1 Clinical Trial.* ARTISTRY-1, our Phase 1/2 clinical proof of concept study for nemvaleukin in which nemvaleukin is administered intravenously, was designed to assess whether nemvaleukin could recapitulate the anti-tumor activity of high-dose rhIL-2 and to assess nemvaleukin’s safety profile. ARTISTRY-1 is a global, multicenter, open-label study with three parts: Part A (dose-escalation monotherapy, 46 subjects), Part B (dose-expansion monotherapy, 47 subjects with melanoma and 27 subjects with renal cell carcinoma (“RCC”)), and Part C (combination therapy with pembrolizumab, 166 subjects including 43 subjects rolled over from Part A or Part B). The primary endpoints are the incidence of dose limiting toxicities (Part A), the incidence and severity of treatment-emergent adverse events (Parts A, B, and C), and the ORR based on RECIST 1.1 as described above (Parts B and C). As ARTISTRY-1 was not designed to generate treatment comparisons, these endpoints are summarized descriptively.

We have observed objective responses with nemvaleukin as monotherapy in cancers for which high-dose rhIL-2 obtained regulatory approval, such as melanoma and RCC. In ARTISTRY-1, among six evaluable mucosal melanoma patients as of October 3, 2022, we observed two PRs (one confirmed, which means it meets the RECIST 1.1 criteria for a PR in two consecutive scans) and two patients with SD, representing an ORR of 33% and an overall DCR of 67%.

Nemvaleukin in combination with pembrolizumab has shown, in some patients, durable and deepening responses in a range of tumor types. In ARTISTRY-1, among 14 evaluable patients with PROC as of October 3, 2022, treatment with nemvaleukin in combination with pembrolizumab resulted in two CRs and two PRs (one confirmed), with a median duration of response of 50.3 weeks, and six patients with SD, representing an ORR of 29% and an overall DCR of 71%. In addition to these responses in PROC, we also observed objective responses, or patients with PRs or CRs, in breast, bladder, cervical, gastrointestinal, head & neck, lung, melanoma, and renal cell cancers when nemvaleukin was administered in combination with pembrolizumab. ARTISTRY-1 is an ongoing study, and all data is provided as of the dates noted herein and is subject to final validation upon database lock.

*ARTISTRY-6 and ARTISTRY-7 Clinical Trials.* In addition, we are currently evaluating nemvaleukin in two potentially registrational studies: ARTISTRY-6, a Phase 2 study in which Cohort 2 is evaluating nemvaleukin as a monotherapy in patients with advanced mucosal melanoma, and ARTISTRY-7, a Phase 3 study which is evaluating nemvaleukin in combination with pembrolizumab in patients with PROC. The U.S. Food and Drug

Administration (“FDA”) has granted Orphan Drug designation to nemvaleukin for the treatment of mucosal melanoma. The FDA also has granted Fast Track designation to nemvaleukin for the treatment of mucosal melanoma and to nemvaleukin in combination with pembrolizumab for the treatment of PROC.

We plan to report top-line results in mucosal melanoma and interim results in PROC in . If the data from one or both of these potentially registrational clinical studies are positive and we, in consultation with the FDA, determine that the results of either or both of these studies are sufficient to support the filing of a Biologics License Application (“BLA”) for nemvaleukin, we plan to submit one or more BLAs to the FDA to obtain approval to market nemvaleukin in the United States. Subsequently, we may pursue similar marketing authorizations in other jurisdictions.

Our clinical-stage pipeline showing the current status of nemvaleukin development across multiple potential indications is shown in the figure below.

**Clinical-Stage Pipeline Overview**



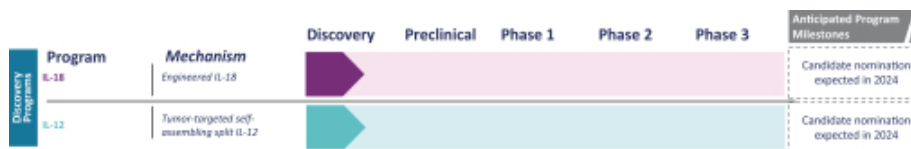
1. Subject to patient enrollment
2. Pending identification of the recommended Phase 2 dose for the less frequent IV (“LFV”) dosing regimen currently being evaluated in ARTISTRY-3

To explore nemvaleukin’s potential broad utility and ability to offer more flexible and convenient options to patients, caregivers, and providers, we are also evaluating subcutaneous dosing and alternative intravenous dosing frequencies in a variety of studies.

*Our IL-18 and IL-12 Programs*

We are also developing engineered IL-18 and IL-12 cytokines, which are currently in the discovery phase. We expect to nominate a product candidate in each program in 2024. For each cytokine pathway, we have developed what we believe is an innovative protein engineering solution designed to address the therapeutic limitations of the native molecules. For IL-18, we are engineering variants that are resistant to the naturally-occurring IL-18 binding protein (“IL-18BP”) with an aim to enhance pharmacokinetic properties, including half-life extension and IL-18 signaling activity. For IL-12, we are developing a tumor-targeted IL-12 molecule that is delivered in the form of inactive subunits that assemble and activate within the tumor, potentially avoiding toxicities associated with systemic exposure.

Discovery Programs



### ***Our Strategy***

Our goal is to discover and develop immunotherapies that may help meaningfully improve the lives of patients with a variety of cancers. Leveraging our immune cell modulation expertise and protein engineering capabilities, we aim to discover, develop and ultimately commercialize, immunotherapies designed to address serious unmet patient needs. Key elements of our strategy include:

- Progress nemvaleukin from clinical development to commercialization, as monotherapy for the treatment of mucosal melanoma and in combination with pembrolizumab for the treatment of PROC.
- Expand nemvaleukin's development into additional tumor types for which scientific rationale supports nemvaleukin's therapeutic potential.
- Explore the next generation of dosing for nemvaleukin.
- Advance our IL-18 and IL-12 programs into clinical development.
- Continue to advance our sophisticated protein engineering capabilities through strategic investment.
- Establish an integrated development and commercial capability.

### **Summary of Risk Factors**

*An investment in Mural ordinary shares is subject to a number of risks, including risks related to our financial position and capital needs, risks related to the separation and distribution and risks related to our ordinary shares. The following list of risk factors is not exhaustive. Please read the information in the section captioned "Risk Factors" for a more thorough description of these and other risks.*

#### ***Risks Related to Our Business***

- Because we have no operating history, valuing our business and predicting our prospects is challenging.
- 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.
- Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future. We have never recognized revenue from product sales and may never be profitable.
- We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.
- Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.
- 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.
- The regulatory approval process for our product candidates will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

- Manufacturing of biological products is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates.
- Unfavorable global economic or political conditions could adversely affect our business, financial condition, or results of operations.

***Risks Related to the Separation and Distribution***

- We may not achieve some or all of the expected benefits of the separation, which may not be completed on the timeline currently contemplated or at all.
- We have no history of operating as a standalone company and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical and pro forma combined financial information included in this information statement is not necessarily representative of the results that we would have achieved and may achieve as a separate, publicly traded company and should not be relied upon as an indicator of our future results.
- The separation may result in disruptions to, and harm our relationships with, our strategic business partners.
- Our agreements with Alkermes may not reflect terms that would have resulted from negotiations with unaffiliated third parties.
- The combined post-separation value of Alkermes' ordinary shares and our ordinary shares may not equal or exceed the pre-separation value of Alkermes ordinary shares.
- Alkermes may fail to perform under various transaction agreements that will be 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.
- The separation may impede our ability to attract and retain key personnel, which could materially harm our business.
- After the distribution we will be an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors.
- 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 the company will be subject to the Irish Takeover Rules.
- The price of our ordinary shares could be subject to volatility related or unrelated to our operations.

***Risk Factors Related to Tax Matters***

- If the separation and distribution, in relevant part and together with certain related transactions, do not qualify as transactions that are tax-free for U.S. federal income tax purposes, certain U.S. subsidiaries

of Alkermes and Alkermes' shareholders could be subject to significant tax liabilities, and we could be required to indemnify Alkermes or its subsidiaries for material taxes pursuant to indemnification obligations under the tax matters agreement.

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

### **The Separation and Distribution**

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore separation of its neuroscience business and oncology business. Alkermes intends to effect the separation through the distribution of the ordinary shares of Mural to Alkermes' shareholders. The distribution is intended to be tax-free for U.S. federal income tax and Irish tax purposes to Alkermes' shareholders. See "The Separation and Distribution—Conditions to the Distribution" and "Material Irish Tax Consequences" for more information.

On \_\_\_\_\_, 2023, Alkermes' board of directors approved the transfer of the oncology business to us in return for which we will issue Mural ordinary shares to Alkermes shareholders on the basis of \_\_\_\_\_ Mural ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares issued and outstanding on the record date, subject to the satisfaction (or waiver) of all conditions to the distribution.

Currently, all of Mural's issued shares are held legally and beneficially by an Irish corporate services provider (which is not a subsidiary of Alkermes). Immediately prior to the distribution, Alkermes will transfer the oncology business to us in return for which we will issue Mural ordinary shares to Alkermes shareholders, pro rata to their respective holdings in Alkermes. Prior to the transfer by Alkermes to us of the oncology business, we will have no business operations.

On \_\_\_\_\_, 2023, the expected distribution date, each person who held Alkermes ordinary shares at the close of business on \_\_\_\_\_, 2023, the record date for the distribution, will receive \_\_\_\_\_ Mural ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares held at the close of business on such date. You will receive cash in lieu of any fractional Mural ordinary shares which you would have received after the application of the above ratio. Immediately following the distribution, the persons entitled to receive Mural ordinary shares in the distribution will own all of the outstanding Mural ordinary shares. You will neither be required to pay anything for the Mural ordinary shares nor be required to surrender any Alkermes ordinary shares to participate in the distribution. In connection with these transactions, we will acquire by surrender all shares currently held by the Irish corporate services provider referred to above for no consideration, following which we will cancel such shares.

The distribution of Mural ordinary shares as described in this information statement is subject to the satisfaction or waiver by Alkermes of certain conditions. For a more detailed description of these conditions, see "The Separation and Distribution—Conditions to the Distribution."

Immediately following the distribution, we estimate that \_\_\_\_\_ Mural ordinary shares will be issued and outstanding based on the number of Alkermes ordinary shares outstanding as of \_\_\_\_\_, 2023. The actual number of Mural ordinary shares issued in the distribution will be determined on \_\_\_\_\_, 2023, the record date for the distribution.

Our ability to fund operations and capital needs will depend on funding from Alkermes that will be contributed to us or one of our subsidiaries immediately prior to or in connection with the separation to cover our capital needs following the separation and until we are able to access capital markets and/or other sources of capital. We believe that the contribution of approximately \$ \_\_\_\_\_ from Alkermes to Mural or one of our subsidiaries



immediately prior to or in connection with the separation will enable us to fund our operating expenses and capital expenditure requirements through . 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. For more information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

#### ***Mural’s Post-Separation Relationship with Alkermes***

Mural intends to enter into a separation agreement with Alkermes, which is referred to in this information statement as the “separation agreement.” Additionally, Mural and Alkermes, or their respective subsidiaries, also intend to enter into various other agreements, including a transition services agreement under which we will temporarily receive certain services from Alkermes, a second transition services agreement, under which we will temporarily provide certain services to Alkermes, a tax matters agreement and an employee matters agreement. These agreements will effectuate the separation and distribution and will provide for the allocation between Alkermes and Mural, or their respective subsidiaries, of Alkermes’ assets, employees, liabilities and obligations (including employee benefits, intellectual property, and tax-related assets and liabilities) attributable to periods prior to, at and after Mural’s separation from Alkermes. These agreements will also govern certain relationships between Alkermes and Mural, or their respective subsidiaries, after the separation. For additional information regarding the separation agreement and the other related agreements, see “Risk Factors—Risks Related to the Separation and Distribution” and “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes.”

#### ***Reasons for the Separation***

The Alkermes board of directors believes that separating its neuroscience business and oncology business is in the best interests of Alkermes and its shareholders for a number of reasons, including that the separation will:

- allow each business to pursue its own operational and strategic priorities and respond to trends, developments and opportunities in its respective markets;
- create two separate and distinct management teams focused on each business’ unique strategic priorities, target markets and corporate development opportunities;
- reduce competition for capital allocation between the neuroscience business and oncology business of revenues generated by Alkermes prior to the separation;
- create two independent companies that are expected to have well-capitalized financial structures and direct access to the debt and equity capital markets to fund each company’s respective growth strategy;
- increase flexibility for each business to pursue its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- enable the board and management team of each business to better align corporate goals with the specific vision, strategy, and objectives of their respective businesses and establish compensation programs designed to attract and retain skilled employees; and
- allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

The Alkermes board of directors considered a number of other factors in evaluating the separation, including risks relating to the creation of a standalone company and possible increased overall costs as well as one-time separation costs, but believes that the potential benefits of the separation outweigh these factors. For more information, see “The Separation and Distribution—Reasons for the Separation” and “Risk Factors” included elsewhere in this information statement.

### **Corporate Information**

Mural is an Irish incorporated limited company established in May 2017 as a shelf company and was recently de-shelved to hold Alkermes' oncology business in connection with the separation described in this information statement. Prior to completion of the separation and distribution, we intend to alter the legal status of Mural under Irish law to that of a public limited company by re-registering it as a public limited company and changing its name to Mural Oncology Public Limited Company. Prior to the separation, the oncology business was held and conducted within Alkermes. The contribution of the oncology business to Mural is expected to occur over a period of time prior to the distribution, and Mural will have no operations prior to such contribution. At the time of the distribution, the address of Mural's principal executive offices will be , . Mural's telephone number will be . Mural will also maintain a website at . Information found on, or accessible through, Mural's website is not incorporated into, and does not form a part of, this information statement.

### **Reason for Furnishing this Information Statement**

This information statement is being furnished solely to provide information to shareholders of Alkermes who will receive Mural ordinary shares in the distribution. It is not, and is not to be construed as, an inducement or encouragement to buy or sell any of Mural's securities.

This document is not a prospectus within the meaning of section 1348 of the Companies Act 2014 of Ireland (as amended) or the EU Prospectus Regulation (Regulation (EU) 2017/1129) of the European Parliament and of the Council. No offer of securities of Mural to the public is made, or will be made, in connection with the distribution or the separation, that requires the publication of a prospectus pursuant to Irish prospectus law within the meaning of section 1348 of the Companies Act 2014 of Ireland in general, or in particular pursuant to the EU Prospectus Regulation. This document has not been reviewed or approved by the Central Bank of Ireland or any other competent authority in the European Economic Area for the purposes of the EU Prospectus Regulation. This document does not constitute investment advice or the provision of investment services within the meaning of the European Union (Markets in Financial Instruments) Regulations 2017 of Ireland (S.I. No. 375 of 2017) (as amended) or otherwise or the Markets in Financial Instruments Directive (2014/65/EU) or otherwise. Neither Alkermes nor Mural is an authorized investment firm within the meaning of the European Union (Markets in Financial Instruments) Regulations 2017 of Ireland (S.I. No. 375 of 2017) (as amended) or the Markets in Financial Instruments Directive (2014/65/EU) and the recipients of this document should seek independent legal and financial advice in determining their actions in respect of, or pursuant to this document.

### **Implications of Being an Emerging Growth Company and Smaller Reporting Company**

Mural qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced disclosure and other obligations that are otherwise generally applicable to public companies. These may include the following:

- being permitted to present only two years of audited financial statements (as a result of our status as a smaller reporting company), in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- exemption from the requirements for holding a non-binding advisory vote on executive compensation or golden parachute arrangements;
- extended transition period for complying with new or revised accounting standards; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions for up to five years from the date of the distribution or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total gross annual revenues of \$1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the distribution; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the U.S. Securities and Exchange Commission. In addition, the JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of the exemption for the delayed adoption of certain accounting standards, and therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standards and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

## SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following tables present our summary historical and unaudited pro forma combined financial information. We derived the summary historical combined financial data as of and for the years ended December 31, 2022 and 2021 from our audited combined financial statements included elsewhere in this information statement.

The summary historical combined financial data includes certain expenses of Alkermes that were allocated to us for certain business and support functions that are provided on a centralized basis within Alkermes, including senior management, legal, human resources, accounting and finance, facilities, information technology and other corporate services. These historical allocations may not be indicative of our future cost structure and may not necessarily represent our financial position or results of operations had we operated as an independent, standalone public company during the periods or as of the dates presented. In addition, our historical financial information does not reflect changes that we expect to experience in the future as a result of our separation from Alkermes, including changes in our cost structure, personnel needs, tax structure, capital structure, financing and business operations.

The following unaudited pro forma combined statement of operations for the year ended December 31, 2022 gives effect to the separation as if it had occurred on January 1, 2022. The following unaudited pro forma combined balance sheet as of December 31, 2022 gives effect to the separation as if it had occurred on December 31, 2022. The unaudited pro forma adjustments are based on assumptions that management believes are reasonable under the circumstances and given the information available at this time. Refer to the notes to the unaudited pro forma combined financial statements included elsewhere in this information statement for a discussion of adjustments reflected in the unaudited pro forma combined financial statements. The financial information included here may not necessarily reflect our financial position, results of operations and cash flows in the future or what our financial position, results of operations and cash flows would have been had we been an independent, publicly traded company during the periods presented.

For a better understanding of the financial information included here, this section should be read in conjunction with the discussion in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the “Unaudited Pro Forma Combined Financial Statements” and corresponding notes, and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

(In thousands)	Year Ended December 31,		
	Pro Forma 2022	2022	2021
<b>Statement of Operations:</b>			
Research and development expenses		\$ 167,191	\$ 159,817
General and administrative expenses		17,732	15,548
Net loss		(189,807)	(175,433)

(In thousands)	As of December 31,		
	Pro Forma 2022	2022	2021
<b>Balance Sheet:</b>			
Total assets		\$33,750	\$35,110
Total current liabilities		41,560	33,247
Total liabilities		55,406	52,989

## RISK FACTORS

*You should consider carefully the following risks and uncertainties, together with all the other information in this information statement, including our 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 no operating history, valuing our business and predicting our prospects is challenging.***

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

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

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

- successfully complete our ongoing and planned preclinical and clinical studies;
- successfully initiate and complete clinical trials for nemvaleurin and other product candidates;
- successfully enroll subjects in, and complete, our ongoing clinical trials and any future clinical trials;

## [Table of Contents](#)

- initiate and/or successfully complete the safety and efficacy studies required to obtain United States (“U.S.”) and/or non-U.S. regulatory approvals for our product candidates;
- establish clinical and commercial manufacturing capabilities or make arrangements with third party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain regulatory approval for our product candidates;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims; and
- maintain an acceptable safety profile for our products following approval.

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

***Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future. We have never recognized revenue from product sales and may never be profitable.***

Our business has incurred operating losses due to costs incurred in connection with our research and development activities and general and administrative expenses associated with our operations and we have not yet generated any revenue for the oncology business or as a standalone company. If our product candidates are not successfully developed and approved, we may never generate any product revenue from product sales. Our net losses for the years ended December 31, 2022 and 2021 were \$189.8 million and \$175.4 million, respectively. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as our product candidates advance through clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities and incur additional costs associated with operating as a public company. If we obtain marketing and regulatory approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

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

Following the completion of the separation, we expect that our cash and cash equivalents will be \$                      million. Our management believes that our cash and cash equivalents at the time of the separation will be sufficient to fund our current operating plan through                      .

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 may need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. We may raise additional funds through public or private equity financings, debt financings, collaborative arrangements, licensing arrangements or other sources. Volatility in the financial markets due to unfavorable global economic conditions, including disruptions in the banking industry and inflationary pressures, has generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities by us, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back, or eliminate expenditures for some of our development programs, including restructuring our operations, refinancing or restructuring our debt, or granting rights to third parties to develop and market product candidates that we would otherwise prefer to internally develop and market. If we grant such rights, the ultimate value of these product candidates to us may be reduced. Regardless of the terms of any debt or equity financings we may enter into, our agreements and obligations under the tax matters agreement with Alkermes may limit our ability to issue ordinary shares to raise capital during the four-year period beginning two years before and ending two years after the distribution. See “—Risks Related to the Separation and Distribution.”

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we anticipate, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

***Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.***

Our recurring losses from operations incurred and financial condition raise substantial doubt about our ability to continue as a going concern. In our financial statements for the year ended December 31, 2022, we concluded that our recurring losses from operations incurred, expectation of continuing operating losses for the

foreseeable future, and the need to raise additional capital to finance our future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2022 with respect to this uncertainty. Our ability to fund operations and capital needs will depend on funding from Alkermes that will be contributed to us or one of our subsidiaries immediately prior to or in connection with the separation to cover our capital needs following the separation and until we are able to access capital markets and/or other sources of capital. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, limit, reduce or eliminate our product development or future commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. After the separation and distribution, in our own required quarterly assessments, we may again conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

In addition, certain restrictions under our tax matters agreement with Alkermes may limit, during a four-year period beginning two years before and ending two years after the distribution, our ability to pursue certain strategic transactions, equity issuances or repurchases or other transactions that we may believe to be in the best interests of our shareholders or that might increase the value of our business. For more information, see “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes—Tax Matters Agreement.”

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

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the “Federal Reserve”) and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve have announced a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

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



Although we expect to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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

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

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

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

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

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

Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. In some instances, significant variability in safety or efficacy appear in different clinical

## [Table of Contents](#)

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

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

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

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

- we may be unable to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to obtain regulatory authorizations to commence a clinical trial;
- the FDA, EMA or comparable other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial or prior to commercialization;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (“CROs”) or contract development and manufacturing organizations (“CDMOs”), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CDMOs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected drug-related adverse effects;

## [Table of Contents](#)

- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators, IRBs or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- we may need to add new or additional clinical trial sites and may experience delays or interruptions in site initiations;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or third-party contractors;
- we may experience manufacturing delays, and any changes to manufacturing processes or third party contractors that may be necessary or desired could result in other delays;
- we or our third-party contractors may experience delays due to complications associated with the COVID-19 pandemic;
- we may not be able to raise funding necessary to initiate or continue a trial;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in clinical trials;
- reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regional regulators, IRBs or ethics committees to suspend or terminate the clinical trials;
- we may elect to, or regional regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical trials for various other reasons, including noncompliance with regulatory requirements; and
- regulators may revise the requirements, timelines or pathways for approval of our product candidates, or such requirements, timelines or pathways may not be as we anticipate.

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

## [Table of Contents](#)

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

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

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

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

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

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

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any other products that may be approved for the indications we are investigating;
- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- adverse events in our clinical trials and in third-party clinical trials of agents similar to our product candidates;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;

## [Table of Contents](#)

- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, including the impacts of the COVID-19 pandemic, 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 that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

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

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

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

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable non-U.S. regulatory authority approval. Furthermore, the approval policies or regulations of the FDA, EMA or comparable non-U.S. regulatory authorities may significantly change in a manner that may render our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable non-U.S. regulatory authorities delaying, limiting or denying approval of our product candidates.

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

From time to time, we may announce, publish or report preliminary, topline or interim data from our clinical trials, including those in the ARTISTRY development program for nemvaleukin. Such data are subject to the risk that one or more of the clinical outcomes may materially change as patients continue progressing through the

## [Table of Contents](#)

study (for example, in oncology studies, a patient may progress from a complete or partial response to progressive disease), as patient enrollment continues and/or as more patient data become available, and such data may not be indicative of final data from such trials, data from future trials or real-world results. In addition, such data may remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary, topline or interim data disclosed. As a result, all preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse differences between preliminary, topline or interim data and final data could significantly harm our business, financial condition, cash flows and results of operations.

***We may seek approval of our product candidates, where applicable, under the FDA’s accelerated approval pathway. This pathway may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

We plan to seek accelerated approval of nemvaleukin in combination with pembrolizumab in platinum-resistant ovarian cancer (“PROC”) using the FDA’s accelerated approval pathway and may seek accelerated approval of nemvaleukin in other indications or of other future product candidates using this pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 (“FDORA”), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product that is granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug’s predicted clinical benefit; and to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway for nemvaleukin or other product candidates, we may not be able to obtain accelerated approval, and even if we do, that product may not experience a faster development or regulatory review or approval process. In addition, receiving accelerated approval does not assure the product’s accelerated approval will eventually be converted to a traditional approval.

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

We are conducting, and intend in the future to conduct, one or more of our clinical trials outside the U.S. For example, we currently conduct or plan to conduct clinical trials in Canada, Australia, South Korea, Poland, Spain, Taiwan, the United Kingdom (“UK”), Italy, Austria, Israel, Singapore, the Netherlands, Germany, Belgium, Lithuania, the Czech Republic, Norway, Denmark, and France. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice (“GCP”). The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the U.S. In addition, while these clinical trials are subject to applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations.

## [Table of Contents](#)

There can be no assurance that the FDA will accept data from clinical trials conducted outside of the U.S. If the FDA does not accept the data from any trial that we conduct outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

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

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

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

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

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

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

## [Table of Contents](#)

- we could be required to pay fines and face other administrative, civil, and criminal penalties; and
- our reputation may suffer.

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

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

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

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

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

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

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

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

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

We are not permitted to market any biological product in the U.S. until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable



## [Table of Contents](#)

non-U.S. regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

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

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

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

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

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

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

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

or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

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

Regulatory authorities also may, at any time following approval of a product for sale, audit our third-party manufacturers’ facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

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

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

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors;
- scheduling and supply risks as a result of using third-party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors;

## [Table of Contents](#)

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, global disruptions such as the COVID-19 pandemic or the military conflict between Russian and Ukraine;
- the inability to obtain components or materials from alternate sources at acceptable prices in a timely manner; and
- substantial delays or difficulties related to the establishment of replacement manufacturers who meet regulatory requirements.

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

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

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

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

Commencing clinical trials in the U.S. is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. In addition, emerging data from other clinical trials and regulatory approvals of other product candidates could impact the acceptability of our clinical trial designs. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union (“EU”).

While we have interacted with the FDA in the development of our study design and protocols for our ARTISTRY clinical development program, we may experience issues that require revisions to our trial design and trial protocols. We have had no interactions with the FDA or other regulatory authorities in respect of 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 will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

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

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

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

Regulatory approval by the FDA or other regulatory authorities can be delayed, limited or not granted at all for many reasons, including because regulatory authorities may not agree with our regulatory approval strategies,

## [Table of Contents](#)

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

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

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

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

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

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain

requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable non-U.S. regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

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

Even if regulatory approval to market a product is granted by the FDA or other regulatory authorities, the approved label for the product may not be consistent with our initial expectations or commercial plans. For example, the FDA or other regulatory authorities may impose limitations on the clinical data that may be included in the label or grant narrower indications for use than we sought or add a limitation of 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.

## [Table of Contents](#)

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

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

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

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

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing, reimbursement and our ability to create meaningful value propositions for patients, prescribers and payors. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

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

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

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

## [Table of Contents](#)

We may also seek Breakthrough Therapy designation for one or more of our product candidates. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

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

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

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

We have received Orphan Drug designation ("ODD") from the FDA for nemvaleukin for the treatment of mucosal melanoma and may seek additional ODD for additional indications or for our other product candidates. Even if we receive orphan drug exclusivity, the exclusivity may be revoked under certain circumstances, such as if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. We will also be required to submit annual reports describing any changes that may affect the orphan drug status of the product. Further, even if we receive orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition during the exclusivity period because different drugs with different active moieties can be approved for the same condition, and the same product can be approved for different uses. Also, in the U.S., even after an orphan drug is approved and receives orphan drug exclusivity, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug, including because it has been shown to be clinically superior to the drug with exclusivity because it is



## [Table of Contents](#)

safer, more effective or makes a major contribution to patient care. In the EU, a marketing authorization may be granted to a similar medicinal product to an authorized orphan product for the same orphan indication if:

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

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

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

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

### **Risks Related to the Commercialization of Our Product Candidates**

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

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

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

- the product's efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product's convenience and ease of administration compared to alternative treatments;

## [Table of Contents](#)

- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- clinicians' and patients' perceptions of other similar immuno-oncology product candidates or products with a similar mechanism of action as ours;
- the approval of other new products for the same indications;
- our ability to offer the product for sale at competitive prices; and
- public perception of our company and the reputation of our business.

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

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

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

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

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

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

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

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

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

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary

widely from country to country. In the U.S., third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the U.S. for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. Moreover, increasing efforts by governmental and other third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted U.S. federal and U.S. state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs further discussed below. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

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

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”). In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. These changes included aggregate reductions

to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act. Pursuant to subsequent legislation, this 2% reduction was suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction began April 1, 2022, lasting through June 30, 2022. The 2% payment reduction resumed on July 1, 2022. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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

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

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

## [Table of Contents](#)

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

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

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

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost and price disclosure and transparency measures. Some states have adopted measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Further, if any of our products are approved, we would be required to calculate and report certain price reporting metrics to the government, such as average sales price, and best price. The calculations necessary to determine the prices reported are complex and penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for our products may be reduced by mandatory discounts or rebates required by government healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional U.S. state and U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that U.S. federal and U.S. state governments will pay for healthcare

products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

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

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

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

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

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

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

## [Table of Contents](#)

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

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

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company’s product. The law is complex and is still being interpreted and implemented by the FDA.

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

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

### **Risks Related to Our Reliance on Third Parties**

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

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

Historically and through the date of the separation, our business was and will continue to be conducted by Alkermes. We continue to build our infrastructure and hire personnel necessary to execute our operational plans.



## [Table of Contents](#)

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

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

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

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

Switching or adding additional CROs involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, which may affect our ability to initiate and complete our preclinical studies and clinical trials. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

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

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

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

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

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

## [Table of Contents](#)

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

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

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

- collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements;
- collaborators or licensors may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators or licensors may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators or licensors could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators or licensors may be acquired by a third party having competitive products or different priorities;
- collaborators or licensors with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidate(s);
- collaborators or licensors may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators or licensors and us that result in the delay or termination of the research, development, or commercialization of our product candidates or any of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

## [Table of Contents](#)

- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations or license grants may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration or license agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator or licensor of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

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

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration or license agreement will depend, among other things, upon our assessment of the resources and expertise of such third-party collaborator or licensor and the terms and conditions of the proposed collaboration or license. Further, if we license rights for use in any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

### **Risks Related to Our Intellectual Property**

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

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

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that the scope of the currently-pending patent applications will not be altered before the U.S. Patent and Trademark Office (“USPTO”), or non-U.S. patent offices. The standards applied by the USPTO, and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. The patent positions of

## [Table of Contents](#)

therapeutic polypeptide and antibody companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, patents may not issue from our pending patent applications, or the scope of the pending patent applications may change. As such, we cannot predict with certainty the degree of future protection that we will have on our proprietary products and technology.

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

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

These changes may affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. The U.S. Supreme Court, and other U.S. courts, have ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to enforce our patents. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Legislation passed by U.S. Congress, for example, the IRA, could potentially impact drug pricing and rebates depending on the success of drug products and the marketplace.

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

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

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

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

Despite the due diligence we have conducted regarding our patent portfolio strategy, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity

and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one of our products and product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

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

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

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

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

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

## [Table of Contents](#)

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

## [Table of Contents](#)

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 us and an adverse party.

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

An unfavorable outcome could result in a loss of our current patent rights. This could require us to obtain a license from the patent owner in order to continue our research and development programs or our partnerships or, if approved, to market our product(s). Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all.

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

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

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- others may identify compounds more quickly than we are able to, and might file their patent applications before us;
- we or our partners might not have been the first to make the inventions covered by our issued patent or pending patent application;
- we or our partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our pending patent applications might not lead to issued patents;



## Table of Contents

- our issued patents that we own or have exclusively licensed may not provide us with a competitive advantage; for example, our issued patents may not be broad enough to prevent the commercialization of competitive products, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our or our partners' existing or potential commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

### **Risks Related to Our Business and Industry**

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

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

- difficulties in staffing and managing non-U.S. operations;
- non-U.S. government taxes, regulations and permit requirements;
- U.S. and non-U.S. government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act ("FCPA");
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular non-U.S. countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- changes in diplomatic and trade relationships.

Our business activities outside of the U.S. are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA and similar anti-corruption laws generally prohibit offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the U.S. Securities and Exchange Commission ("SEC") and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and

## [Table of Contents](#)

Consumer Protection Act (“Dodd-Frank”), private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

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

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

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

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

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

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

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain

## [Table of Contents](#)

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 of this information statement titled “Business – Government Regulation – Healthcare and Privacy Laws.”

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. U.S. federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company’s attention from the business.

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

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

Among other matters, U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations (collectively, “Trade Laws”) prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

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

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

As of , 2023, we had full-time employees, part-time employees and engaged independent contractors. We expect to experience significant growth 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

## [Table of Contents](#)

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

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

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

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

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

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

## [Table of Contents](#)

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

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

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

We depend on our employees, consultants, third-party manufacturers, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including terrorist attacks, wars or other armed conflicts, geopolitical tensions or trade wars, pandemics or natural disasters, these events could result in significant disruptions to our research and development, manufacturing, preclinical studies, clinical trials, and, ultimately, if approved, the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, such as natural disasters, which are increasing in frequency due to the impacts of climate change, the outbreak of wars or other armed conflicts, the escalation of hostilities, geopolitical tensions or trade wars, acts of terrorism or “acts of God,” particularly involving geographies in which we or third parties on whom we depend have offices, manufacturing or clinical trial sites, could adversely affect our businesses. For example, the current military conflict between Russia and Ukraine 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.

***The COVID-19 pandemic, or a future pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.***

Outbreaks of contagious diseases and other adverse public health developments affecting us and/or the third parties on which we rely, could have a material and adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic impacted many aspects of society, including the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide. Ireland, all U.S. states, and many local jurisdictions and countries around the world experienced, at times during the pandemic, closures, restrictions, labor shortages and other disruptions, which could occur in the future.

The COVID-19 pandemic caused varying degrees of disruption to our employees and our business operations. We experienced, at times during the pandemic, labor or supply chain disruptions and may continue to experience such disruptions. In addition, the COVID-19 pandemic impacted at times the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines.

In addition, we rely upon third parties for many aspects of our business, including the provision of goods and services related to the manufacture of our product candidates and the conduct of our clinical trials and preclinical studies. The COVID-19 pandemic disrupted, to varying degrees, the business operations of the third parties on which we rely, including our suppliers, CROs and third-party manufacturers, clinical site investigators, and others, and may continue to do so for so long as impacts of the pandemic persist. For example, the third-party sites and investigators involved in our clinical trials experienced, and may continue to experience, interruptions which impacted the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data, and our ability to complete them in a timely manner or at all. If, during a future pandemic, our clinical programs are significantly delayed as a result of similar impacts, there could be adverse effects on our expected timelines for regulatory review and potential approval of our product candidates. Any prolonged material disruption to these or other third parties on which we rely could negatively impact our ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operations and financial condition.

Although the acute COVID-19 public health emergency has lapsed in the U.S., we will work with our internal teams, our clinical investigators, research and development (“R&D”) vendors and critical supply chain vendors to continually assess, and mitigate, any potential ongoing impacts of COVID-19 or other pandemics on our operations and R&D activities. The degree to which such disruptions may impact our employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic and the manner in which it evolves, which is uncertain and cannot be predicted as of the date of this information statement.

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

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

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

Further, each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject

## [Table of Contents](#)

to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“HIPAA”).

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the collection and use of personal information, including health information, in the EU are governed by the provisions of the EU General Data Protection Regulation (“EU GDPR”), as well as transposing and supplementary national data protection legislation in force in relevant Member States. While the UK is no longer a Member State of the EU, the EU GDPR forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (the “UK GDPR”, together with the EU GDPR the “GDPR”) and is supplemented by the Data Protection Act 2018 in the UK. The GDPR and relevant national laws impose a broad range of strict requirements on companies subject to them, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area (“EEA”) (or in the case of the UK GDPR, outside of the UK), providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals’ requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates in certain circumstances, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

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

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

In the absence of an adequacy decision, the most commonly used appropriate safeguard is the standard contractual clauses issued by the European Commission. On June 4, 2021, the European Commission issued new forms of standard contractual clauses (“SCCs”) for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The SCCs are a contract between a data exporter and a data importer where the parties agree to the provision of specific protections for personal data and the terms cannot generally be amended by the parties. As of December 27, 2022, the new SCCs must be used for all transfers outside of the EEA in place of the SCCs that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission’s new SCCs but has published the UK International Data Transfer Agreement (the “IDTA”) and International Data Transfer Addendum to the new SCCs (the “UK Addendum”), which provides modifications to the European Commission’s SCCs to enable transfers from the UK in compliance with UK GDPR. For new transfers, the IDTA or the UK Addendum needs to be in place. For any existing transfers relying on pre-Brexit



## [Table of Contents](#)

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 Maximilian Schrems*, Case C-311/18 (“Schrems II”), companies relying on SCCs to govern transfers of personal data to third countries (in particular the U.S.) need to perform a transfer impact assessment (“TIA”) to assess whether the data importer can ensure that personal data will be subject to an essentially equivalent level of protection as under the GDPR in the jurisdiction to which the data is imported. Where the TIA concludes that the level of protection will not be essentially equivalent, the data importer must consider whether it can implement additional guarantees to safeguard the personal data and ensure that the level of protection for the personal data is raised. The TIA includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. We are required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost.

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

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

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

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

Our computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to damage from computer viruses, unauthorized access,

## [Table of Contents](#)

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

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

### **Risks Related to the Separation and Distribution**

***We may not achieve some or all of the expected benefits of the separation, which may not be completed on the timeline currently contemplated or at all.***

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 occur at all. The separation is expected to provide the following benefits, among others: (i) allowing us to focus exclusively on our business and distinct needs from those of Alkermes, and pursue our own operational and strategic priorities and respond to trends, developments and opportunities in our target markets; (ii) reduce competition for capital allocation and (iii) more direct potential access to the capital markets as a standalone company.

These anticipated benefits are based on a number of assumptions and uncertainties, which may prove to be incorrect or incomplete and we may not achieve these and other anticipated benefits for a variety of reasons, including, among others: the separation has required, and will continue to require, significant amounts of time and effort from Alkermes' management team, which may divert Alkermes' management team's attention from

## [Table of Contents](#)

operating and growing our business prior to the separation. Following the separation, we may be more susceptible to market fluctuations and other adverse events than if we were still a part of Alkermes; our business will be less diversified than Alkermes' business prior to completion of the separation and the actions required to separate Alkermes' and our respective businesses could disrupt our operations. If we fail to achieve some or all of the benefits expected to result from the separation, or if such benefits are delayed, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

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

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

***We have no history of operating as a standalone company and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical and pro forma combined financial information included in this information statement is not necessarily representative of the results that we would have achieved and may achieve as a separate, publicly traded company and should not be relied upon as an indicator of our future results.***

Historically and through the date of the separation, our business was and will continue to be conducted by Alkermes. Our historical information provided in this information statement refers to our business as operated by and integrated with Alkermes. Our historical and pro forma combined financial information included in this information statement is derived from the consolidated financial statements and accounting records of Alkermes. Accordingly, the historical and pro forma combined financial information included in this information statement 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 and pro forma combined financial information included in this information statement as a result of the following factors, among others:

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

## [Table of Contents](#)

Our financial condition and future results of operations, after giving effect to the separation, will be materially different from results reflected in our historical financial statements included elsewhere in this information statement. 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 distribution is subject to conditions, including certain conditions that may be waived. If Alkermes waives one or more conditions to the distribution, it could adversely impact Mural's operations, the tax treatment of the separation, the liquidity of Mural ordinary shares or have other consequences.***

The completion of the distribution is subject to a number of conditions. Alkermes can waive any of the conditions to the distribution in its sole discretion. For example, if Alkermes waived the condition that Mural's ordinary shares be approved for listing on the Nasdaq Global Market ("Nasdaq"), and Mural's ordinary shares were not eligible for listing on the Nasdaq Capital Market, or another exchange, Mural's ordinary shares would not be listed on an exchange and would be less liquid. Further, if Alkermes waived the condition that it receive a private letter ruling from the Internal Revenue Service ("IRS") and an opinion from Goodwin Procter LLP together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended ("Code"), except for cash received in lieu of fractional ordinary shares, certain U.S. subsidiaries of Alkermes may recognize taxable gain and Alkermes shareholders who receive our ordinary shares in the distribution may be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares. Waivers of other conditions by Alkermes also could have material adverse consequences. For more information, see "The Separation and Distribution—Conditions to the Distribution."

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

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

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

The agreements related to the separation, including, among others, the separation agreement, the transition services agreements, the tax matters agreement and the employee matters agreement will have been entered into in the context of the separation while we are still controlled by Alkermes. Until the distribution occurs, Alkermes will effectively have the sole and absolute discretion to determine and change the terms of the separation and distribution, including the terms of any agreements between Alkermes and us and the establishment of the record date and distribution date. As a result, any changes could be unfavorable to us and may not reflect terms that would have resulted from negotiations between unaffiliated third parties in an arms-length transaction. In addition, Alkermes may decide at any time not to proceed with all or any part of the separation. For a more detailed description, see "Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes."

***The combined post-separation value of Alkermes' ordinary shares and our ordinary shares may not equal or exceed the pre-separation value of Alkermes ordinary shares.***

Following the distribution, the trading price of our ordinary shares may not reflect the full value of our business and assets, due to market inefficiencies in the initial trading of our ordinary shares or variations in investor views regarding our business and prospects, among other market forces. The aggregate market value of

## [Table of Contents](#)

Alkermes ordinary shares and our ordinary shares as separate entities at any time following the separation may be higher or lower than the market value of Alkermes ordinary shares immediately prior to the separation while both the oncology business and neuroscience business are operated within Alkermes, and may fluctuate, particularly during the period immediately following the distribution.

***No vote of Alkermes shareholders is required in connection with the distribution. As a result, if you do not want to receive our ordinary shares in the distribution, your sole recourse will be to divest yourself of your Alkermes ordinary shares prior to the record date or of our ordinary shares following the distribution.***

No vote of the Alkermes shareholders is required in connection with the distribution. Accordingly, if you do not want to receive our ordinary shares in the distribution, your only recourse will be to divest yourself of your Alkermes ordinary shares prior to the record date for the distribution or of our ordinary shares following the distribution.

***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.***

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

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

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

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

## [Table of Contents](#)

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

Although Alkermes has historically tested, and currently tests, its internal control over financial reporting on a regular basis, we have never done so as a standalone entity. Doing so for ourselves will require our management and other personnel to devote a substantial amount of time to establish these controls in order to comply with these requirements and will also increase our legal and financial compliance costs. In particular, compliance with Section 404 of the Sarbanes-Oxley Act will require a substantial accounting expense and significant management efforts. We cannot be certain at this time that all of our controls will be considered effective and our internal control over financial reporting may not satisfy the regulatory requirements when they become applicable to us.

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

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

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

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

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

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

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

**Risk Factors Related to Tax Matters**

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

It is a condition to the distribution that Alkermes receives a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes' board of directors and each continuing to be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. Any opinion of Goodwin Procter LLP and any IRS private letter ruling will be based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings from us and Alkermes (including those relating to the past and future conduct of us and Alkermes) and will be subject to certain caveats. If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or Alkermes breach any of our respective covenants relating to the separation, any IRS private letter ruling and any tax opinion may be invalid. Accordingly, notwithstanding receipt of an IRS private letter ruling and an opinion of Goodwin Procter LLP, the IRS could determine that the separation and distribution, in relevant part and together with certain related transactions, should be treated as taxable transactions for U.S. federal income tax purposes if it determines that any of the facts, assumptions, representations, statements or undertakings that were included in the request for any 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, and any IRS private letter ruling will not address all of the issues that are relevant to determining whether the separation and distribution, in relevant part and together with certain related transactions, qualify as transactions that are tax-free for U.S. federal income tax purposes. Accordingly, notwithstanding receipt by Alkermes of the tax opinion referred to above and an IRS private letter ruling, the IRS could assert that the separation and distribution and certain related transactions do not qualify for tax-free treatment for U.S. federal income tax purposes.

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

In connection with the distribution, we and Alkermes will enter into a tax matters agreement pursuant to which we will be responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the separation and distribution, in relevant part and together with

## [Table of Contents](#)

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

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

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

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

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



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

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

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

### **Risks Related to Ownership of Our Ordinary Shares**

***After the separation we will be an “emerging growth company” and a “smaller reporting company” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our ordinary shares less attractive to investors.***

After the separation, we will qualify as an “emerging growth company”, as defined in the JOBS Act. We may remain an emerging growth company until December 31, 2029, although if the market value of our ordinary shares that is held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have annual gross revenues of \$1.235 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than \$1.0 billion of non-convertible debt over a three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

## [Table of Contents](#)

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

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

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

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

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

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

## Table of Contents

- our cash position;
- sales of our ordinary shares by us or our shareholders in the future;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry and those developing immuno-oncology products;
- publication of research reports or other media articles about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits that may be filed against us;
- investors' general perception of our company and the reputation of our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our ordinary shares;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or shareholder litigation;
- proposed changes to healthcare laws or pharmaceutical pricing in the U.S. or non-U.S. jurisdictions, or speculation regarding such changes;
- developments with respect to the COVID-19 pandemic;
- general political and economic conditions, including disruptions in the banking industry; and
- other events or factors, many of which are beyond our control.

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

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

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in the manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in one or more transaction(s), investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

We plan to adopt an equity incentive plan in connection with the separation, 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, the vesting or settlement of outstanding equity awards will cause our shareholders to experience additional dilution, which could cause our share price to fall.

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

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

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

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

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

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

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

Following the separation, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. Our

## [Table of Contents](#)

financial results historically were included within the consolidated results of Alkermes, and until the separation occurs, we have not been and will not be directly subject to reporting and other requirements of the Exchange Act and Section 404 of the Sarbanes-Oxley Act. After the separation, we will qualify as an emerging growth company. 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, however, be immediately subject to Section 404(a) of the Sarbanes-Oxley Act and, as of the expiration of our emerging growth company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. These and other obligations will place significant demands on our management, administrative and operational resources, including accounting and information technology resources. To comply with these requirements, we anticipate that we will need to further upgrade our systems, including duplicating computer hardware infrastructure, implement additional financial and management controls, reporting systems and procedures and hire additional accounting, finance and information technology staff. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. If we are unable to do this in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired and our business, prospects, financial condition and results of operations could be harmed.

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

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

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

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

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

Following the separation, as a public company, we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, Dodd-Frank, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire

additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly.

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

Pursuant to Section 404, in our second annual report due to be filed with the SEC, after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company with less than \$100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

As a public company, we are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal control over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of

our equity securities, including our ordinary shares, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may not be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize any or all potential benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

#### **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 the company will be subject to the Irish Takeover Rules.***

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

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

Our Constitution will however also provide that unless we consent in writing to the selection of an alternative forum, the U.S. federal district courts of the U.S. shall be the sole and exclusive forum for resolving any dispute asserting a cause of action arising under the Securities Act of 1933, as amended (the “Securities Act”), and the Exchange Act, or the respective rules and regulations promulgated thereunder. However, there is some uncertainty as to whether a court would enforce such a provision and, in any event, our shareholders will not be deemed to have waived our compliance with U.S. federal securities laws and the rules and regulations thereunder. Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for U.S. federal and

## [Table of Contents](#)

state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These provisions may limit, or increase the difficulty of, shareholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors and officers under the Securities Act and Exchange Act, or may result in increased costs to bring a claim.

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

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

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

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

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

### ***Mural might not meet the conditions for reconstruction relief on separation and distribution.***

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



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

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

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

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

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

***Irish law imposes restrictions on certain aspects of capital management.***

Irish law allows our shareholders to pre-authorize shares to be issued by our board of directors without further shareholder approval for up to a maximum of five years. This authorization will be contained in our constitution on re-registration as a public limited company and will therefore lapse approximately five years after the distribution unless renewed by shareholders and we cannot guarantee that such renewal will always be approved. Additionally, subject to specified exceptions, including the opt-out that will be included in our articles of association upon consummation of the distribution, 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 always be approved. We cannot assure you that these Irish legal restrictions will not interfere with our capital management.

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

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

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

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

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

## **General Risks**

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and the COVID-19 pandemic has caused significant volatility and uncertainty in the U.S. and international markets. In addition, the current military conflict between Russia and Ukraine 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 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,

---

## [Table of Contents](#)

many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

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

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

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

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This information statement and other materials we have filed or will file with the SEC include, or will include, forward-looking statements. All statements in this information statement, in other materials we have filed or will file with the SEC and in related comments by our management, other than statements of historical facts, including statements about future events, future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words “may,” “will,” “would,” “could,” “should,” “believes,” “estimates,” “projects,” “potential,” “expects,” “plans,” “seeks,” “intends,” “evaluates,” “pursues,” “anticipates,” “continues,” “designs,” “impacts,” “affects,” “forecasts,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal” or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

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

- the completion and timing of the separation and distribution, the business and operations of Mural following the separation and any benefits or costs of the separation, including the tax treatment of the separation and distribution;
- our post-separation relationships with Alkermes, third parties, collaborators and our employees;
- our ability to operate as a standalone company and execute our strategic priorities;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to efficiently discover and develop product candidates;
- our ability and the potential of third parties to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials, and on a larger scale, for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- the safety profile and related adverse events of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;

## [Table of Contents](#)

- estimates of our future expenses, revenue, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any product, if approved;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the U.S. and relevant non-U.S. countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to manufacture, or have manufactured, our products or product candidates;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of U.S. and non-U.S. laws and regulations;
- developments relating to our competitors and our industry;
- potential indemnification liabilities that we may owe to Alkermes after the separation;
- the tax treatment of the separation and distribution and the limitations imposed on us under the tax matters agreement that we enter into with Alkermes;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials;
- the impact of global economic and political developments on our business, including rising inflation and interest rates, and capital market disruptions, bank failures, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our ordinary shares and our ability to access capital markets; and
- other risks and uncertainties, including those under the caption “Risk Factors.”

See “Risk Factors” for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this information statement. 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 information statement. 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 information statement. Any forward-looking statement made by us in this information statement 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.

## DIVIDEND POLICY

We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and other factors deemed relevant by our board of directors. Moreover, even if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

### Creation of Distributable Reserves

Under Irish law, dividends and distributions (including by way of the payment of cash dividends or share repurchases) may be made only from profits available for distribution, or “distributable reserves” on our unconsolidated balance sheet prepared in accordance with the Irish Companies Act 2014. In addition, no distribution or dividend may be paid or made by us unless our net assets are equal to, or exceed, the aggregate of our share capital that has been paid up or that is payable in the future plus non-distributable reserves, and the distribution does not reduce our net assets below such aggregate. For more information regarding distributable reserves, see “Description of Mural’s Share Capital—Dividends” and “Description of Mural’s Share Capital—Share Repurchases, Redemptions and Conversions.”

Immediately following the separation and distribution, our unconsolidated balance sheet will not contain any distributable reserves and we will capitalize the merger reserve which will be created as a result of the distribution. At that time, our unconsolidated balance sheet will show “shareholders’ equity” which will be comprised entirely of “share capital” (equal to the aggregate nominal value of Mural ordinary shares issued in the distribution) and “share premium” (equal to (a) the aggregate historical book value of the oncology business at the time of its transfer to Mural less (b) the share capital). We will not have the ability to pay dividends (or make other forms of distributions) immediately following the distribution until we obtain the court approval described below or create distributable reserves as a result of the profitable operation of our business.

Following the separation and distribution, we expect to capitalize the reserves created pursuant to the distribution and implement a court-approved reduction of that capital in order to create a reserve of an equivalent amount of distributable reserves to support the payment of possible future dividends or future share repurchases. The current pre-distribution shareholder of Mural is expected to pass a resolution that would (subject to the approval of the High Court of Ireland) create distributable reserves following the distribution by converting to distributable reserves up to all of our share premium. To complete this process, we will seek the approval of the High Court of Ireland, which is required for the creation of distributable reserves to be effective, as soon as practicable following the distribution. The approval of the High Court of Ireland is expected to be obtained within approximately two months of the consummation of the distribution, but is dependent on a number of factors, such as the case load of the High Court of Ireland at the time of our initial application, and court vacations.

Until the approval of the High Court of Ireland is obtained or distributable reserves are created as a result of the profitable operation of our business, we will not have sufficient distributable reserves to make distributions by way of dividends, share repurchases or otherwise. Although we are not aware of any reason why the High Court of Ireland would not approve the creation of distributable reserves, there is no guarantee that we will obtain such approval.

## CAPITALIZATION

The following table sets forth Mural’s capitalization as of December 31, 2022 on a historical basis and on a pro forma basis to give effect to the pro forma adjustments included in Mural’s unaudited pro forma combined financial information. The information below is not necessarily indicative of what Mural’s capitalization would have been had the separation and distribution been completed as of December 31, 2022. In addition, it is not necessarily indicative of Mural’s future capitalization. This table should be read in conjunction with “Unaudited Pro Forma Combined Financial Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Summary Historical and Unaudited Pro Forma Combined Financial Information” and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

<b>(In thousands)</b>	<b>As of December 31, 2022</b>	
	<b>Actual</b>	<b>Pro Forma</b>
Cash and cash equivalents	\$ —	\$
<b>Debt:</b>		
Long-term debt	\$ —	\$
Total debt	\$ —	\$
<b>Equity:</b>		
Net parent investment	\$(21,656)	\$
Ordinary shares	\$ —	\$
Additional paid-in capital	\$ —	\$
<b>Total Capitalization</b>	<b>\$(21,656)</b>	<b>\$</b>

## UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS

The unaudited pro forma combined financial data of Mural consists of an unaudited pro forma combined statement of operations for the year ended December 31, 2022 and an unaudited pro forma combined balance sheet as of December 31, 2022 that have been prepared by management in accordance with Article 11, Pro Forma Financial Information, under Regulation S-X of the Securities Exchange Act of 1934, as amended, and are for illustrative and informational purposes only. The unaudited pro forma combined financial data reported below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Summary Historical and Unaudited Pro Forma Combined Financial Information” and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

The following unaudited pro forma combined financial data is subject to assumptions and adjustments described in the accompanying notes. Mural’s management believes these assumptions and adjustments are reasonable under the circumstances and given the information available at this time. However, these adjustments are subject to change as Alkermes and Mural finalize the terms of the separation and distribution, including the separation agreement and related transaction agreements.

The unaudited pro forma combined financial data does not purport to represent what Mural’s financial position and results of operations actually would have been had the separation and distribution occurred on the dates indicated, or to project Mural’s financial performance for any future period following the separation and distribution.

The unaudited pro forma combined statement of operations for the year ended December 31, 2022 gives effect to the separation and distribution as if they had occurred on January 1, 2022. The unaudited pro forma combined balance sheet as of December 31, 2022 gives effect to the separation and distribution as if they had occurred on December 31, 2022. The oncology business’ historical financial information, which was the basis for the unaudited pro forma combined financial statements, was prepared on a carve-out basis as the oncology business did not operate as a separate, independent company for the period presented. Accordingly, such historical financial information reflects an allocation for certain business and support functions that are provided on a centralized basis within Alkermes, including senior management, legal, human resources, accounting and finance, facilities, information technology, and other corporate services. These historical allocations may not be indicative of Mural’s future cost structure and may not necessarily represent the financial position or results of operations of Mural had it operated as an independent, separate public company during the period or at the date presented.

The pro forma adjustments include transaction accounting adjustments that reflect the accounting for transactions in accordance with U.S. generally accepted accounting principles and autonomous entity adjustments that reflect certain incremental expenses or other changes necessary to reflect the financial condition and results of operations as if Mural was a separate standalone entity. The unaudited pro forma combined financial data includes adjustments to reflect the estimated impact of the following:

- the expected transfer and contribution by Alkermes to Mural, pursuant to the separation agreement, of the assets and liabilities that comprise the oncology business;
- incremental costs Mural expects to incur as an standalone entity;
- the estimated impacts of the separation agreement, transition services agreements, tax matters agreement and employee matters agreement and between Mural and its subsidiaries and Alkermes; and
- the distribution of Mural’s ordinary shares to Alkermes’ shareholders in connection with the separation.



---

[Table of Contents](#)

A final determination regarding Mural's capital structure has not yet been made, and the separation agreement, transition services agreements, tax matters agreement and employee matters agreement have not yet been finalized. As such, the unaudited pro forma combined financial data may be revised in future amendments to the registration statement on Form 10 of which this information statement is a part to reflect the impact on Mural's capital structure and the final form of those agreements, to the extent any such revisions would be deemed material.

**Mural****Unaudited Pro Forma Combined Statement of Operations**  
**Year Ended December 31, 2022**  
**(In thousands, except per share data)**

	<u>Historical Oncology Business</u>	<u>Transaction Accounting Adjustments</u>	<u>Autonomous Entity Adjustments</u>	<u>Pro Forma</u>
<b>Operating expenses</b>				
Research and development	\$ 167,191			\$ 167,191
General and administrative	17,732	(B)	(E)	17,732
<b>Total operating expenses</b>	<u>184,923</u>			<u>184,923</u>
<b>Operating loss</b>	<u>(184,923)</u>			<u>(184,923)</u>
<b>Income tax provision</b>	<u>4,884</u>			<u>4,884</u>
<b>Net loss</b>	<u>\$(189,807)</u>			<u>\$(189,807)</u>
Net loss per share—basic and diluted			(D)	
Weighted average shares outstanding—basic and diluted			(D)	

*See Notes to Unaudited Pro Forma Combined Financial Data.*

**Mural**

**Unaudited Pro Forma Combined Balance Sheet**  
**As of December 31, 2022**  
**(In thousands)**

	<b>Historical Oncology Business</b>	<b>Transaction Accounting Adjustments</b>	<b>Autonomous Entity Adjustments</b>	<b>Pro Forma</b>
<b>ASSETS</b>				
<b>CURRENT ASSETS:</b>				
Cash and cash equivalents	\$ —	(A)		\$ —
Prepaid expenses	2,987			2,987
Other current assets	1,830			1,830
<b>Total current assets</b>	<b>4,817</b>			<b>4,817</b>
Property and equipment, net	10,617			10,617
Right-of-use assets	18,316			18,316
<b>TOTAL ASSETS</b>	<b>\$ 33,750</b>			<b>\$ 33,750</b>
<b>LIABILITIES AND EQUITY</b>				
<b>CURRENT LIABILITIES:</b>				
Accounts payable	\$ 2,966			\$ 2,966
Accrued expenses	32,750	(B)		32,750
Operating lease liabilities—short-term	5,844			5,844
<b>Total current liabilities</b>	<b>41,560</b>			<b>41,560</b>
Operating lease liabilities—long-term	13,542			13,542
Other long-term liabilities	304			304
<b>Total liabilities</b>	<b>55,406</b>			<b>55,406</b>
Net parent investment	(21,656)	(C)		(21,656)
Ordinary shares	—	(C)		—
Additional paid-in capital	—	(C)		—
<b>Total equity</b>	<b>(21,656)</b>			<b>(21,656)</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 33,750</b>			<b>\$ 33,750</b>

*See Notes to Unaudited Pro Forma Combined Financial Data.*

## Notes to Unaudited Pro Forma Combined Financial Data

### 1. Transaction Accounting Adjustments

(A) Reflects the impact of the initial cash contribution of approximately \$ \_\_\_\_\_ for funding from Alkermes to Mural in connection with the separation.

(B) Reflects the impact of estimated nonrecurring transaction costs of \$ \_\_\_\_\_ that are expected to be incurred by Mural in connection with the separation but that were not yet incurred and, therefore, not included in Mural's historical combined financial statements.

(C) Reflects the distribution of Mural's ordinary shares to Alkermes shareholders, calculated based on \_\_\_\_\_ Alkermes ordinary shares issued and outstanding on the record date, and a distribution ratio of \_\_\_\_\_ Mural's ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares. This amount is a reclassification of Alkermes' investment in Mural that is allocated between ordinary shares and additional paid-in capital based on the number of Mural's ordinary shares outstanding on the distribution date.

(D) The number of Mural's ordinary shares used to compute basic net loss per share is based on (i) the number of Mural's ordinary shares assumed to be outstanding on the distribution date, after giving effect to the distribution, calculated based on \_\_\_\_\_ Alkermes ordinary shares issued and outstanding on the record date, and a distribution ratio of \_\_\_\_\_ Mural's ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares. In periods in which Mural reports a net loss, diluted net loss per share is the same as basic net loss per share since the inclusion of ordinary share equivalents such as options and restricted stock awards would be anti-dilutive.

### 2. Autonomous Entity Adjustments

(E) As an independent, standalone, public company following the separation, Mural expects to incur certain additional costs, including accounting, auditing, communications, tax, legal, employee benefits, human resources, information technology and other general and administrative functions, beyond those reflected in the historical combined financial statements. Mural estimates that the net impact of incremental costs related to the separation agreement, transition services agreements, tax matters agreement and employee matters agreement, as compared to its historical combined financial statements, would have been incremental expense of approximately \$ \_\_\_\_\_ for the year ended December 31, 2022. Accordingly, the unaudited pro forma combined financial statements have been adjusted to depict Mural as an autonomous entity. The additional costs have been based on estimates that Mural's management believes are reasonable. However, actual incremental costs that will be incurred could differ materially from these estimates.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with “Unaudited Pro Forma Combined Financial Statements,” “Summary Historical and Unaudited Pro Forma Combined Financial Information” and the audited combined financial statements and corresponding notes included elsewhere in this information statement. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, including those set forth under “Risk Factors” appearing elsewhere in this information statement, our actual results may differ materially from those anticipated in these forward-looking statements. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

### Overview

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

### Separation from Alkermes

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore separation of its neuroscience business and oncology business. Alkermes intends to effect the separation through the distribution of the ordinary shares of Mural to Alkermes’ shareholders.

As part of the planned separation, Alkermes intends to transfer the assets, liabilities and operations of the historical oncology business to us, pursuant to the terms of a separation agreement, to be entered into between Mural and Alkermes. On the distribution date, Mural will issue its ordinary shares to Alkermes shareholders on a pro rata basis, with each Alkermes shareholder receiving ordinary shares of Mural for every ordinary shares of Alkermes held of record as of close of business on , 2023, the record date for the distribution. Registered shareholders will receive cash in lieu of any fractional Alkermes’ ordinary shares that they would have received as a result of the application of the distribution ratio. Following the separation and distribution, Mural will operate as an independent, publicly traded company. The distribution is subject to the satisfaction or waiver by Alkermes of certain conditions. For a more detailed description of these conditions, see the section of this information statement captioned “The Separation and Distribution—Conditions of the Distribution.”

## [Table of Contents](#)

The distribution is intended to be tax-free for U.S. federal income tax and Irish tax purposes to Alkermes shareholders.

We expect to complete the separation and distribution in the \_\_\_\_\_ quarter of 2023; however, there can be no assurance regarding the ultimate timing of the separation and distribution or that the separation and distribution will be completed at all.

Our historical financial statements have been prepared on a carve-out basis and are derived from Alkermes plc's consolidated financial statements and accounting records. Our financial statements are presented in conformity with accounting principles generally accepted in the U.S. ("GAAP"). See Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, in the notes to the combined financial statements appearing elsewhere in this information statement for additional information on the preparation and basis of presentation of the combined financial statements. Our financial position, results of operations and cash flows historically operated, and will continue to operate, as part of Alkermes plc's financial position, results of operations and cash flows prior to and until the distribution of our ordinary shares to Alkermes plc's shareholders. The historical combined financial statements may not be indicative of our future performance and do not necessarily reflect what our combined results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company during the periods presented. We expect that changes will occur in our operating structure and our capitalization as a result of the separation from Alkermes. See the section of this information statement entitled "The Separation and Distribution" for additional detail.

### **Results of Operations**

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

#### *Revenue*

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

#### *Research and Development Expenses*

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

## [Table of Contents](#)

The following table sets forth our R&D expenses for the years ended December 31, 2022 and 2021 relating to our development programs, listed by nature of such services:

(In millions)	Year Ended December 31,		Change
	2022	2021	
<b>External R&amp;D expenses:</b>			
Development programs:			
nemvaleukin			
ARTISTRY-1	\$ 14.4	\$ 30.6	\$(16.2)
ARTISTRY-2	11.2	13.4	(2.2)
ARTISTRY-3	2.1	1.8	0.3
ARTISTRY-6	9.7	6.0	3.7
ARTISTRY-7	15.6	5.3	10.3
Other program spend	24.8	23.0	1.8
Early discovery programs	7.0	3.5	3.5
Other external R&D expenses	13.2	12.6	0.6
Total external R&D expenses	98.0	96.2	1.8
<b>Internal R&amp;D expenses:</b>			
Employee-related	58.0	52.7	5.3
Occupancy	9.9	9.7	0.2
Depreciation	1.3	1.2	0.1
Total internal R&D expenses	69.2	63.6	5.6
Research and development expenses	\$167.2	\$159.8	\$ 7.4

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

The decrease in expenses related to nemvaleukin was primarily due to decreased spend on the ARTISTRY-1 and ARTISTRY-2 studies, partially offset by increased spend on the ARTISTRY-6 and ARTISTRY-7 studies. For additional detail on the ARTISTRY development program for nemvaleukin, see “Business—Our Programs—Nemvaleukin Program” in this information statement. The increase in early discovery programs was primarily due to increased spend on the IL-18 and IL-12 early-stage oncology development programs. The increase in employee-related expense was primarily related to an increase of \$3.9 million in salaries, benefits, and temporary labor.

### *General and Administrative Expenses*

(In millions)	Year Ended December 31,		Change
	2022	2021	
General and administrative expense	\$ 17.7	\$ 15.5	\$ 2.2

General and administrative (“G&A”) expenses consist primarily of an allocation of salaries and related costs for personnel, including share-based compensation and travel expenses for Alkermes employees in executive, operational, finance, legal, business development, information technology, and human resource functions. Other

## [Table of Contents](#)

G&A expenses include an allocation of Alkermes' facility-related costs, professional fees for accounting, tax, legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents. We recognize all G&A expenses as incurred.

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

### *Income Tax Provision*

(In thousands)	Year Ended December 31,		Change
	2022	2021	
Income tax provision	\$ 4,884	\$ 68	\$ 4,816

The income tax provision in 2022 was primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Internal Revenue Code of 1986, as amended (the "Code"). The income tax provision in 2021 was primarily due to taxes on U.S. taxable income.

Effective in 2022, the Tax Cuts and Jobs Act of 2017 requires us to capitalize, and subsequently amortize, R&D expenses over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. In 2022, this resulted in a material increase to our U.S. income tax liability and a material decrease to cash flows from operating activity. We expect an impact from this legislative change throughout the amortization period.

As of December 31, 2022, we had \$583.8 million of Irish net operating loss carryforwards, \$4.6 million of U.S. federal R&D credits and \$5.9 million of state R&D credits, which will either expire on various dates through 2042 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish taxable income and non-U.S. tax, respectively. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities and may be subject to limitations based upon changes in the ownership of our ordinary shares. Note that the tax attributes referred to above were calculated based on the separate return method and do not represent the tax attributes that will transfer with us on separation.

### **Liquidity and Capital Resources**

We have historically participated in Alkermes' centralized approach to cash management, and, therefore, there were no cash amounts specifically attributable to us for the historical periods presented. Historically, the primary source of liquidity for our business was funding by Alkermes of the expenses allocated to the oncology business from Alkermes. Prior to the separation, transfers of cash to and from Alkermes have been reflected in net parent investment in the historical combined balance sheets, statements of cash flows and statements of changes in net parent investment. We have not reported cash or cash equivalents for the periods presented in the combined balance sheets. We expect Alkermes to continue to fund the cash needs of the oncology business through the date of the separation.

### *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 may incur additional costs associated with operating as a public company. Our expenses may also increase as we:

- leverage our programs to continue advancing our product candidates into preclinical and clinical development;



## Table of Contents

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

We believe that the contribution of approximately \$ \_\_\_\_\_ from Alkermes to us or one of our subsidiaries immediately prior to or in connection with the separation will enable us to fund our operating expenses and capital expenditure requirements through \_\_\_\_\_. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including medical affairs, manufacturing and distribution, if any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the cost of establishing sales, marketing and distribution capabilities if any of our product candidates receive regulatory approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates or products, if any.

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

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

## [Table of Contents](#)

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

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

### *Going Concern*

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

Our ability to fund operations and capital needs will depend on funding from Alkermes that will be contributed to us or one of our subsidiaries immediately prior to or in connection with the separation to cover our capital needs following the separation and until we are able to access capital markets and/or other sources of capital, as further described below. We have incurred recurring losses, including net losses of \$189.8 million and \$175.4 million for the years ended December 31, 2022 and 2021, respectively.

As Alkermes manages our cash and financing arrangements, excess cash generated, if any, is deemed remitted to Alkermes and all sources of cash are deemed funded by Alkermes. We expect to continue to generate operating losses for the foreseeable future. Our continued operations are dependent on continued funding by Alkermes and our ability to generate cash from operating activities and to raise additional capital to finance our future operations. Our failure to raise capital as and when needed will have a negative impact on our financial condition and our ability to continue to pursue our business strategies, which would adversely affect our business prospects, or we may be unable to continue operations.

If we are unable to obtain funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned R&D programs or be unable to expand or continue operations. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. Based on our recurring losses from operations incurred, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance our future operations, we have concluded that there is substantial doubt about our ability to continue as a going concern for a period of one year from the date that the combined financial statements are issued. See Note 1, Organization and Description of Business, in the notes to the combined financial statements appearing elsewhere in this information statement.

## [Table of Contents](#)

### *Cash Flows*

The following table summarizes our cash flow activity:

(In millions)	Year Ended December 31,	
	2022	2021
Cash, cash equivalents and restricted cash, beginning of period	\$ —	\$ —
Cash flows used in operating activities	(168.6)	(156.7)
Cash flows used in investing activities	(5.5)	(4.4)
Cash flows provided by financing activities	174.1	161.1
Cash, cash equivalents and restricted cash, end of period	<u>\$ —</u>	<u>\$ —</u>

### *Operating Activities*

Net cash used in operating activities for the year ended December 31, 2022 was \$168.6 million which is primarily the result of our net loss of \$189.8 million, partially offset by non-cash charges of \$13.5 million. The most significant non-cash charge we incurred was share-based compensation of \$11.9 million. We generated \$7.7 million in cash from working capital, primarily related to an \$8.4 million increase in accounts payable and accrued expenses, partially offset by a \$5.9 million decrease in our right-of-use assets and a \$5.9 million decrease in our operating lease liabilities.

Net cash used in operating activities for the year ended December 31, 2021 was \$156.7 million which is primarily the result of our net loss of \$175.4 million, partially offset by non-cash charges \$13.0 million. The most significant non-cash charge we incurred was share-based compensation of \$11.5 million. We generated \$5.8 million from working capital primarily due to a \$5.5 million increase in accounts payable and accrued expenses, partially offset by a \$5.7 million decrease in our right-of-use assets and a \$4.8 million decrease in our operating lease liabilities.

### *Investing Activities*

Net cash used in investing activities was \$5.5 million and \$4.4 million for the years ended December 31, 2022 and 2021, respectively, which was attributed to the purchase of property and equipment.

### *Financing Activities*

As Alkermes manages our cash and financing arrangements, all sources of cash are deemed funded by Alkermes. Net cash provided by financing activities for the years ended December 31, 2022 and 2021 was due to the funding of our operating and investing activities by Alkermes.

### **Contractual Obligations and Commitments**

Our only lease at December 31, 2022 and 2021 was an operating lease for approximately 180,000 square feet of corporate office space, administrative areas and laboratories at 850 and 852 Winter Street in Waltham, Massachusetts, which includes 34,000 square feet of laboratory space (as amended, the "Winter Street Lease"). Under the terms of the Winter Street Lease, we also have the ability to sub-lease our corporate office and laboratory space. The original lease commenced in 2010 and was extended, at Alkermes' option, for approximately five years in 2020. The extension term commenced in March 2021 for approximately 163,000 square feet of space and in September 2021 for the remaining approximately 17,000 square feet of space. The Winter Street Lease expires in 2026 and includes a tenant option to extend the term of the Winter Street Lease for an additional five-year period, which we are not reasonably certain to exercise. We expect the Winter Street

## [Table of Contents](#)

Lease will be assigned to us in connection with the separation and will be used solely for our operations. Alkermes has been primarily obligated to the landlord for the Winter Street Lease, and, following the separation, we expect that Alkermes will be jointly and severally liable with us for, and will continue to guarantee, all obligations under the Winter Street Lease. Furthermore, Alkermes is the applicant with respect to the letter of credit security deposit that secures the obligations of the tenant under the Winter Street Lease. Alkermes currently maintains the \$1.9 million collateralized letter of credit. As we did not have legal ownership over any bank accounts, there were no cash or cash equivalents balances specifically attributable to us for the historical periods presented and, accordingly, no amount is reflected in the combined financial statements related to the letter of credit.

As of December 31, 2022, the remaining contractual operating lease liability associated with the Winter Street Lease was \$19.4 million. Our future payments under this lease are \$6.4 million, \$6.5 million, \$6.6 million and \$2.5 million in 2023 through 2026, respectively. For additional information on our operating lease, see Note 5, Leases, in the notes to the combined financial statements appearing elsewhere in this information statement.

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.

We have open purchase orders for equipment as part of our normal course of business. At December 31, 2022 and 2021, our open purchase orders for capital commitments were \$0.8 million and \$0.4 million, respectively.

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

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

#### *Accrued Research and Development*

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

## [Table of Contents](#)

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

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

### *Share-Based Compensation Expense*

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

### *Leases*

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

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

Operating lease liabilities and their corresponding right-of-use assets are initially recorded at the lease commencement date based on the present value of lease payments over the expected remaining lease term. Certain adjustments to right-of-use assets may be required for items such as prepaid or accrued lease payments as well as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we

## [Table of Contents](#)

utilize an incremental borrowing rate to discount lease payments, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate the incremental borrowing rate, a credit rating applicable to us is estimated using a synthetic credit rating analysis since we do not currently have a rating agency-based credit rating.

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

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

### *Income Taxes*

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

### *Allocation of Expenses*

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

### *Recently Issued and Adopted Accounting Pronouncements*

A description of recently issued and adopted accounting pronouncements 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 combined financial statements appearing elsewhere in this information statement.

### **Transition From Alkermes and Costs to Operate as an Independent Company**

The combined financial statements reflect our operating results and financial position as our business was operated by Alkermes, rather than as an independent company. We may incur additional ongoing operating expenses to operate as an independent company. These costs will 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 are currently building our administrative infrastructure. We expect to enter into a transition services agreement with Alkermes that will provide us with certain services and resources related to corporate functions for an initial term of \_\_\_\_\_, as applicable. Historically, Alkermes has provided our business with significant corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, which we refer to collectively as the “Alkermes Services.” We will pay Alkermes fees for the Alkermes Services, to be mutually agreed upon by us and Alkermes as provided under the transition services agreement, which fees will be based on Alkermes’ cost of providing the Alkermes Services. This transition services agreement will allow us to operate our business independently prior to establishing a standalone infrastructure. During the transition from Alkermes, we will incur non-recurring expenses to establish and expand our infrastructure.

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

### **Transactions with Related and Certain Other Parties**

Prior to or concurrently with the distribution, we expect to enter into certain agreements with Alkermes relating to the separation, including a separation agreement, transition services agreements, a tax matters agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail in the section captioned “Certain Relationships and Related Person Transactions,” appearing elsewhere in this information statement.

### **Quantitative and Qualitative Disclosures about Market Risk**

We have historically participated in Alkermes’ centralized approach to cash management and, therefore, there were no cash or investment amounts specifically attributable to us for the historical periods presented as subject to interest rate risk. All of our employees and substantially all of our operations are currently located in the U.S. and as a result have had minimal exposure to fluctuations in non-U.S. currency exchange rates. Accordingly, we believe we do not have a material exposure to interest rate or non-U.S. currency risk.

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

### **Emerging Growth Company and Smaller Reporting Company Status**

In April 2012, the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”) was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to “opt out” of the exemption for the delayed adoption of certain accounting standards, and therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standards and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

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



## BUSINESS

### **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 novel, investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers. Our lead product candidate, nemvaleukin alfa (“nemvaleukin”), is an investigational, engineered interleukin-2 (“IL-2”) cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human IL-2 (“rhIL-2”), while mitigating its hallmark toxicities. In our clinical proof of concept study, nemvaleukin generated durable responses as a single agent and in combination with pembrolizumab across a range of tumor types. Nemvaleukin is currently in two potentially registrational studies, one for the treatment of mucosal melanoma as a monotherapy and one for the treatment of platinum-resistant ovarian cancer (“PROC”) in combination with pembrolizumab. A registrational study is a clinical trial designed to obtain data that will be sufficient to support registration for regulatory approval. We plan to report topline results in mucosal melanoma and interim results in PROC in . In addition to nemvaleukin, we are also developing engineered therapies targeting the interleukin-18 (“IL-18”) and interleukin-12 (“IL-12”) pathways, which have demonstrated therapeutic potential in third-party preclinical and clinical studies. We are currently conducting discovery-phase activities for our IL-18 and IL-12 programs, and we plan to nominate a product candidate in each program in 2024.

### **What are Cytokines?**

Cytokines are biologically active proteins that play an essential role in immune cell function. These proteins regulate immune responses by acting as chemical messengers for the body’s immune cells through receptor site binding. In patients with cancer, cytokines can help prime, expand, activate, and/or enhance activity of the immune system to recognize and eliminate tumor cells. Because of these characteristics, various cytokine pathways have been investigated as cancer immunotherapies. However, administering unmodified cytokines as therapeutics can present challenges, including narrow therapeutic indexes and unmanageable side effect profiles. For example, while rhIL-2 has been shown to be an effective treatment, having demonstrated complete and durable responses in patients with metastatic melanoma and renal cell carcinoma (“RCC”), use of rhIL-2 has been significantly limited due to associated toxicities such as capillary leak syndrome (“CLS”) and end-organ dysfunction, which can be severe and life-threatening.


### **Our Programs**

We are developing a portfolio of immunotherapies currently focused on proinflammatory cytokines, that leverages our significant immune cell modulation expertise and protein engineering capabilities. When developing product candidates, we apply a consistent analytical framework to focus on targets with sound biologic rationale and what we believe to be a surmountable technical challenge (e.g., overexpansion of regulatory T cells (“T<sub>regs</sub>”)) that has limited the mechanism to date. Once a target is identified, we apply our protein engineering capabilities to design a molecule that we believe can address the technical challenge. Our multi-faceted approach to cytokine engineering is aimed at maximizing the utility of identified cytokines and includes binding selectivity, tumor-targeting, half-life modification and *in-vivo* assembly. As shown in the figure

## Table of Contents

below, our approach has yielded three distinct investigational immuno-oncology programs, each based on unique design approaches that we believe are potentially best suited for each cytokine:

### Multi-Faceted Immuno-Oncology Approach to Molecular Design Grounded in Strong Scientific Rationale



Program	Nemvaleukin alfa <sup>1</sup> [IL-2]	Engineered IL-18	Tumor-targeted split IL-12
Technical challenge	<ul style="list-style-type: none"> <li>Systemic toxicities due to overexpansion of T<sub>H1</sub> related to high-affinity IL-2R binding</li> </ul>	<ul style="list-style-type: none"> <li>Limited clinical efficacy due to IL-18BP tightly binding to IL-18, neutralizing IL-18 receptor activation</li> </ul>	<ul style="list-style-type: none"> <li>Limited rhIL-12 clinical utility due to severe toxicities where tolerable systemic dosing regimens are not efficacious</li> </ul>
Protein engineering solution	<ul style="list-style-type: none"> <li>Fusion of circularly permuted IL-2 with the IL-2Rα subunit resulting in only activating intermediate-affinity IL-2R</li> </ul>	<ul style="list-style-type: none"> <li>Engineered IL-18 designed with a half-life extension and to be resistant to IL-18BP neutralization, while retaining and optimizing the activity of IL-18</li> </ul>	<ul style="list-style-type: none"> <li>Separate inactive tumor-targeted IL-12 subunits assemble and activate in the tumor</li> </ul>

1. Intrinsically active stable, not degraded fusion protein, sterically occluded from binding to the high-affinity IL-2R

#### Nemvaleukin Alfa

We used our protein engineering approach to design the molecular structure of nemvaleukin, our lead product candidate. Nemvaleukin is engineered to selectively bind to the intermediate-affinity IL-2 receptor (“IL-2R”) complex and preferentially expand tumor-killing immune cells, such as CD8+ T cells and natural killer cells (“NK cells”), with minimal expansion of immunosuppressive Tregs. Nemvaleukin is an intrinsically active, stable fusion protein and, once administered, does not degrade to unmodified IL-2, which we believe contributes to its potential for enhanced tolerability.

**Objective Criteria to Assess Change in Tumor Burden.** We assessed clinical response in ARTISTRY-1 using the Response Evaluation Criteria in Solid Tumors guidelines version 1.1 (“RECIST 1.1”), which are widely accepted, published criteria for assessing tumor burden and disease progression in oncology clinical trials. Under RECIST 1.1, (a) a partial response (“PR”) requires at least a 30% decrease in the sum of diameters of target lesions compared to the baseline sum diameters, (b) progressive disease (“PD”) requires at least a 20% increase in the sum of diameters of target lesions, (c) stable disease (“SD”) is defined as neither sufficient lesion shrinkage to qualify as a PR nor sufficient lesion increase to qualify as PD, and (d) a complete response (“CR”) means the disappearance of all target lesions and reduction in short axis of any pathological lymph nodes to <10mm.

Objective response rate (“ORR”) often used in oncology clinical trials, is the percentage of evaluable patients who had a CR or PR, and disease control rate (“DCR”) is the percentage of evaluable patients who had a CR, PR, or SD.

**ARTISTRY-1 Clinical Trial.** ARTISTRY-1, our Phase 1/2 clinical proof of concept study for nemvaleukin in which nemvaleukin is administered intravenously (“IV nemvaleukin”), was designed to assess whether nemvaleukin could recapitulate the anti-tumor activity of high-dose rhIL-2 and to assess nemvaleukin’s safety profile. ARTISTRY-1 is a global, multicenter, open-label study with three parts: Part A (dose-escalation monotherapy, 46 subjects), Part B (dose-expansion monotherapy, 47 subjects with melanoma and 27 subjects with RCC), and Part C (combination therapy with pembrolizumab, 166 subjects including 43 subjects rolled over from Part A or Part B). The primary endpoints are the incidence of dose limiting toxicities (Part A), the incidence and severity of treatment-emergent adverse events (Parts A, B, and C), and the ORR based on RECIST 1.1 as described above (Parts B and C). As ARTISTRY-1 was not designed to generate treatment comparisons, these endpoints are summarized descriptively.

We have observed objective responses with nemvaleukin as monotherapy in cancers for which high-dose rhIL-2 obtained regulatory approval, such as melanoma and RCC. In ARTISTRY-1, among six evaluable mucosal melanoma patients as of October 3, 2022, we observed two PRs (one confirmed, which means it meets the RECIST 1.1 criteria for a PR in two consecutive scans) and two patients with SD, representing an ORR of 33% and an overall DCR of 67%. Under RECIST 1.1 criteria, which are widely accepted criteria for assessing tumor burden in clinical trials, a PR requires at least a 30% decrease in the sum of diameters of target lesions compared to the baseline sum diameters, a CR means the disappearance of all target lesions and reduction in

## [Table of Contents](#)

short axis of any pathological lymph nodes to <10mm, and SD is defined as neither sufficient shrinkage to qualify for a PR nor sufficient increase to qualify for progressive disease (which is at least a 20% increase in the sum of diameters of target lesions). ORR means the percentage of patients who had a CR or PR among the subjects evaluable for antitumor activity. DCR means the percentage of patients who had a CR, PR, or SD.

Nemvaleukin in combination with pembrolizumab has shown, in some patients, durable and deepening responses in a range of tumor types. A durable response is a response with a duration that exceeds the response generally observed with standard of care treatment. In the context of high unmet need disease states such as mucosal melanoma and PROC, and taking into account standard of care treatment in these disease states, we regard a response that exceeds six months as durable. In ARTISTRY-1, among 14 evaluable patients with PROC as of October 3, 2022, treatment with nemvaleukin in combination with pembrolizumab resulted in two CRs and two PRs (one confirmed), with a median duration of response of 50.3 weeks, and six patients with SD, representing an overall response rate of 29% and an overall DCR of 71%. A deepening response is a response in which tumors have continued to shrink in subsequent scans. In ARTISTRY-1 (Part C), for example, one patient began treatment in February 2020, achieved a 55% reduction (a PR per RECIST 1.1 criteria) in tumor at Cycle 4, and complete resolution of the tumor twenty cycles later (a CR per RECIST 1.1 criteria). This patient remained on treatment for over two years. In addition to the responses in PROC, we also observed objective responses, or patients with PRs or CRs, in breast, bladder, cervical, gastrointestinal, head & neck, lung, melanoma, and renal cell cancers when nemvaleukin was administered in combination with pembrolizumab. ARTISTRY-1 is an ongoing study, and all data is provided as of the dates noted herein and is subject to final validation upon database lock.

*ARTISTRY-6 and ARTISTRY-7 Clinical Trials.* In addition, we are currently evaluating nemvaleukin in two potentially registrational studies: ARTISTRY-6, a Phase 2 study in which Cohort 2 is evaluating nemvaleukin as a monotherapy in patients with advanced mucosal melanoma, and ARTISTRY-7, a Phase 3 study which is evaluating nemvaleukin in combination with pembrolizumab in patients with PROC. The U.S. Food and Drug Administration (“FDA”) has granted Orphan Drug designation (“ODD”) to nemvaleukin for the treatment of mucosal melanoma. The FDA also has granted Fast Track designation (“FTD”) to nemvaleukin for the treatment of mucosal melanoma and to nemvaleukin in combination with pembrolizumab for the treatment of PROC.

ARTISTRY-6 is a global, multi-center, open-label cohort study of nemvaleukin monotherapy in patients with advanced cutaneous melanoma or advanced mucosal melanoma who have previously received anti-programmed death-ligand 1 (“PD-L1”) therapy. The primary endpoint is ORR based on RECIST 1.1 while secondary endpoints include duration of response, progression-free survival (“PFS”), DCR, time to response and safety and tolerability. ARTISTRY-6 is planned to enroll up to 176 patients, including up to 106 patients with advanced cutaneous melanoma and approximately 70 patients with advanced mucosal melanoma. Subjects will be enrolled into one of three cohorts based on tumor type: advanced cutaneous melanoma (Cohorts 1 and 3) and advanced mucosal melanoma (Cohort 2). The study endpoints will be summarized descriptively and analyzed and reported separately for each cohort and dosing schedule tested in the study. ARTISTRY-7 is a global, multicenter, open-label, randomized study of nemvaleukin in combination with pembrolizumab compared to investigator’s choice chemotherapy in patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. The primary endpoint is PFS, with ORR as a key secondary endpoint. This study is planned for approximately 376 patients across four arms: 141 patients in the combination therapy arm, 47 patients in the pembrolizumab monotherapy arm, 47 patients in the nemvaleukin monotherapy arm, and 141 patients in the investigator’s choice chemotherapy arm. Summary statistics will be provided by treatment arm, and a statistical comparison will be conducted between the combination therapy arm and the chemotherapy arm. The pembrolizumab and nemvaleukin monotherapy arms are included in the study to discern the treatment effect of nemvaleukin and pembrolizumab individually.

We plan to report top-line results in mucosal melanoma and interim results in PROC in . If the data from one or both of these potentially registrational clinical studies are positive and we, in consultation with the FDA, determine that the results of either or both of these studies are sufficient to support the filing of a Biologics License Application (“BLA”) for nemvaleukin, we plan to submit one or more BLAs to the FDA to obtain approval to market nemvaleukin in the United States (“U.S.”). Subsequently, we may pursue similar marketing authorizations in other jurisdictions. The FDA may grant ODD to a product candidate being developed to treat a rare disease or condition that affects fewer than 200,000 patients in the U.S. Benefits of ODD include tax credits for qualified clinical trials, exemption from user fees, and the potential for seven years of market exclusivity if the product

## [Table of Contents](#)

candidate receives FDA approval for the orphan-designated disease or condition. The FDA may grant FTD a product candidate that has the potential to address an unmet medical need for a serious condition. Potential advantages of FTD include more frequent interactions with the FDA during development, eligibility for accelerated approval and priority review (if the relevant criteria are met), and the ability to submit completed sections of a BLA for FDA review on a rolling basis, rather than waiting to submit the BLA when the entire application is complete. FTD does not assure a faster development or FDA review process, however.

To explore nemvaleukin's potential broad utility and ability to offer more flexible and convenient options to patients, caregivers, and providers, we are also evaluating subcutaneous dosing and alternative intravenous ("IV") dosing frequencies in a variety of studies.

### **Our IL-18 and IL-12 Programs**

We are also developing engineered IL-18 and IL-12 cytokines, which are currently in the discovery phase. We expect to nominate a product candidate in each program in 2024. For each cytokine pathway, we have developed what we believe is an innovative protein engineering solution designed to address the therapeutic limitations of the native molecules. For IL-18, we are engineering variants that are resistant to the naturally-occurring IL-18 binding protein ("IL-18BP"), with an aim to enhance pharmacokinetic ("PK") properties, including half-life extension, and IL-18 signaling activity. For IL-12, we are developing a tumor-targeted IL-12 molecule that is delivered in the form of inactive subunits that assemble and activate within the tumor, potentially avoiding toxicities associated with systemic exposure.

### **Our Strategy**

Our goal is to discover and develop immunotherapies that may help meaningfully improve the lives of patients with a variety of cancers. Leveraging our immune cell modulation expertise and protein engineering capabilities, we aim to discover, develop and ultimately commercialize, immunotherapies designed to address serious unmet patient needs. Key elements of our strategy include:

- ***Progress nemvaleukin from clinical development to commercialization, as monotherapy for the treatment of mucosal melanoma and in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer.*** We are developing nemvaleukin, a novel IL-2 variant, in two potentially registrational studies, ARTISTRY-6 and ARTISTRY-7, which, to our knowledge, make nemvaleukin the IL-2 variant furthest advanced in clinical development. Cohort 2 of ARTISTRY-6 is evaluating nemvaleukin as monotherapy in patients with advanced mucosal melanoma. This trial was designed based on the objective responses observed with nemvaleukin monotherapy in ARTISTRY-1 in tumor types for which high-dose rhIL-2 had previously obtained regulatory approval, such as melanoma and RCC, validating the potential therapeutic benefit of nemvaleukin. In that study, among the six evaluable patients with mucosal melanoma as of October 3, 2022, nemvaleukin single agent activity was observed as follows: two PRs (one confirmed) and two patients with stable disease, representing an overall DCR of 67%. ARTISTRY-7 is evaluating nemvaleukin in combination with pembrolizumab in patients with PROC. This study was designed based on data from ARTISTRY-1, in which, among 14 evaluable patients with PROC treated with nemvaleukin in combination with pembrolizumab as of October 3, 2022, two CRs, two PRs (one confirmed) were observed, with a median duration of response of 53 weeks, and six patients had stable disease, representing an overall DCR of 71%. ARTISTRY-1 is an ongoing study, and all data is provided as of the dates noted herein and is subject to final validation upon database lock. We currently expect each of ARTISTRY-7 and the mucosal melanoma cohort of ARTISTRY-6 to have data readouts in . The FDA has granted ODD and FTD to nemvaleukin for the treatment of mucosal melanoma and FTD to nemvaleukin in combination with pembrolizumab for the treatment of PROC. If the data from either, or both of these, potentially registrational clinical studies is positive, we plan to submit a BLA to the FDA for marketing approval in the U.S.
- ***Expand nemvaleukin's development into additional tumor types for which scientific rationale supports nemvaleukin's therapeutic potential.*** The IL-2 pathway is a key regulator of the body's immune response. Selective binding to the intermediate affinity IL-2R, as observed with nemvaleukin, is associated with the ability to expand and activate antitumor effector cells including CD8+ T cells and NK

cells, with minimal expansion of T<sub>regs</sub>, which are associated with immune suppression. We believe these pharmacodynamic properties, in combination with nemvaleukin's clinical profile to date, support nemvaleukin's potential utility in a range of tumor types, whether as monotherapy or in combination with other treatments. Across ARTISTRY-1 and ARTISTRY-2, our Phase 1/2 studies evaluating the efficacy, safety and tolerability of nemvaleukin in monotherapy and combination settings, objective responses have been observed in a wide array of solid tumors, including in difficult-to-treat tumors for which checkpoint inhibitors ("CPIs") are not approved and in patients with tumors that progressed following CPI treatment. In the nemvaleukin monotherapy setting, responses were observed in RCC and melanoma. Using nemvaleukin in combination with pembrolizumab, objective responses were observed in breast, bladder, cervical, gastrointestinal, head & neck, Hodgkin's lymphoma, lung, melanoma, ovarian and renal cell cancers. Based on these responses, and subject to the availability of funding, we plan to explore the potential of nemvaleukin in a number of additional tumor types. Our current plans include continued development of nemvaleukin in cutaneous melanoma, where we have observed objective responses using nemvaleukin as both monotherapy and in combination with pembrolizumab.

- **Explore the next generation of dosing for nemvaleukin.** We believe that nemvaleukin has potential to be utilized across a range of tumor types and in combination with multiple treatment options. The initial IV nemvaleukin dosing regimen that we have studied is daily times five in three-week cycles, which was modeled after the currently approved high-dose rhIL-2 dosing schedule. To explore nemvaleukin's potential broad utility and ability to offer more flexible and convenient options to patients, caregivers, and providers, we are also evaluating subcutaneous dosing and alternative IV dosing frequencies.
- **Advance our IL-18 and IL-12 programs into clinical development.** We believe there is significant opportunity for the development of additional cytokines as therapeutic treatments in cancer. IL-18 and IL-12 are cytokines that have shown potential in preclinical and clinical studies of other product candidates targeting the IL-18 and IL-12 pathways. IL-18 is a potent cytokine that plays a key role in reinvigorating exhausted T cells and activating existing immune cells to release interferon gamma ("IFN-g"), resulting in anti-tumor activity. IL-12 is another potent, proinflammatory cytokine that plays a key role in the body's response to pathogen infection, by signaling through the IL-12 receptor complex on T cells, among others. However, both IL-18 and IL-12 have been limited in their development due to limitations of the native molecules, such as limited activity in the case of IL-18 due to neutralizing IL-18BP and systemic toxicity in the case of IL-12. With our advanced immune cell modulating expertise and protein engineering capabilities, we have developed programs designed to leverage IL-18 and IL-12 biology and address the therapeutic limitations of the native molecules. For IL-18, we are engineering variants that are designed to be resistant to IL-18BP to enhance PK properties and IL-18 signaling. For IL-12, we are developing a tumor-targeted IL-12 molecule that is delivered in the form of two inactive subunits that assemble and activate within the tumor to avoid systemic exposure. Each of these programs is currently in the discovery phase, and we plan to nominate a candidate in each program in 2024.
- **Continue to advance our sophisticated protein engineering capabilities through strategic investment.** We have over \_\_\_\_\_ years of cytokine and protein engineering experience and we continually seek to build and improve upon our existing capabilities. Our multi-faceted engineering approach, aimed at maximizing cytokine utility, includes binding selectivity, tumor-targeting, half-life modification and *in-vivo* assembly. We plan to continue to invest in our capabilities with the goal of developing and delivering meaningful therapeutic options to patients with cancer.
- **Establish an integrated development and commercial capability.** We currently own worldwide development and commercialization rights to each of our development programs and product candidates. Subject to regulatory approval, we plan to commercialize our product candidates in key geographies. For example, in January 2023, we announced that the UK's Medicines and Healthcare Products Regulatory Agency (the "MHRA") had granted an Innovation Passport designation for nemvaleukin for the treatment of mucosal melanoma, under the UK's Innovative Licensing and Access Pathway (the "ILAP"), and we intend to continue the application process of designating nemvaleukin under the ILAP. In addition, in order to maximize the potential of our product candidates and reach the broadest number of patients, we may selectively seek partnerships or collaborations to develop and/or commercialize our products.

## **Disease and Investigational Therapeutic Background**

### **Cancer Immunotherapies & Cytokines**

The introduction of immunotherapies has ushered in a new era of cancer treatments and has brought significant benefits for patients beyond those achieved with previous standards of care such as chemotherapy, radiotherapy, and surgery. The goal of immunotherapy is to harness the natural immune system to fight cancer. Immunotherapy approaches have evolved and expanded to consider a multitude of mechanisms targeting multiple steps across the cancer immunity cycle. These include targeting of immunoinhibitory pathways (e.g., immune CPIs) and immunostimulatory pathways (e.g., IL-2 and antitumor vaccines). Checkpoint modulation has driven the growth of the immuno-oncology field and is forecasted to reach approximately \$88 billion by 2027; however, there remains significant unmet need for patients.

Cytokines are biologically active proteins that play an essential role in immune cell function within both innate and adaptive elements of the immune system. Cytokines regulate immune responses by acting as chemical messengers for the body's immune cells through receptor site binding. Interleukins, such as IL-2, IL-12, IL-18 and interferon alpha ("IFN- $\alpha$ "), are specific types of cytokines produced primarily by cells of the immune system to signal and organize immune responses. In cancer, cytokines can help prime, expand, activate, and/or enhance activity of the immune system to recognize and eliminate tumor cells. Because of these characteristics, various cytokines have been investigated as cancer immunotherapies.

Despite advances in immunotherapy, significant unmet need remains, as not all patients are able to derive benefit from existing immunotherapies, and further, certain of those patients who initially respond to existing immunotherapies experience a subsequent relapse in their cancer. With respect to cytokines specifically, although high-dose rhIL-2 and IFN- $\alpha$  are approved immunotherapies, cytokine therapies have not achieved broad therapeutic success due to a variety of limitations, including limited efficacy and severe toxicity. Additional research and new approaches to harness the potential of immunotherapies, including cytokine immunotherapies, are needed.

### **IL-2 Pathway as a Therapeutic Target**

The IL-2 pathway is an important and validated target in the immuno-oncology field. IL-2 is a naturally occurring cytokine that plays a pivotal role in regulating immune responses and can activate both immunosuppressive and antitumor mechanisms. IL-2 binds both the high-affinity trimeric IL-2R complex expressed on immunosuppressive CD4<sup>+</sup> T<sub>regs</sub> and vascular endothelial cells, and the intermediate-affinity dimeric IL-2R complex expressed predominantly on subsets of cells associated with antitumor activity including CD8<sup>+</sup> T cells and NK cells.

High-dose rhIL-2 was one of the first approved immuno-oncology agents. It has been shown to be an effective treatment, demonstrating complete and durable responses, including in metastatic melanoma and RCC, and in certain cases, patients with RCC remained disease free for ten years following surgical resection of residual disease. However, in clinical studies, only a fraction of patients achieved complete responses using this therapy; 6% in metastatic melanoma patients and 7% in metastatic RCC patients. Further, the use of high-dose rhIL-2 has been significantly limited due to associated toxicities such as CLS and end-organ dysfunction, which can be severe and life-threatening.

Mechanistically, the therapeutic potential of high-dose rhIL-2 is thought to be limited due to its potent binding to the high-affinity IL-2R, resulting in preferential expansion of immunosuppressive T<sub>regs</sub>, and due to the toxicities associated with upregulation of the high-affinity IL-2R on vascular endothelial cells.

A long-standing challenge in the immuno-oncology field has been to design a molecule that can leverage and expand upon the established antitumor effects of high-dose rhIL-2 while mitigating its hallmark toxicities. We believe this may be accomplished by designing a therapy that preferentially activates the intermediate affinity IL-2R, as described below in the section entitled "Nemvaleukin Program".

## IL-18 Pathway

IL-18 is a potent immune-stimulator of innate and adaptive immunity that has been shown to activate CD8+ T cells and NK cells. IL-18 was initially discovered as an IFN- $\gamma$ -inducing factor and recent research has shown IL-18's functional capacity to reinvigorate exhausted T cells and mature dendritic cells. However, the observed activity in clinical studies of IL-18 has been limited by rapid upregulation of the checkpoint protein IL-18BP, which neutralizes and inhibits IL-18 signaling.

## IL-12 Pathway

IL-12 is a heterodimeric protein consisting of two covalently linked subunits, p35 and p40, whose antitumor activity is driven through activation of both innate and adaptive immune compartments and production of immune-stimulating cytokines. IL-12 is recognized as a highly potent proinflammatory cytokine that has shown preclinical responses and clinical activity when delivered intratumorally by strongly activating CD8+ T and NK cells. However, the clinical utility of IL-12 therapy has been limited due to severe toxicities.

## Potential for Combination Therapies


Strategic combinations of therapies with complementary—and potentially synergistic—mechanistic effects may enhance the effectiveness of cancer treatments. For example, combining immunotherapies that target different steps in the cancer immunity cycle may provide an opportunity to enhance antitumor activity. Immunotherapy in combination with chemotherapy or radiotherapy may result in further enhancement of tumor killing and an increased durability of response. Additionally, combining immunotherapies with targeted therapies is another potential approach that may yield a synergistic benefit to augment antitumor effects.

## Our Approach

We are developing immunotherapies designed to optimize immune cell activity, a key driver of immune response, to treat a variety of cancers and improve patient outcomes. We are initially focused on proinflammatory cytokines, which can modulate multiple immune pathways and act across several phases of the cancer immunity cycle. Our investigational cytokine-based therapies are designed to expand, activate, and reinvigorate T cells and NK cells, while aiming to mitigate the negative effects associated with unmodified cytokines.

Cytokines have the potential to be potent immunotherapies against cancer. However, using unmodified cytokines as therapeutics presents challenges, including narrow therapeutic indexes and unmanageable side effect profiles. Furthermore, there are challenges in transforming cytokines into immunotherapies that are specific to each cytokine. Leveraging our significant immune cell modulation expertise and protein engineering capabilities, we approach each cytokine in a customized fashion with the goals of addressing its specific limitations and seeking to optimize its impact on immune cell activities. As shown in the figure below, our approach has yielded three distinct investigational immuno-oncology programs, each based on unique design approaches that we believe are potentially best suited for each cytokine:

### Multi-Faceted Immuno-Oncology Programs Grounded in Strong Scientific Rationale



Program	Nemvalcukin alfa <sup>3</sup> (IL-2)	Engineered IL-18	Tumor-targeted split IL-12
<b>Technical challenge</b>	<ul style="list-style-type: none"> <li>Systemic toxicities due to overexpansion of T<sub>H</sub>17 related to high-affinity IL-2R binding</li> </ul>	<ul style="list-style-type: none"> <li>Limited clinical efficacy due to IL-18BP tightly binding to IL-18, neutralizing IL-18 receptor activation</li> </ul>	<ul style="list-style-type: none"> <li>Limited rhIL-12 clinical utility due to severe toxicities where tolerable systemic dosing regimens are not efficacious</li> </ul>
<b>Protein engineering solution</b>	<ul style="list-style-type: none"> <li>Fusion of circularly permuted IL-2 with the IL-2R<math>\alpha</math> subunit resulting in only activating intermediate-affinity IL-2R</li> </ul>	<ul style="list-style-type: none"> <li>Engineered IL-18 designed with a half-life extension and to be resistant to IL-18BP neutralization, while retaining and optimizing the activity of IL-18</li> </ul>	<ul style="list-style-type: none"> <li>Separate inactive tumor-targeted IL-12 subunits assemble and activate in the tumor</li> </ul>

1. Intrinsically active stable, not degraded fusion protein, sterically occluded from binding to the high-affinity IL-2R

When developing our therapeutic candidates, we apply a consistent analytical framework to focus on targets with sound biologic rationale and what we believe to be a surmountable technical challenge (e.g., overexpansion

[Table of Contents](#)

of T<sub>regs</sub>) that has limited the mechanism to date. Once a mechanism is identified, we apply our protein engineering capabilities to design a molecule that we believe can address the technical challenge. Our multi-faceted approach to cytokine engineering is aimed at maximizing the utility of identified cytokines, and includes binding selectivity, tumor-targeting, half-life modification and *in-vivo* assembly.

**Our Programs**

**Our Pipeline**

Leveraging our protein engineering capabilities, we have advanced our lead product candidate, nemvaleukin, into potentially registrational clinical trials. Our clinical-stage pipeline showing the current status of nemvaleukin development across multiple indications is shown in the figure below.

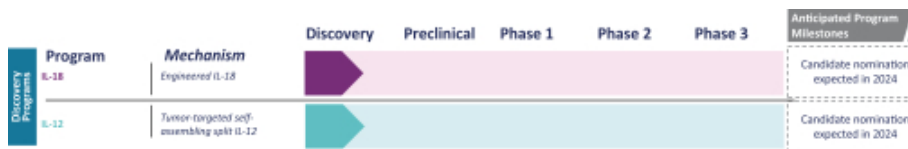
Clinical-Stage Pipeline Overview



1. Subject to patient enrollment
2. Pending identification of the recommended Phase 2 dose for the less frequent IV (“LFIV”) dosing regimen currently being evaluated in ARTISTRY-3

In addition to nemvaleukin, we have also applied our protein engineering capabilities to our IL-18 and IL-12 programs, which are currently in discovery phase and outlined in the figure below.

Discovery Programs



**Nemvaleukin Program**

**Goal**

Our nemvaleukin program seeks to leverage and expand upon the established antitumor effects of high-dose rhIL-2, while mitigating its hallmark toxicities. We believe that a molecule that achieves this goal could have potential applicability beyond those indications for which high-dose rhIL-2 therapy is approved, across a broad range of tumor types and as a complementary combination partner to a wide range of therapeutic approaches.

**Systematic Approach & Differentiation**

We have taken an intentional and systematic approach throughout our development of nemvaleukin, from the structure of the molecule to its clinical development, including designing the clinical development program to assess whether nemvaleukin could replicate and potentially expand the established clinical activity of high-dose rhIL-2, as measured by RECIST 1.1, while mitigating its associated toxicities. We believe that nemvaleukin is



differentiated from other IL-2 variants in development by its unique molecular design and resulting pharmacology, and the clinical development approach that we have taken:

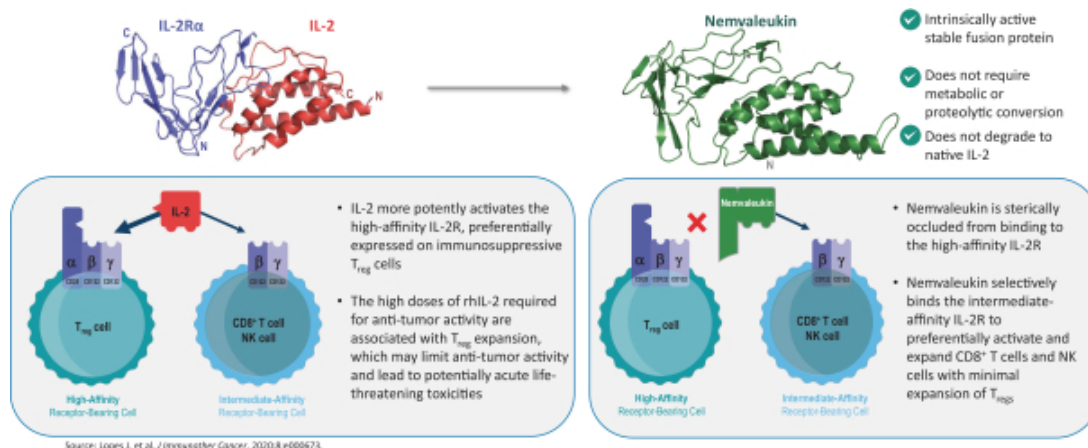
- **Molecule Design:** Nemvaleukin's unique molecular design arises directly from the natural biology of IL-2 and its receptors, which are leveraged to confer differentiated properties. Nemvaleukin is an engineered, stable fusion protein that selectively binds to the intermediate-affinity IL-2R complex. Nemvaleukin is designed to be inherently active without requiring any metabolic or proteolytic conversion, does not degrade into native IL-2 and has shown a unique pharmacodynamic profile.
- **Clinical Rationale:** We designed nemvaleukin's development program to assess whether nemvaleukin could recapitulate the clinical activity of high-dose rhIL-2. We have observed nemvaleukin monotherapy activity in cancers for which high-dose rhIL-2 obtained regulatory approval, such as in RCC and melanoma. To our knowledge, limited monotherapy activity has been demonstrated in solid tumors with other IL-2 variants in development. Nemvaleukin in combination with pembrolizumab has also shown, in some patients, durable and deepening responses in a range of tumor types.
- **Development Program:** Our current clinical development program for nemvaleukin is differentiated and tailored to address key unmet needs in the oncology treatment paradigm, with a focus on difficult-to-treat tumors for which CPIs are not approved (e.g., PROC) or where patients have progressed following CPI treatment (e.g., mucosal melanoma). In the future, we plan to broaden the areas of clinical development for nemvaleukin.

### Design of the Nemvaleukin Molecule

Nemvaleukin is a unique, investigational, engineered cytokine designed to potentially capture and expand the therapeutic benefits of high-dose rhIL-2. Nemvaleukin selectively binds to the intermediate-affinity IL-2R to preferentially activate antitumor effector cells, including CD8<sup>+</sup> T cells and NK cells, while mitigating both IL-2-associated expansion of T<sub>regs</sub>, which dampen immune responses against cancer, and activation of vascular endothelial cells that express the high-affinity IL-2R, which are associated with severe toxicities, including vascular leak syndrome.

To achieve this selectivity for the intermediate affinity IL-2R, we focused on the natural biology of IL-2 and its receptors, which we leveraged to confer differentiated properties to nemvaleukin. As shown in the figure below, nemvaleukin consists of a fusion between IL-2 and IL2R alpha ("IL-2R $\alpha$ "), which sterically occludes, or spatially blocks, nemvaleukin from binding to the high-affinity receptor. By combining the native IL-2 and IL-2R $\alpha$  sequences, we engineered a stable fusion protein that is designed to be highly selective for the intermediate affinity IL-2 receptor. Furthermore, nemvaleukin is designed to be inherently active without requiring any metabolic or proteolytic conversion, and does not degrade into native IL-2, which is associated with a lack of receptor binding specificity and hallmark IL-2 toxicity. These properties ensure that the molecule is immediately active and precludes conversion to a potentially more toxic form of IL-2.

Nemvaleukin Molecule Design



This molecule design theory has been supported by the clinical data we have generated to date. Cell expansion data from ARTISTRY-1 has shown that nemvaleukin expanded and activated cancer fighting CD8+ T cells and NK cells both systemically and in the tumor microenvironment (“TME”). We believe that activation and expansion of these effector cells in the periphery may be key in driving anti-tumor responses. Importantly, consistent with its design, nemvaleukin’s selectivity for the intermediate affinity receptor has, in the clinic, resulted in only minimal expansion of immunosuppressive T<sub>regs</sub>, which, as previously noted, dampen immune responses against cancer. We believe these features of nemvaleukin may widen its potential therapeutic window, including as discussed in the chart immediately below:

**Property**

Selective binding to the intermediate-affinity IL-2R

Intrinsically stable fusion protein that does not degrade to IL-2

Does not include non-natural/synthetic sequences or additional functionality

Does not require or undergo metabolic or proteolytic conversion

**Potential Benefit**

Preferentially expands antitumor effector cells, including CD8+ T cells and NK cells with limited effect on T<sub>regs</sub>, which have been shown to dampen immune responses against cancer, and mitigates activation of vascular endothelial cells, which are associated with severe toxicities, including vascular leak syndrome, both systemically and in the TME

Remains selective for the intermediate-affinity IL-2R, (as compared to native IL-2 that is preferential to the high-affinity IL-2R, which is associated with a lack of receptor binding specificity and hallmark IL-2 toxicity)

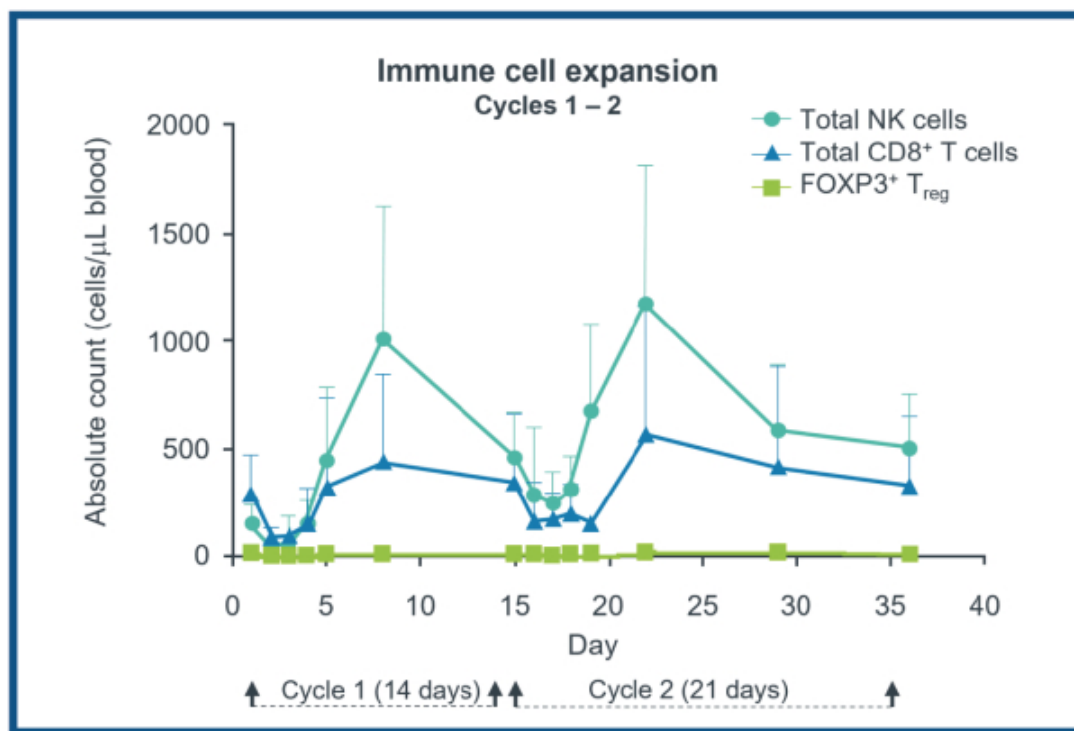
Designed to limit the potential for undesired off-target effects or counterproductive activities (e.g., immunogenicity)

Designed to be an inherently and immediately active molecule upon administration

## Table of Contents

The figure below shows results from cell expansion analyses from our initial clinical trial, ARTISTRY-1. The graphic shows the absolute count of immune cell expansion over time. Administration of nemvaleukin resulted in dose-dependent expansion of CD8+ T cells and NK cells with minimal non-dose-dependent effects on T<sub>regs</sub>. Our ongoing, potential registrational clinical trials are evaluating whether, and the manner in which, the clinical pharmacodynamic data presented below may correlate with a benefit-risk profile in mucosal melanoma and PROC.

### Clinical Pharmacodynamic Effects of Nemvaleukin



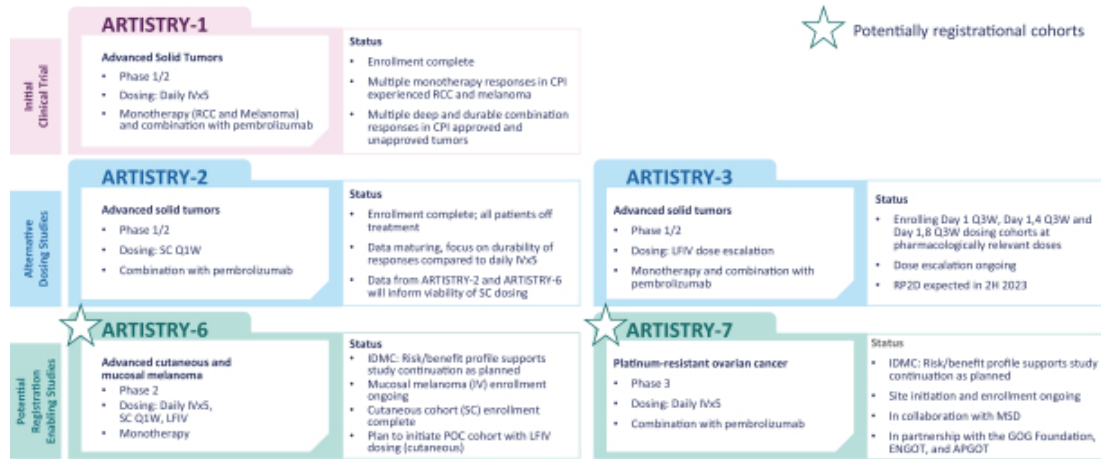
Nemvaleukin data are from the 6 mg/kg cohort in Part A of the study. For fold change plots, data are mean + SE (N=10). For time course plot, data are mean + SD (N=12). 1. Bhatt et al. Poster P123 presented at SITC 2018.

Fmax, maximum fold change; HD, high-dose; IL-2, interleukin-2; IV, intravenous; NK, natural killer; PD, pharmacodynamic; SD, standard deviation; SE, standard error; TID, 3 times daily; Treg, regulatory T cell.

### Nemvaleukin Clinical Data To-Date

We have several ongoing clinical studies of nemvaleukin including ARTISTRY-1, ARTISTRY-2, ARTISTRY-3, ARTISTRY-6, ARTISTRY-7.

ARTISTRY Development Program

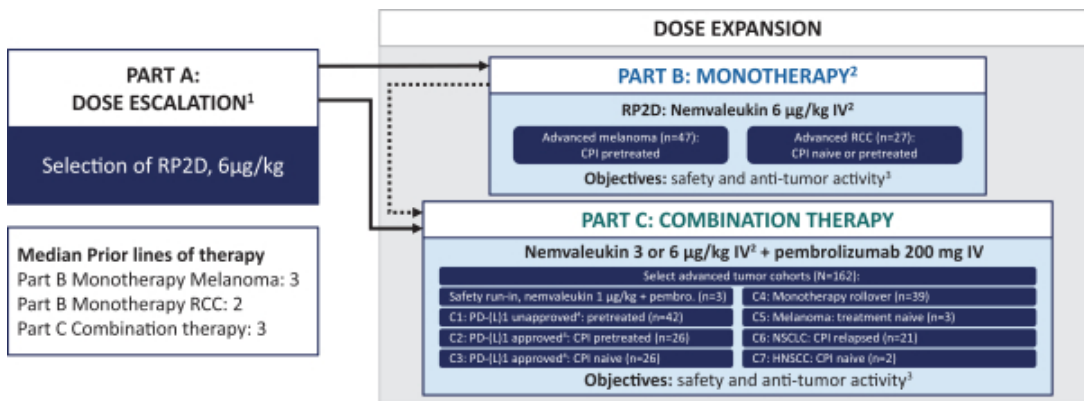


Abbrev.: IV: Intravenous; LFIV: Less frequent IV; SC: Subcutaneous; IDMC: Independent Data Monitoring Committee; MSD: A tradename of Merck & Co., Inc. Kenilworth, NJ, USA; ENGOT: European Network of Gynaecological Oncological Trial Groups; APOGOT: Asia-Pacific Gynecologic Oncology Trials Group; GOG: Gynecologic Oncology Group.

ARTISTRY-1

ARTISTRY-1, a global, open-label Phase 1/2 study, is the first-in-human study of IV nemvaleukin and has generated our largest and most mature clinical data set. The design of and dosing regimen used in ARTISTRY-1 are described in the figure below.

ARTISTRY-1 Trial Design and Dosing Regimen



NCT02799095

1. Patients from Parts A and B could roll over to Part C upon progression or stable disease (after > 4 cycles) on monotherapy.
2. Nemvaleukin daily Q5D, then off treatment for 9 days (cycle 1) or 16 days (cycle 2+).
3. ORR assessed by investigator (RECIST v1.1)
4. Nemvaleukin 3 µg/kg/d in C1-C4, 6 µg/kg/d in C5-C7. PD-(L)1 approved/unapproved indication based on FDA prescribing information and may have changed over time.

We established a clear set of objectives for ARTISTRY-1, designed to demonstrate nemvaleukin’s differentiated profile.

## [Table of Contents](#)

First, we aimed to validate nemvaleukin's molecular design by demonstrating a dose-dependent and selective expansion of CD8+ and NK cells, with minimal expansion of T<sub>regs</sub>, as described above.

Second, we sought to demonstrate that this immunological response could translate into clinical activity, with a focus on demonstration of monotherapy antitumor activity in tumor types where high-dose rhIL-2 obtained regulatory approval, as we believe this an essential element of validating potential therapeutic benefit and supporting advancement of our clinical program.

Third, we designed ARTISTRY-1 to evaluate nemvaleukin's potential clinical benefit in combination with pembrolizumab in a wide range of advanced solid tumor types, including both anti-programmed death 1 ("PD-1") and PD-L1 approved and unapproved tumors, and in CPI-experienced patients and patients rolling over from the nemvaleukin monotherapy cohort.

Finally, we aimed to establish a differentiated safety and tolerability profile for nemvaleukin, both as monotherapy and in combination with pembrolizumab, with a particular focus on mitigation of the hallmark toxicities associated with high-dose IL-2.

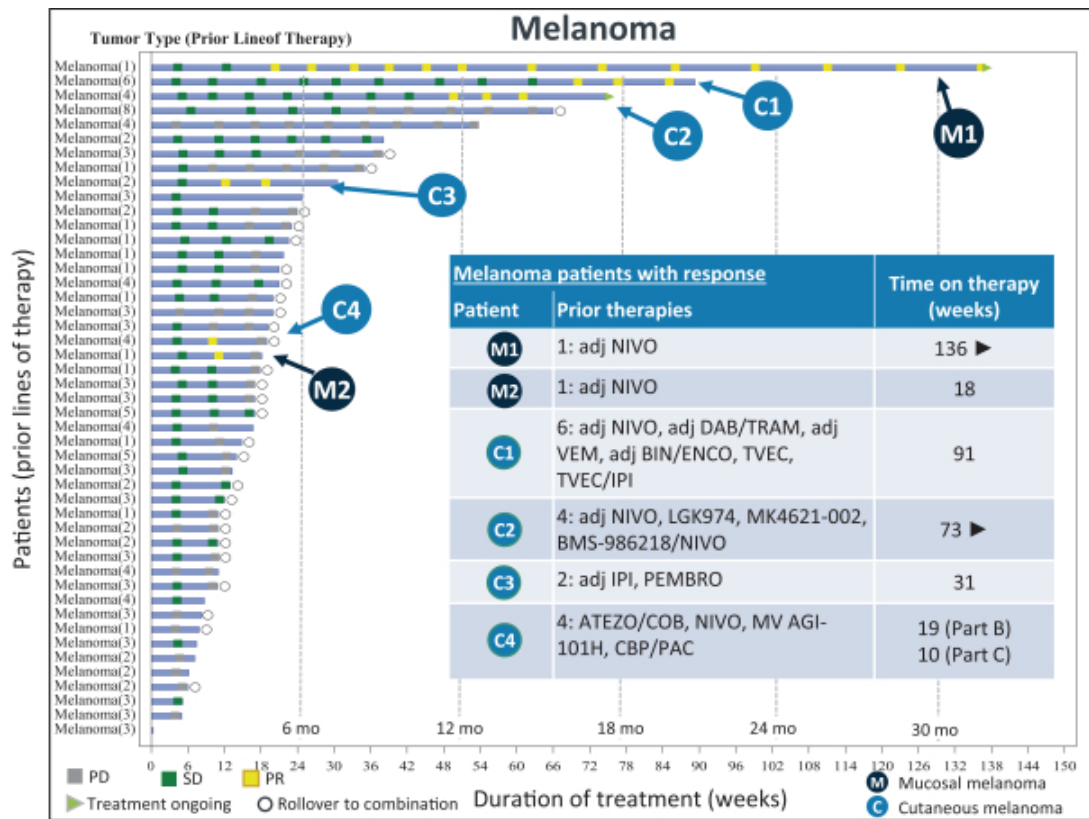
### *Monotherapy Activity*

ARTISTRY-1 Part B was designed to assess single-agent safety and antitumor activity in RCC and melanoma, two tumor types where high-dose rhIL-2 has shown monotherapy activity. In contrast to the original studies evaluating high-dose rhIL-2, which were conducted more than 20 years ago and before the discovery of CPIs and other targeted agents, the majority of patients in the ARTISTRY-1 Part B monotherapy cohort were previously treated with CPIs and progressed. Patients in this cohort had a median of two to three prior lines of treatment, although some patients had up to eight prior lines of treatment.

Clinically meaningful responses were observed with nemvaleukin monotherapy in patients with RCC and melanoma. All responders had been previously treated with CPI therapy and their disease had progressed. Overall, as of the data cut-off date of October 3, 2022, 10 objective responses were observed in the monotherapy cohorts. In the melanoma cohort, among 46 evaluable patients, two PRs (one confirmed) were observed in mucosal melanoma and four PRs (three confirmed) were observed in cutaneous melanoma. In the RCC cohort, among 22 evaluable patients, four PRs (three confirmed) were observed. See figures below for details on the melanoma monotherapy cohort, including ORR, DCR, and time on therapy. ARTISTRY-1 is an ongoing study, and all data is provided as of the dates noted herein and is subject to final validation upon database lock.

The swimmers plot graphic below outlines the duration of treatment across the melanoma cohort patient population, as well as observed responses and durability of response; notably, as of the data cut-off date of October 3, 2022, a number of the monotherapy responders had been on treatment for over a year, including one mucosal melanoma patient who had been on therapy for over two years.

IV Nemvaleukin Monotherapy Responses in Melanoma (Part B)



adj, adjuvant; ATEZO, atezolizumab; BIN, binimetinib; CBP, carboplatin; C1, confidence interval; COB, cobimetinib; CPI, checkpoint inhibitor; CR, complete response; DAB, dabrafenib; DCR, disease control rate (CR+PR+SD); DOR, duration of response; ENCO, encorafenib; FDA, US Food and Drug Administration; IPI, ipilimumab; MV, melanoma vaccine; NA, not applicable; NIVO, nivolumab; ORR, overall response rate; PAC, paclitaxel; PD, progressive disease; PEMBRO, pembrolizumab; PR, partial response; SD, stable disease; TRAM, trametinib; TVEC, talimogene laherparepvec; VEM, vemurafenib.

The table below summarizes our clinical data in the melanoma monotherapy cohort as of the most recent data cut on October 3, 2022.

IV Nemvaleukin Monotherapy Response Summary in Melanoma (Part B)

	All <sup>a,b</sup> (n=46)	Mucosal (n=6)
Best overall response, n (%)		
CR	0	0
PR	6 (13.0) <sup>c</sup>	2 (33.3) <sup>d</sup>
SD	30 (65.2)	2 (33.3)
PD	10 (21.7)	2 (33.3)
ORR, n (%) [95% CI]	6 (13.0) [4.9-26.3] <sup>c</sup>	2 (33.3) [4.3-77.8] <sup>d</sup>
DCR, n (%) [95% CI]	36 (78.3) [63.6-89.1] <sup>c</sup>	4 (66.7) [22.3-95.7] <sup>d</sup>
DOR in weeks <sup>e</sup> , Mean (SD)	29.3 (42.8) <sup>c</sup>	NA <sup>d</sup>
Median (range)	13.4 (6.1-116.1)	NA (6.1-116.1)

## [Table of Contents](#)

<sup>a</sup> Excludes 1 patient who did not meet tumor-evaluable criteria. <sup>b</sup> Patients with mucosal, cutaneous, uveal, acral included in 'All'. <sup>c</sup> Includes four confirmed PRs, two unconfirmed PRs. <sup>d</sup> One confirmed PR. <sup>e</sup> DOR for Part B only and does not include patients who rolled over to Part C; some patients may still be on treatment.

CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; ORR = objective response rate; DCR = disease control rate; DOR = duration of response; CI = confidence interval

As shown in the table above, among the six evaluable patients in this study with mucosal melanoma, a challenging patient population with limited treatment options, nemvaleukin monotherapy resulted in two PRs (one confirmed) and two patients achieved stable disease, representing an overall DCR of 67%.

These data supported the FDA's grant of ODD and FTD, and an ILAP designation by the MHRA, in each case for nemvaleukin for the treatment of mucosal melanoma, and led to our design and initiation of ARTISTRY-6, which includes potentially registrational Cohort 2, which is ongoing.

### *Combination Activity with Pembrolizumab*

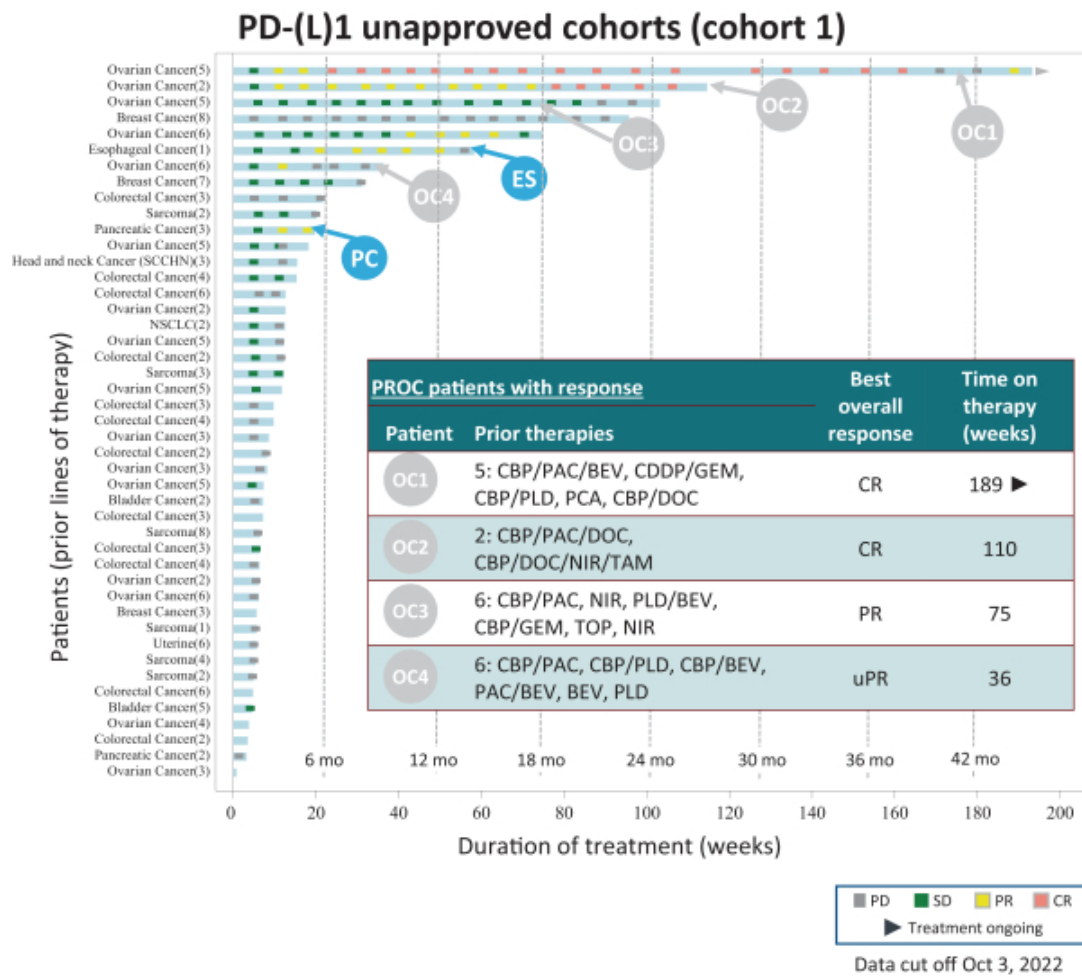
ARTISTRY-1 Part C was a dose expansion cohort of the study that evaluated the efficacy and safety of nemvaleukin in combination with pembrolizumab across a variety of cohorts, including in patients with CPI-unapproved tumor types and patients that have progressed on or following CPI therapy.

Responses were observed across a range of tumor types, with several patients continuing on therapy at the time of the most recent data cut on October 3, 2022. Overall, among the 137 evaluable patients in ARTISTRY-1 Part C, 23 objective responses were observed (four CRs, 19 PRs (16 confirmed)).

These responses were observed in both PD-1 and PD-L1 approved and unapproved tumor types including melanoma, ovarian, esophageal, cervical, bladder, breast, pancreatic, colorectal, renal cell, Hodgkin lymphoma, lung, and head and neck cancer.

Of particular note, among 14 evaluable patients with PROC, two CRs and two PRs (one confirmed) were observed, and six patients achieved stable disease, representing an overall DCR of 71%. Importantly, the median duration of response for these patients was 53 weeks. These data supported the FDA's grant of FTD for nemvaleukin in combination with pembrolizumab in PROC and led to the design and initiation of ARTISTRY-7, another potentially registrational study of nemvaleukin, which is currently ongoing.

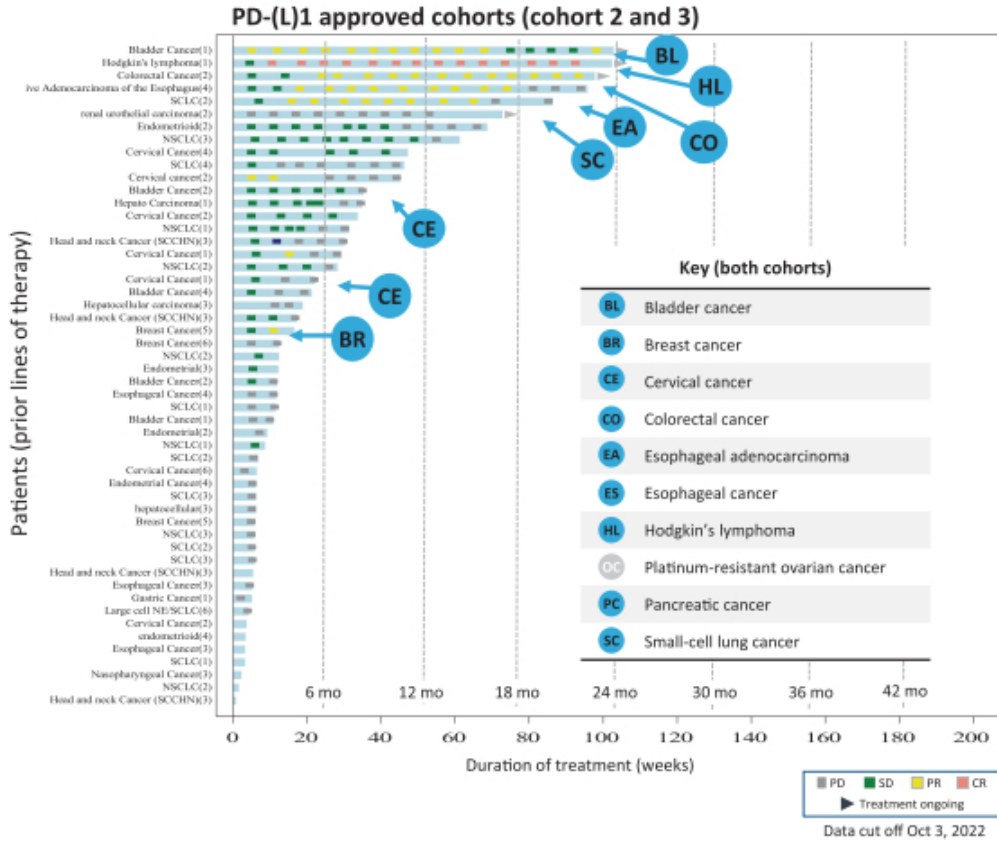
ARTISTRY-1 Part C Combination Responses (Unapproved Tumor Type Cohorts)



PD-(L)1 approved/unapproved indication based on FDA prescribing information and may have changed over time. Responses per RECIST v1.1. BEV, bevacizumab; CBP, carboplatin; CDDP, cisplatin; CR, complete response; DOC, docetaxel; FDA, Food and Drug Administration; GEM, gemcitabine; mo, month; NIR, niraparib; NSCLC, non-small cell lung cancer; PAC, paclitaxel; PCA, paclitaxel albumin; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PLD, pegylated liposomal doxorubicin hydrochloride; PR, partial response; PROC, platinum-resistant OC; SCLC, small-cell lung cancer; SD, stable disease; TAM, tamoxifen; TOP, topotecan; uPR, unconfirmed PR.



ARTISTRY-1 Part C Combination Responses (Approved Tumor Type Cohorts)

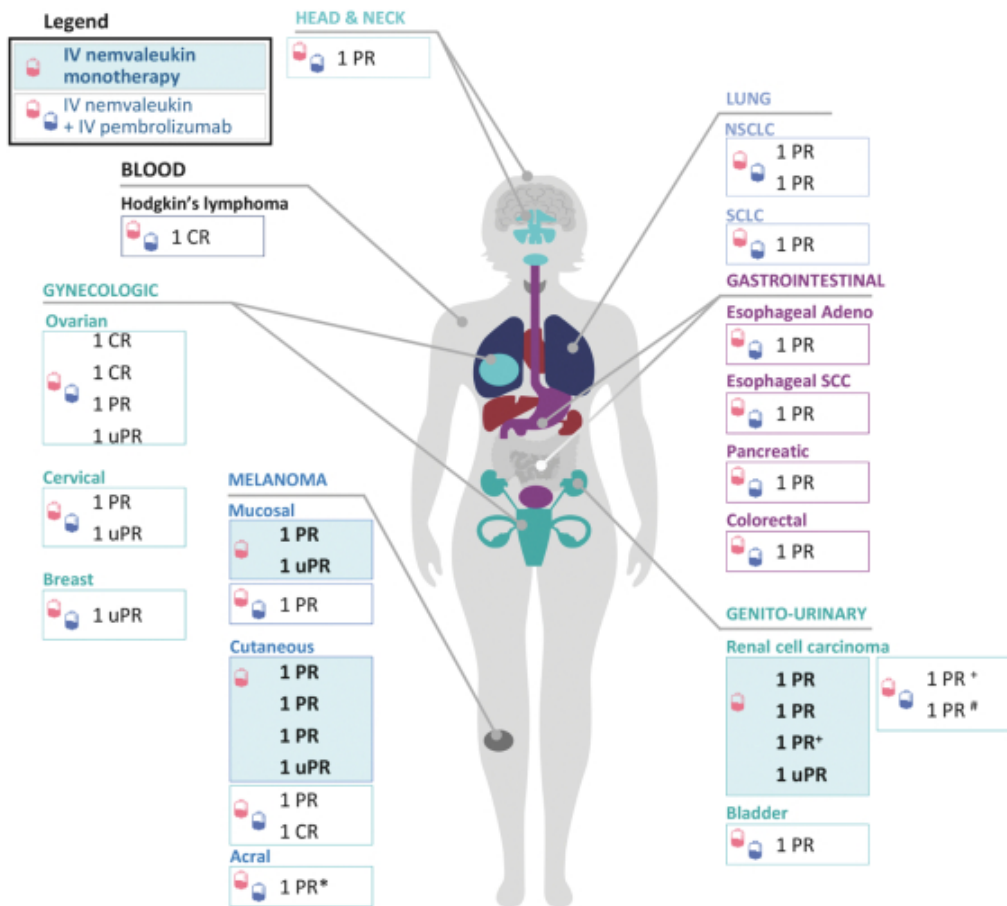


PD-(L)1 approved/unapproved indication based on FDA prescribing information and may have changed over time. Responses per RECIST v1.1. BEV, bevacizumab; CBP, carboplatin; CDDP, cisplatin; CR, complete response; DDC, docetaxel; FDA, Food and Drug Administration; GEM, gemcitabine; mo, month; NIR, niraparib; NSCLC, non-small cell lung cancer; PAC, paclitaxel; PCA, paclitaxel albumin; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PLD, pegylated liposomal doxorubicin hydrochloride; PR, partial response; PROC, platinum-resistant OC; SCLC, small-cell lung cancer; SD, stable disease; TAM, tamoxifen; TOP, topotecan; uPR, unconfirmed PR.

ARTISTRY-1 Overall Clinical Activity Summary

The figure below provides a summary of the objective responses observed across ARTISTRY-1 with IV nemvaleukin as of August 2022. Monotherapy responses are denoted in green boxes and responses in combination with pembrolizumab are denoted in white boxes. We observed objective responses as well as clinically meaningful disease control when nemvaleukin was used as both monotherapy and in combination with pembrolizumab across a wide array of tumor types.

ARTISTRY-1 (IV Nemvaleukin) Objective Response Summary



Data as of October 3, 2022

Patients achieved SD (\*acral), PR (+RCC), and PD (#RCC) on nemvaleukin monotherapy, rolled over to combination therapy and achieved PR.

*Safety Observations*

Nemvaleukin’s adverse event profile in ARTISTRY-1 was consistent with our expectations based on its mechanism of action. Nemvaleukin in combination with pembrolizumab had a similar safety profile as monotherapy nemvaleukin, with no additive toxicities observed.

As set forth in the figure below, as of March 27, 2023, the most frequent nemvaleukin-related adverse events (>30%) reported were consistent with those expected from a cytokine-based therapy: pyrexia, chills, nausea, neutropenia/neutrophil count decrease, hypotension and aspartate transaminase (“AST”) increase. The majority of the adverse events were grade 1/2 in nature.

ARTISTRY-1 Safety Summary

Monotherapy (Part B only; N=74) <sup>1</sup>		Combination with Pembrolizumab (Part C only; N=166) <sup>1</sup>	
Event, n (%)	Overall N = 74	Event, n (%)	Combination N = 166
Any AE, regardless of causality	73 (99%)	Any AE, regardless of causality	162 (98%)
Grade 3 or 4 nemvaleukin-related AE	56 (76%)	Grade 3 or 4 nemvaleukin-related AE	86 (52%)
Nemvaleukin-related AEs leading to discontinuation	3 (4%)	Nemvaleukin-related AEs leading to discontinuation	6 (4%)
Nemvaleukin-related AEs leading to death	0	Nemvaleukin-related AEs leading to death	1 (1%)
<ul style="list-style-type: none"> <li>• Most frequently (&gt;30%) reported TRAEs include pyrexia, chills, neutropenia, increased AST, nausea, and hypotension; consistent with anticipated effects of cytokine administration</li> <li>• Most frequent Grade 3-4 TRAE (&gt;10%) was neutropenia</li> <li>• Three patients discontinued due to TRAEs (Grade 3 failure to thrive in melanoma, Grade 2 ECG T wave abnormal and Grade 1 cardiac troponin I increase in melanoma, and Grade 3 bronchospasm in RCC)</li> </ul>		<ul style="list-style-type: none"> <li>• Chills and pyrexia were most frequently (&gt;30%) reported TRAEs; and fatigue was most frequently reported nemvaleukin and pembrolizumab-related TRAE; consistent with anticipated effects of cytokine release and/or pembrolizumab administration (generally transient, majority Grade ≤2 in severity)</li> <li>• Most frequent Grade 3-4 nemvaleukin-related AEs (&gt;10%) were neutropenia and anaemia</li> <li>• Discontinuations due to nemvaleukin-related AEs included: Grade 3 arthralgia, Grade 2 cytokine release syndrome, Grade 3 fatigue, Grade 2 infusion related reaction, Grade 3 pneumonitis, and Grade 5 starvation.</li> </ul>	

1. Data as of March 27, 2023

The most frequent Grade 3-4 nemvaleukin-related adverse event was neutrophil count decrease/neutropenia, with certain instances considered nemvaleukin-related serious adverse events. These neutropenic events were generally not associated with fever or infection and generally did not require growth factor support. We believe the events are associated with the overall mechanism of action of nemvaleukin and a margination of overall cell populations, as the majority of events were transient in nature (lasting a shorter duration of approximately 4 days although recovery overall could be longer), and most did not lead to discontinuation of treatment. Only a small number of patients had a nemvaleukin-related adverse event leading to discontinuation: 4.1% and 3.6% of patients using nemvaleukin as monotherapy and in combination, respectively. To date, no CLS events have been reported by investigators or identified in our extensive analysis of a broad spectrum of adverse events of special interest.

As set forth in the figure below, as of March 27, 2023, we have observed the following nemvaleukin-related serious adverse events in Parts B and C:

**All Nemvaleukin-Related Serious Adverse Events in Parts B & C of ARTISTRY-1 by Preferred Term**

System Organ Class Preferred Term	Part B N=74 n(%)	Part C N=166 n(%)
<b>Blood and lymphatic system disorders</b>	<b>5 (6.8)</b>	<b>6 (3.6)</b>
Anaemia	3 (4.1)	4 (2.4)
Neutropenia	1 (1.4)	2 (1.2)
Immune thrombocytopenia	1 (1.4)	—
<b>General disorders and administration site conditions</b>	<b>2 (2.7)</b>	<b>4 (2.4)</b>
Pyrexia	1 (1.4)	3 (1.8)
Extravasation	1 (1.4)	—
Fatigue	—	1 (0.6)
<b>Injury, poisoning and procedural complications</b>	<b>1 (1.4)</b>	<b>5 (3.0)</b>
Infusion related reaction	—	5 (3.0)
Overdose	1 (1.4)	—
<b>Metabolism and nutrition disorders</b>	<b>2 (2.7)</b>	<b>3 (1.8)</b>
Dehydration	—	1 (0.6)
Failure to thrive	1 (1.4)	—

## Table of Contents

Hypocalcaemia	1 (1.4)	—
Hypoglycaemia	—	1 (0.6)
Hyponatraemia	—	1 (0.6)
Hypovolaemia	—	1 (0.6)
Starvation	—	1 (0.6)
<b>Hepatobiliary disorders</b>	<b>3 (4.1)</b>	<b>2 (1.2)</b>
Hypertransaminaemia	1 (1.4)	2 (1.2)
Hyperbilirubinaemia	2 (2.7)	—
<b>Investigations</b>	<b>2 (2.7)</b>	<b>2 (1.2)</b>
Alanine aminotransferase increased	—	2 (1.2)
Aspartate aminotransferase increased	—	2 (1.2)
Blood bilirubin increased	1 (1.4)	—
Electrocardiogram T wave abnormal	1 (1.4)	—
Troponin I increased	1 (1.4)	—
<b>Cardiac disorders</b>	<b>1 (1.4)</b>	<b>3 (1.8)</b>
Supraventricular extrasystoles	—	3 (1.8)
Acute myocardial infarction	1 (1.4)	—
Tachycardia	—	1 (0.6)
<b>Immune system disorders</b>	<b>—</b>	<b>3 (1.8)</b>
Cytokine release syndrome	—	3 (1.8)
<b>Gastrointestinal Disorders</b>	<b>—</b>	<b>3 (1.8)</b>
Diarrhoea	—	1 (0.6)
Immune-mediated enterocolitis	—	1 (0.6)
Nausea	—	1 (0.6)
Vomiting	—	1 (0.6)
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>—</b>	<b>3 (1.8)</b>
Asthma	—	1 (0.6)
Pleural effusion	—	1 (0.6)
Pneumonitis	—	1 (0.6)
<b>Nervous system disorders</b>	<b>—</b>	<b>2 (1.2)</b>
Depressed level of consciousness	—	1 (0.6)
Myelopathy	—	1 (0.6)
<b>Infections and infestations</b>	<b>1 (1.4)</b>	<b>—</b>
Bacteraemia	1 (1.4)	—
Cellulitis	1 (1.4)	—
<b>Eye Disorders</b>	<b>1 (1.4)</b>	<b>—</b>
Iritis	1 (1.4)	—
Vitritis	1 (1.4)	—
<b>Vascular disorders</b>	<b>1 (1.4)</b>	<b>—</b>
Hypotension	1 (1.4)	—

## Ongoing Potential Registrational Programs

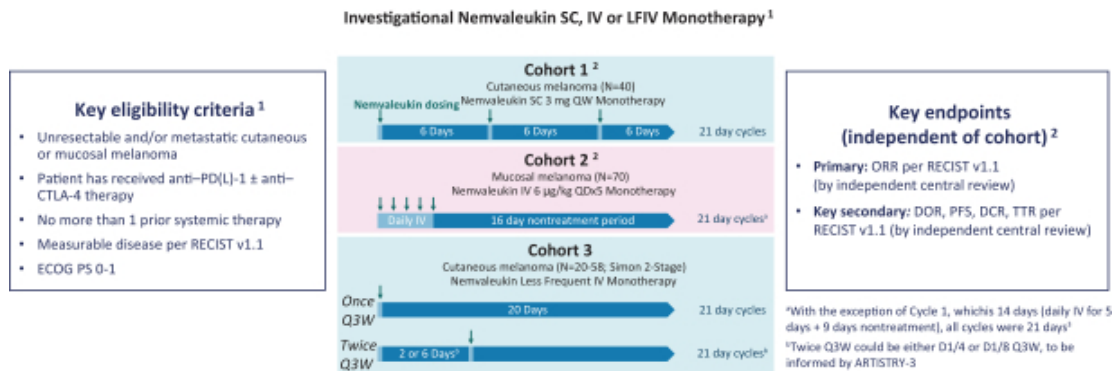
### ARTISTRY-6

ARTISTRY-6 is a Phase 2, global, multicenter, open-label study evaluating nemvaleukin monotherapy in patients with advanced mucosal or cutaneous melanoma who have received prior treatment with an anti-PD-L1 therapy with or without anti-cytotoxic T lymphocyte associated antigen 4 (“CTLA-4”) therapy. Based on the responses observed in ARTISTRY-1 in patients with mucosal melanoma, Cohort 2 of ARTISTRY-6 is dedicated to exploring IV nemvaleukin in mucosal melanoma (n=70) and is potentially registrational. ARTISTRY-6 is also designed to explore signals using alternative doses, frequencies, and routes of administration of nemvaleukin.

## Table of Contents

Cohort 1 of this study is evaluating nemvaleukin administered subcutaneously in advanced cutaneous melanoma and we have completed enrollment of this cohort. Cohort 3 will evaluate a less frequent dosing regimen for IV nemvaleukin in advanced cutaneous melanoma, pending identification of the recommended Phase 2 dose (“RP2D”) for the less frequent IV dosing regimen, which is currently being evaluated in ARTISTRY-3. The trial design of ARTISTRY-6 is outlined below.

### ARTISTRY-6 Trial Design



1. <https://clinicaltrials.gov, NCT04830124>.

2. Lewis K, et al. Presentation at the Melanoma and Immunotherapy Bridge 2021 Virtual Congress; December 1-4, 2021.

3. Data on file. ARTISTRY-6 Protocol Amendment 1 (Version 2.0). January 5, 2021.

Key data readouts for the ARTISTRY-6 study are expected in . If the data readouts from the potentially registrational Cohort 2 of this clinical study are positive, the data may support submission of a BLA to the FDA for marketing approval in the U.S.

#### Unmet Need & Competitive Landscape for Mucosal Melanoma

Mucosal melanoma is a highly aggressive variant of malignant melanoma, with a 5-year survival rate of approximately 25% (as compared to cutaneous melanoma, which has a 5-year survival rate of approximately 80%).

There are no therapies currently approved specifically for mucosal melanoma, and there have been no randomized controlled trials addressing the activity of CPI in this patient population. Instead, treatment of metastatic disease for mucosal melanoma generally consists of the same therapies approved for cutaneous melanoma, such as chemotherapy and CPI-based approaches, despite evidence that such therapies are less effective in the mucosal melanoma setting. Other current treatments include targeted therapies for those with relevant mutations, and CPI immunotherapy as monotherapy or combination of anti-PD-1 (e.g., pembrolizumab or nivolumab) and/or anti-CTLA-4 therapy (e.g., ipilimumab). Benefits from these therapies are usually short lived, with a median PFS rate of three months or less. Moreover, upon recurrence/progression, treatment options in the post-CPI setting are even more sparse and often associated with worse outcomes, further highlighting the persistent and significant unmet need for new therapies. It is estimated that there are nearly 2,000 mucosal melanoma patients in the U.S. and Europe.

#### ARTISTRY-7

Based on the responses observed with nemvaleukin in combination with pembrolizumab in patients with PROC in the ARTISTRY-1 study, we launched ARTISTRY-7, an ongoing, global, Phase 3, open-label, randomized potentially registration-enabling study evaluating the antitumor activity and safety of IV nemvaleukin in combination with pembrolizumab compared to investigator’s choice chemotherapy in patients with PROC (n=376). This study is being conducted in collaboration with the Gynecologic Oncology Group (“GOG”), the European Network of Gynecological Oncological Trial groups (“ENGOT”), and the Asia-Pacific

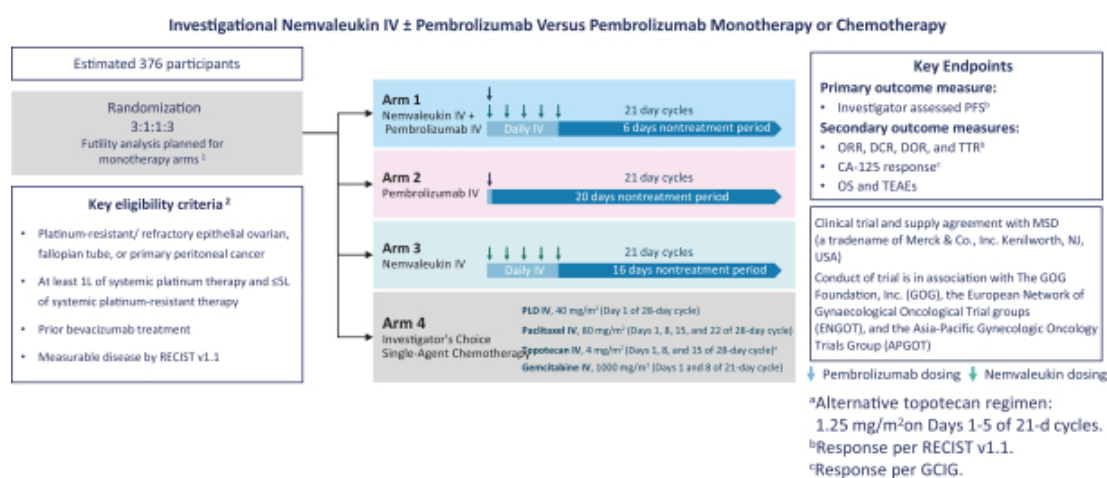
## Table of Contents

Gynecologic Oncology Trials Group (“APGOT”). GOG, ENGOT and APGOT are large, regional cooperative groups that coordinate and promote clinical research involving patients with gynecological cancers. We have contracted with these groups to assist us with the implementation and execution of the ARTISTRY-7 study globally, including in the selection of clinical trial sites. In addition, these groups provide oversight and advice regarding the conduct of the ARTISTRY-7 study within their respective regions in collaboration with our contract research organizations (“CROs”) that operationalize the ARTISTRY-7 study. This study is also being conducted in collaboration with MSD (a tradename of Merck & Co., Inc. Kenilworth, NJ, USA), which provides the pembrolizumab for the study. We and MSD will jointly own any clinical data and inventions (including patents that cover such inventions) that result from the combined use of nemvaleukin and pembrolizumab in the ARTISTRY-7 clinical trial, but will each retain all data and intellectual property rights relating solely to our respective compounds.

In order to enroll in this study, patients must have received  $\geq 1$  prior line of systemic anticancer therapy in the platinum-sensitive setting and  $\leq 5$  prior lines of therapy in the platinum-resistant setting, including bevacizumab, a poly ADP-ribose polymerase (“PARP”) inhibitor for patients with a breast cancer gene mutation.

There are four arms in the study that are enrolling in a 3:1:1:3 fashion (IV nemvaleukin in combination with pembrolizumab, IV nemvaleukin monotherapy, pembrolizumab monotherapy, and investigators’ choice (“IC”) chemotherapy). The primary objective is to compare investigator-assessed PFS in the nemvaleukin in combination with pembrolizumab arm as compared to the IC chemotherapy arm. The trial design for ARTISTRY-7 is shown in the graphic below.

### ARTISTRY-7 Trial Design



- Herzog T et al. Poster presented at the Society for Gynecologic Cancers Annual Meeting (SGO), Phoenix, AZ, March 18-21, 2022.
- <https://clinicaltrials.gov, NCT05092360>. Accessed January 28, 2022.

ARTISTRY-7 is expected to have a topline data readout in . The FDA has granted FTD to nemvaleukin in combination with pembrolizumab for the treatment of PROC and, if the data readouts from this potentially registrational clinical study are positive, such data may support submitting a BLA to the FDA for marketing approval in the U.S. We have discussed with the FDA the potential to seek accelerated approval for nemvaleukin in combination with pembrolizumab for the treatment of PROC. To the extent the data from ARTISTRY-7 support doing so, and subject to further discussion with the FDA, we intend to file a BLA under the accelerated approval pathway. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening illness and has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA generally requires

post-marketing confirmatory clinical studies to verify clinical benefit. We may not be able to obtain accelerated approval, and even if we do, it may not lead to a faster development, regulatory review or approval process.

#### *Unmet Need & Competitive Landscape for PROC*

Ovarian, fallopian tube, and primary peritoneal cancers identified as epithelial ovarian cancers (“EOC”) are life-threatening diseases and together comprise the seventh most common cause of cancer mortality in women. Standard frontline treatment for EOC is platinum-based chemotherapy with or without an antiangiogenic, such as bevacizumab, which may be followed by maintenance therapy with bevacizumab, a PARP inhibitor, or both, depending on biomarker status.

Platinum-based regimens provide clinically meaningful benefit for a majority of patients in the first instance; however, among those who initially respond, it has been estimated that approximately 70-80% have recurrent disease within two years of completing treatment. The standard of care for PROC is single-agent nonplatinum chemotherapy (e.g., topotecan, gemcitabine, liposomal doxorubicin, oral etoposide, docetaxel or paclitaxel).

Importantly, the likelihood of durable response in the platinum-resistant setting is low, and the median overall survival (“OS”) drops significantly, with an expected OS timeframe of  $\leq$  one year and PFS timeframe of three to four months. A subset of patients with folate receptor alpha (“FR $\alpha$ ”) positive tumors can also be treated with mirvetuximab soravtansine-gynx, a FR $\alpha$ -directed antibody and microtubule inhibitor.

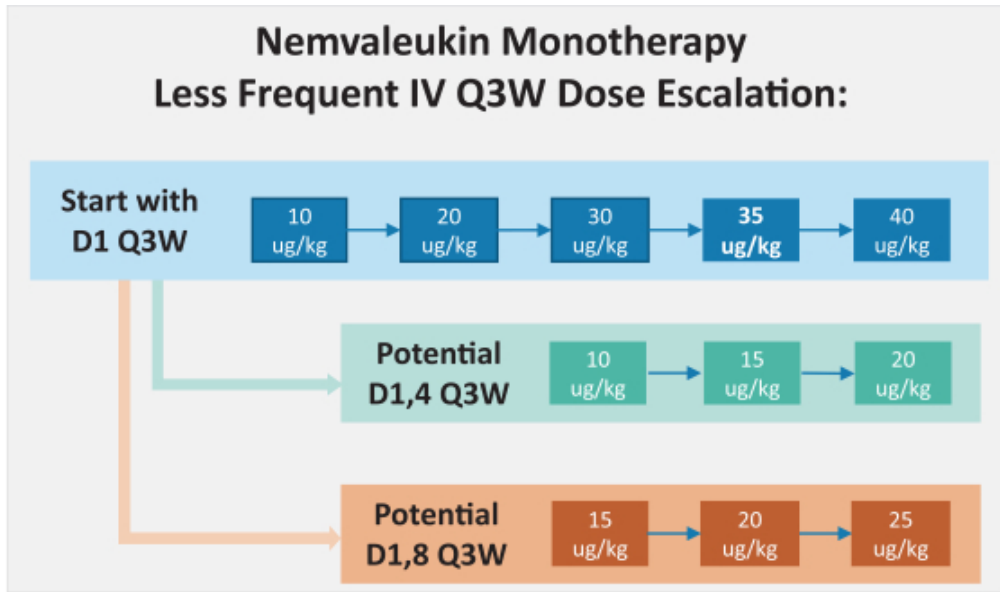
However, durable and effective treatment options are still needed for the majority of patients with PROC, reflecting the high unmet medical need for this population. There are approximately 13,000 third-line PROC patients in the U.S. and Europe.

#### **Exploring the Next Generation of Dosing**

We believe that nemvaleukin has potential to be utilized across a range of tumor types and in combination with multiple treatment options. The initial IV nemvaleukin dosing regimen that we studied is daily times five in three-week cycles, which was modeled after the currently approved high-dose rhIL-2 dosing. To explore nemvaleukin’s potential broad utility and ability to offer more flexible and convenient options to patients, caregivers, and providers, we are also evaluating subcutaneous dosing and alternative IV dosing frequencies.

Subcutaneous dosing is being explored in a dedicated cohort of cutaneous melanoma patients in ARTISTRY-6 and in ARTISTRY-2. ARTISTRY-2 is a Phase 1/2 open-label study of subcutaneous nemvaleukin in combination with pembrolizumab in patients with advanced solid tumors. The RP2D for ARTISTRY-2 was established as 3 mg q7d. At the American Society of Clinical Oncology 2021 annual meeting, we reported that of the 57 patients treated during ARTISTRY-2 dose escalation, 31 achieved stable disease on the first scan. In the dose expansion cohort of ARTISTRY-2, one PR was reported in a patient with PROC who received nemvaleukin in combination with pembrolizumab.

ARTISTRY-3 is a Phase 1/2 open-label study of IV nemvaleukin in patients with advanced solid tumors after treatment failure or intolerance to one to three prior FDA-approved targeted therapies. Cohort 2 of ARTISTRY-3 is evaluating the safety and tolerability of higher doses of IV nemvaleukin administered on a less frequent IV dosing schedule of one or two doses per three-week cycle. Our ARTISTRY-3 trial design is outlined in the graphic below.



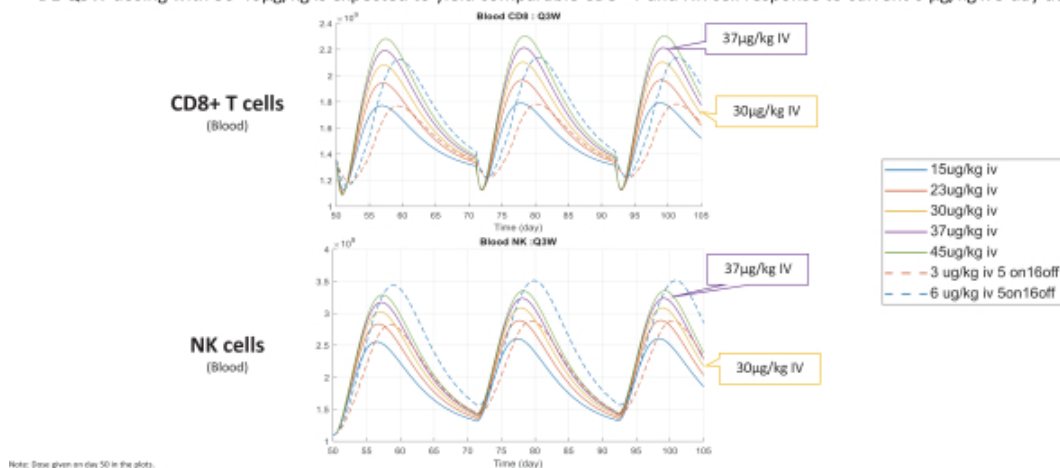
Q3W: Administered every 3 weeks. MTD: Maximum tolerated dose.

The dosing strategy of this cohort was based on extensive pharmacodynamic modeling that helped us predict the pharmacodynamic profile of IV nemvaleukin in lymph nodes and tumors. Quantitative systems pharmacology model simulations, as shown in the figure below, showed that a higher single IV nemvaleukin dose in a 21-day cycle were comparable to the target pharmacodynamic response observed with nemvaleukin dosing at 3 and 6  $\mu\text{g}/\text{kg}/\text{day}$  for five consecutive days in a 21-day cycle. Additionally, a two-dose regimen in a 21-day cycle with administration on days 1 and 4 or days 1 and 8 may achieve target cell expansion at a lower nemvaleukin dose compared with the single-dose schedule.



### Pharmacodynamic Modeling for Q3W IV Dosing

- D1 Q3W dosing with 30-40 $\mu$ g/kg is expected to yield comparable CD8+ T and NK cell response to current 6  $\mu$ g/kg x 5 day dosing



For the once-every-three-week dosing schedule (“Q3W”), we are currently enrolling patients and dose escalation continues in once per cycle and twice per cycle schedules.

We are also currently enrolling two dosing schedules with administration of nemvaleukin twice within a three-week cycle, dosed on day 1 and day 4 and dosed on day 1 and day 8, respectively. Data from these evaluations will assess the impact of relative dosing intensity, safety and pharmacodynamic effect of both less frequent IV dosing schedules.

Upon identification of the RP2D for each less frequent IV dosing regimen, we plan to further evaluate safety, tolerability and antitumor activity of these dosing intervals in expansion cohorts of ARTISTRY-3 in combination with pembrolizumab and in a dedicated cutaneous melanoma cohort of ARTISTRY-6 (cohort 3).

#### Future Expansion for Nemvaleukin

##### Potential Future Indications

We believe that nemvaleukin has the potential to benefit patients with other tumor types and intend to evaluate its therapeutic utility in additional indications, such as cutaneous melanoma and earlier lines of treatment for ovarian cancer, based on results we have seen in our trials and in additional tumor types for which we believe there is strong scientific rationale based on scientific literature. In our trials, we observed multiple responses in cutaneous melanoma using both nemvaleukin monotherapy and in combination with an anti-PD-1/L1 and multiple complete and partial responses in ovarian cancer using nemvaleukin in combination with pembrolizumab.

##### Potential Combination Therapies

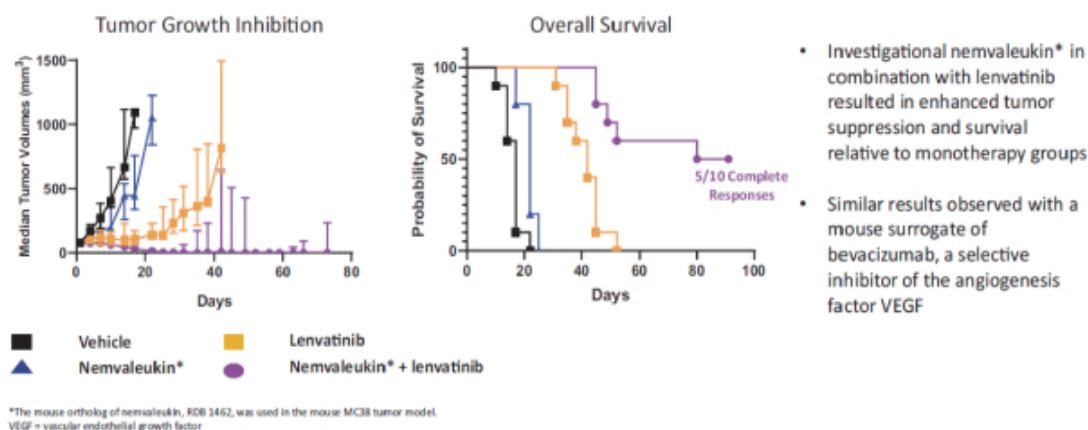
We also believe there is strong scientific rationale supporting the potential of nemvaleukin as a complementary, and potentially synergistic, combination treatment with standard of care therapies that result in immunogenic tumor cell death. In these combinations, nemvaleukin may provide an opportunity to augment the clinical activity associated with both agents.

In preclinical studies, we evaluated a mouse ortholog of nemvaleukin in combination with several growth factor pathway inhibitors, including lenvatinib. Nemvaleukin in combination with lenvatinib resulted in enhanced

## [Table of Contents](#)

tumor suppression and survival in a mouse preclinical model, as shown in the figure below. Similar results were observed with nemvaleukin in combination with lenvatinib, a multi-tyrosine kinase inhibitor (“TKI”) and a mouse surrogate of bevacizumab, a selective inhibitor of vascular endothelial growth factor.

### Tumor Growth Inhibition in Preclinical Mouse Models



In addition to immunotherapies, agents that induce immunogenic cell death (“ICD”) may offer synergistic advantages in combination with nemvaleukin. Some examples of agents that are known to effectively induce ICD include chemotherapy, radiation, and targeted therapies such as growth factor inhibitors. These therapies have been known to induce cancer cell death leading to release of tumor specific antigens, which can be picked up by antigen presenting cells and drive new T cell activation. In combination with nemvaleukin, we believe this immune response may be further augmented. Our hypothesis is that the net result of utilizing agents that induce ICD with nemvaleukin would be further enhancement of tumor killing, with increased durability of response because of the resulting antitumor immunity.

### ***Continued Clinical Development***

Our clinical development strategy for nemvaleukin has been deliberate and systematic.

- First, we established the clinical proof of concept for nemvaleukin in ARTISTRY-1.
- Currently, we are focused on bringing nemvaleukin to market by executing on the ongoing potential registrational studies (ARTISTRY-6 (Cohort 2) and ARTISTRY-7) in mucosal melanoma and PROC, respectively, both of which represent areas of high unmet medical need.
- In parallel, in order to potentially expand the utility of nemvaleukin, we are exploring differing dosing regimens. Less frequent IV dosing is being explored in ARTISTRY-3. An efficacy assessment of monotherapy nemvaleukin treatment in a less frequent IV dosing regimen is planned for incorporation in a dedicated cutaneous melanoma cohort of ARTISTRY-6 (Cohort 3). Subcutaneous dosing is being explored in ARTISTRY-2 and in a dedicated cutaneous melanoma cohort of ARTISTRY-6 (Cohort 1).
- Finally, we are continuing to generate preclinical and clinical data to evaluate potential opportunities for additional indications and therapeutic combinations.

The current development program is designed to evaluate nemvaleukin as a potential new therapy for patients with limited treatment options and for whom few clinical advances have been made in recent years. The current clinical program is also designed to lay the foundation for exploration of nemvaleukin’s broad potential

## [Table of Contents](#)

utility, from combination opportunities with CPIs in a range of tumor types and lines of therapy—building on the activity seen in PROC—to combination opportunities with other agents given nemvaleukin’s previously observed monotherapy activity.

### **Engineered IL-18 Program**

IL-18 is a key cytokine with therapeutic potential whose clinical efficacy is limited by IL-18BP. Our IL-18 program is designed to create an IL-18 variant that is engineered to be resistant to IL-18BP and with adjusted potency and PK to achieve the desired IL-18 anti-tumor activity.

IL-18 is a multi-faceted cytokine that demonstrates a range of immune mechanisms with high therapeutic potential for solid tumors. Discovered as a Type 1 T helper polarizing cytokine, IL-18 stimulates both adaptive and innate elements of the immune system; antigen-experienced CD8+ T-cells are stimulated for cytotoxic activity and IFN-g production and exhausted CD8+ T-cells, which are dysfunctional in the tumor microenvironment, are re-invigorated for antitumor activity. IL-18 also stimulates the cytotoxic NK cells of innate immunity for proliferation and IFN-g production, and matures dendritic cells for expansion and antigen-presentation. We believe this unique combination of immune functions has the potential to be transformative in the solid tumor cancer immunotherapy landscape.

IL-18BP is a soluble IL-18 decoy receptor that serves as a checkpoint of the IL-18 pathway. As its name implies, IL-18BP tightly binds to IL-18 and neutralizes its ability to bind and activate the IL-18 receptor. In Phase 1 clinical trials, recombinant human IL-18 (“rhIL-18”) rapidly upregulated IL-18BP. As IL-18BP levels increased, the pharmacodynamic response to rhIL-18 was significantly curtailed, thereby limiting clinical efficacy. Based on pre-clinical studies, tumors that support the potential of an IL-18 therapeutic include, but are not limited to: RCC, non-small cell lung cancer, mesothelioma and head and neck squamous cell carcinoma.

#### **Our Solution: Engineered IL-18**

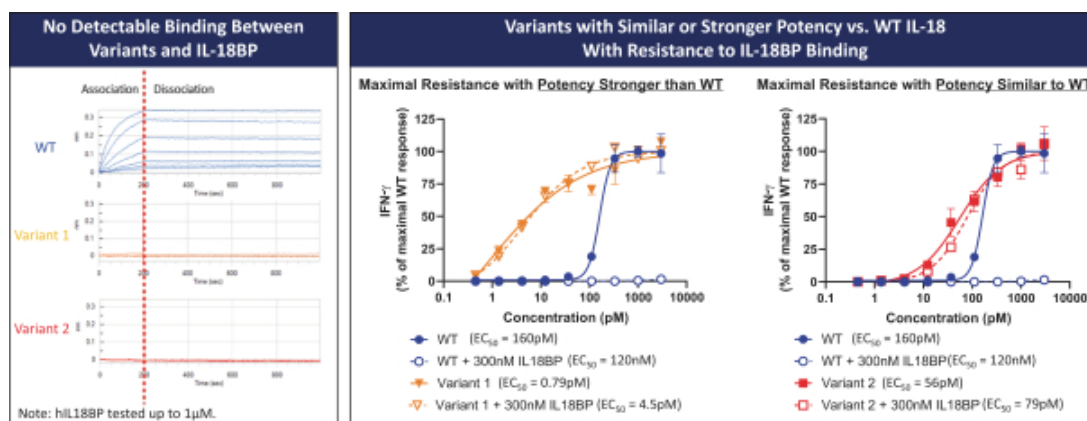
Our IL-18 program is focused on engineering an IL-18 variant that has a half-life extension and is designed to be resistant to IL-18BP neutralization, while retaining and optimizing the activity of IL-18. In order to achieve this, we are introducing targeted mutations into IL-18 that prevent IL-18BP binding while retaining IL-18 signaling activity and cellular function. We also plan to fuse our IL-18BP-resistant variant to protein scaffolds in order to enhance PK and further optimize potential antitumor activity and patient experience.

With this engineered design, our goal is to create a molecule that has resistance to the IL-18BP checkpoint in order to unleash the therapeutic potential of IL-18. We believe an optimal molecule will also have (i) strong potency to activate the multi-faceted antitumor immune mechanisms of IL-18, including reinvigoration of exhausted CD8+ T cells and (ii) enhanced PK to support potential efficacy, safety and patient/clinician convenience.

#### **Overview of Preclinical Studies and Data**

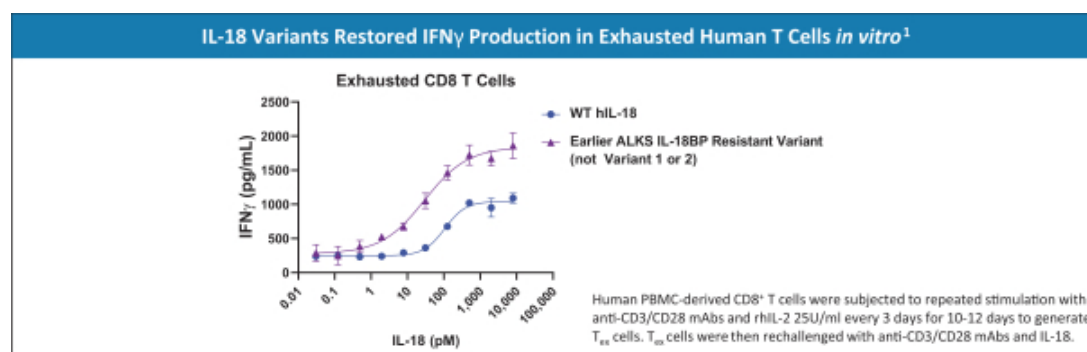
We applied rational protein design and combinatorial approaches to generate a pool of IL-18 variants that we could screen for potency and resistance to IL-18BP. As shown in the graphic below, certain of these variants have displayed undetectable binding to IL-18BP (left panel) and potency stronger than or similar to wild-type IL-18 with maximal resistance to IL-18BP inhibition (right panel).

Our Engineered IL-18 Variants' Activity and Resistance to IL-18BP



Solid tumors evoke immunosuppression in part by inducing a state of exhaustion in cytotoxic CD8+ T cells (“CD8+ Tex”). T-cell exhaustion also results in acquired resistance to existing checkpoint inhibitors. Our IL-18 program includes a focus on engineering an IL-18 variant that exhibits the maximal capacity to reinvigorate CD8+ Tex and thereby overcome significant hurdles of immune evasion and acquired immune-resistance. The figure below shows results from a preclinical study in which one of our variants restored IFN-g production in exhausted CD8+ T cells to a greater extent than WT hIL-18.

Engineered IL-18 Variant with the Maximal Capacity to Re-Invigorate Exhausted CD8+ T Cells



**Current Status and Clinical Development Plan**

Based on these data we are currently advancing our IL-18 program to candidate nomination and Investigational New Drug (“IND”) enabling studies, including cell line development and manufacturing and non-clinical toxicology programs to support our planned IND submission and progression into clinical development, we plan to nominate a candidate for this program in 2024.

**Tumor-targeted IL-12 Program**

IL-12 is recognized as a highly potent proinflammatory cytokine that has shown preclinical responses and clinical activity when delivered intratumorally by strongly activating CD8+ T and NK cells. However, clinical utility of IL-12 as a therapeutic has been limited due to severe toxicities. Our tumor-targeted IL-12 program is designed to overcome these toxicity challenges by sequential administration of IL-12’s subunits, each enhanced with tumor-targeting antibody fragments, thereby reducing serum exposure while enabling self-assembly of functional IL-12 in the tumor microenvironment.

IL-12 is a key cytokine in the body's response to pathogens that activates both innate and adaptive elements of the immune system. IL-12 is a powerful, proinflammatory cytokine produced by antigen-presenting cells such as macrophages, dendritic, and B cells in response to pathogenic infection. It is made of two subunits, p35 and p40, that are covalently linked intracellularly and then secreted as a functional heterodimer IL-12p70. IL-12 interacts with multiple immune cells, including T cells, NK cells, monocytes, and macrophages, and activates a proinflammatory response, suggesting significant potential as an oncology pathway. In third-party studies, IL-12 has repeatedly demonstrated activity in preclinical models in combination with other agents and to some extent as a monotherapy. rhIL-12 has also been evaluated in clinical trials, and antitumor activity was observed in a small number of patients across several tumor types.

However, use of systemic IL-12 therapy has historically been unsuccessful and caused severe adverse events in patients with cancer. The severe toxicity associated with rhIL-12 is generally attributed to a rapid upregulation of inflammatory cytokines IFN-g, TNF $\alpha$ , and IL-6, that cause a cytokine storm syndrome characterized by systemic inflammation, multi-organ dysfunction, and immune cytopenias. Despite activity in local lesions, cancer can be a systemic disease that requires systemic treatment, especially in later stage disseminated disease. Therefore, to capitalize on IL-12's potential, a safe and effective systemically delivered IL-12 therapeutic is needed.

The failure of systemic IL-12 to induce meaningful clinical activity is attributed to a poor therapeutic index, which limits the dose and prevents the ability to reach therapeutic concentrations within the TME. Thus, maximizing tumor IL-12 concentrations, while minimizing systemic exposure, is critical for initiating a safe and effective antitumor response.

### **Our Solution: Tumor-targeted IL-12**

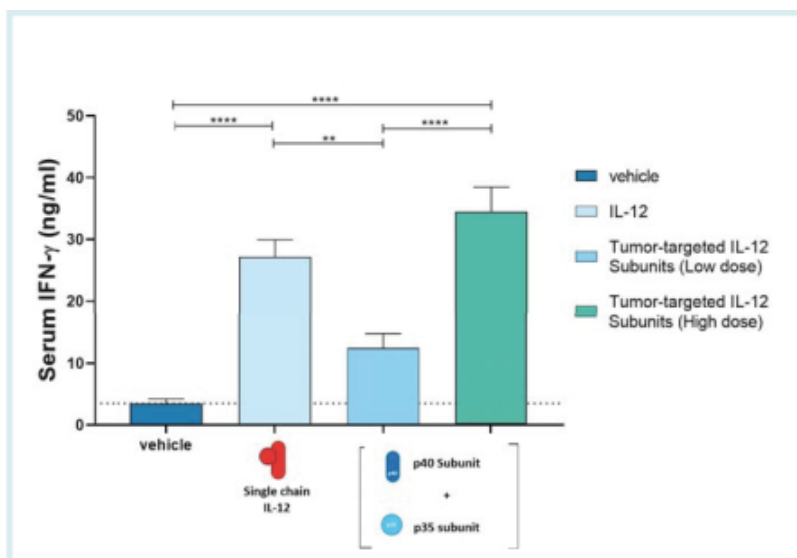
The goal of our IL-12 program is to create a self-assembling tumor-targeted split IL-12 therapeutic that maximizes tumor exposure and minimizes systemic exposure to functional IL-12. We have designed two separate inactive subunits, IL-12p35 and IL-12p40, that target the tumor for assembly. Each subunit includes the inactive component and is fused to a proprietary tumor-targeting antibody or fragment thereof. These subunits are designed to preferentially assemble and activate in the TME. Compared to localized IL-12 delivery, we believe this novel approach has the potential to achieve the desired tumor and systemic profile. We believe we can achieve an improved therapeutic index for systemically delivered IL-12 through careful engineering of the PK parameters of our molecules, use of an interval between doses to modulate systemic exposure of IL-12, not relying on extrinsic factors such as proteases to activate the molecule, and targeting our subunits to a proprietary tumor-associated antigen ("TAA").

### **Overview of Preclinical Studies and Data**

Our preclinical data have shown that sequentially administered targeted split IL-12 subunits (p35 and p40) can target and be retained in tumors, modulate systemic exposure using an increasing interval between subunit injections, and function upon assembly.

Our initial preclinical data showed the accumulation of the TAA-targeted subunits as compared to non-targeted IL-12. We then observed that *in-vitro* and *in-vivo* targeting of the two subunits yielded a greater recovery in IL-12 activity compared to single chain IL-12, and enhanced tumor targeting compared to single targeted agents. Further preclinical studies showed that the dual-targeted combination resulted in higher levels of retention of assembled IL-12 in tumor-bearing mice versus single-targeted or untargeted combinations of the subunits. We then tested this approach by evaluating IFN-g, a pharmacodynamic measure of IL-12 activity, in a mouse model. As shown in the figure below, this approach showed that sequential administration of the two subunits can achieve a similar pharmacodynamic response in an apparent dose-dependent manner.

Sequential Administration of Split IL-12 Subunits Resulted in Dose-Dependent PD Response in PBMC Humanized NCG Mouse Model



1. Nguyen KG et. al. Cancer Immunotherapy. Front. Immunol. October 15 2020 11:575597.
2. Vecchio MD et. al. Clin Cancer Res August 15 2007 (13) (16) 4677-4685. 3. Strauss J et. al. Clin Cancer Res January 1 2019 (25) (1) 99-109.
3. Clinical activity based on third party data

We have generated several unique non-competitive antibodies against our TAA, allowing us to target both subunits to the antigen.

In our next phase of preclinical work, we sought to characterize the IL-12 subunits in mouse in order to select a candidate for each tumor-targeted subunit and delivery parameters to achieve optimal serum and tumor PK. Based on preclinical studies, we have (i) selected antibody formats for each subunit, (ii) determined the dosing order of the subunits and dosing interval between the subunits, and (iii) observed that the sequentially administered targeted split IL-12 subunits are functional when combined.

**Current Status and Clinical Development Plan**

Currently our tumor-targeted IL-12 program is advancing to candidate nomination. We plan to nominate a candidate for this program in 2024.

**Competition**

The biotechnology and biopharmaceutical industries are characterized by rapid evolution of technologies, sharp competition and strong emphasis on intellectual property. Any product candidates that we successfully develop and products that we commercialize will have to compete with existing therapies and new therapies that may become available in the future. We believe that our protein engineering capabilities, development experience and scientific knowledge provide us with competitive advantages, however, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

Many of our competitors, either independently or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than

## Table of Contents

we are in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and achieving widespread market acceptance of approved products. Merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and clinical trial patient recruitment and acquiring intellectual property that may be complementary to, or necessary for, our programs. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our lead product candidate nemvaleukin, if approved, may face competition from other IL-2-based cancer therapies. For example, Proleukin® (aldesleukin), a synthetic protein similar to IL-2, is approved and marketed for the treatment of metastatic melanoma as well as metastatic RCC. In addition, we are aware of several companies that have IL-2-based programs in development for the treatment of different cancers, including Anaveon AG, Ascendis, Inc., Cue Biopharma, Inc., Cullinan Oncology Inc., Medicenna Therapeutics Corp., Roche AG, Sanofi, Xilio Therapeutics Inc., and Werewolf Therapeutics Inc.

In addition to IL-2-based therapies, we may also face competition from other therapies targeting our current and future target indications for nemvaleukin. For example, we may face competition in melanoma from companies with approved and marketed therapies, and/or programs in development, including, but not limited to, Bristol-Myers Squibb Co., Iovance Biotherapeutics, Inc., Merck Inc., and Pfizer, Inc. In ovarian cancer, we may face competition from companies with approved and marketed therapies, and/or programs in development including, but not limited to, Immunogen Inc., Merck, Inc., and Mersana, Inc.

With respect to our IL-18 program, while there are no approved IL-18 therapies currently on the market for the treatment of cancer, we are aware of several other companies that have IL-18-based cancer therapies that are in development, including, but not limited to, Bright Peak Therapeutics, Inc. and Simcha Therapeutics, Inc.

With respect to our IL-12 program, while there are no approved IL-12 therapies currently on the market for the treatment of cancer, we are aware of several other companies that have modified IL-12 or intra-tumoral IL-12 delivery programs in development for the treatment of cancer, including, but not limited to, Amunix, Inc., a subsidiary of Sanofi, Cullinan Oncology Inc., DragonFly Therapeutics, Inc., Moderna Inc., Merck KGaA, Werewolf Therapeutics Inc., Xencor, Inc. and Xilio Therapeutics, Inc.

## License Agreements

Mural and Alkermes will enter into a separation agreement in connection with the separation, which will contain intellectual property licenses pursuant to which each party will grant a license to certain intellectual property and/or technologies to the other company. Under the terms of the separation agreement, Alkermes will grant Mural a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property controlled by Alkermes as of the distribution date to allow Mural to use such intellectual property for the oncology business, and Mural will grant Alkermes a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property transferred to Mural as part of the separation for use outside of the oncology business.

## Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely substantially on third parties for the manufacture of our product candidates for preclinical and clinical development, and expect to continue to rely on third parties for commercial manufacturing of any of our products that receive marketing approval. For example, we have entered into certain agreements with external partners in the U.S. and China for the manufacture of preclinical and clinical product candidates. We require all third-party

## [Table of Contents](#)

manufacturing facilities that we engage to attest that all materials manufactured for human use are manufactured in accordance with current Good Manufacturing Practices (“cGMP”) requirements. We believe that we will be able to maintain and/or continue to negotiate third-party manufacturing arrangements on commercially reasonable terms and that it will not be necessary for us to obtain internal manufacturing capabilities in order to develop or, if approved, commercialize our products; however, we may experience unanticipated difficulties in maintaining or negotiating such arrangements with third parties. In addition, we may experience challenges related to the quality, quantity and timeliness of the supply of our preclinical, clinical or future commercial requirements due to our reliance on third-party manufacturers and circumstances that may be outside of our control.

### **Intellectual Property**

All intellectual property relating to the oncology business is being assigned to us under the terms of the separation agreement and, following the separation, we will own the patents and patent applications described below.

Our intellectual property is critical to our business and we strive to protect it, including by seeking to obtain and maintain patent protection in the U.S. and internationally to cover our product candidates and potential future products, their respective methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets and proprietary know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our oncology patent portfolio includes patents and patent applications with composition of matter and method of use claims with respect to our product candidates, nemvaleukin, IL-18 and IL-12. In general, for our product candidates, we will initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional opportunities for obtaining patent protection that has potential to enhance commercial success, including through additional methods of use, processes for manufacture, formulation and dosing regimen-related claims.

Our commercial success will depend in part on our ability to obtain and maintain proprietary protection for our current and future products and product candidates, novel discoveries, product development technologies, trade secrets, and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and non-U.S. patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. We also rely, or may rely in the future, on trademarks, trade secrets, copyright protection, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position. For the product candidates we develop and plan to commercialize if approved, as a normal course of business, we have been granted and intend to continue to pursue composition and method of manufacture and use patents, including therapeutic use patents, as well as patents related to novel indications for our products and product candidates. We also have obtained and will continue to seek patent protection with respect to novel discoveries. We have also sought and plan to continue to seek patent protection, either alone or jointly with our collaborators or other third parties, as our relevant agreements may dictate.

In some instances, we submit patent applications directly with the U.S. Patent and Trademark Office (“USPTO”) as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing option in the U.S. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, and obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage or at all.



## [Table of Contents](#)

We file U.S. non-provisional applications and non-U.S. applications in other territories (including via the Patent Cooperation Treaty (“PCT”)), that claim the benefit of the priority date of earlier filed provisional applications, when applicable, under the Paris Convention. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and designation of up to 153 PCT member states in which national patent applications can later be pursued based on the patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in non-U.S. countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine our claiming strategy on a case-by-case basis, considering advice of counsel and our business strategy and needs. We file patent applications containing claims for protection of all applications of our proprietary technologies and products that we believe to be useful, as well as new applications and/or uses we discover for existing technologies and products that we believe may have strategic value. We continuously reassess the number and type of patent applications, as well as existing patent claims, to ensure that maximum coverage and value are sought for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution, or new applications may be filed, to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention and the ability to satisfy the enablement requirement of the patent laws. 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, we may not obtain or maintain adequate patent protection for any of our current and future product candidates or future products. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our oncology portfolio of patents and patent applications comprises three distinct portfolios related to nemvaleukin, IL-18 and IL-12, which include patents and patent applications that are in various stages of the patent application filing and examination process in various jurisdictions worldwide, and include claims to our product candidates. Our patents and patent applications related to nemvaleukin include:

- four issued patents in the U.S.;
- seven pending U.S. non-provisional patent applications;
- ten pending patent applications filed under the PCT; and
- 129 pending patent applications based on the corresponding PCT, including pending applications in Australia, New Zealand, Brazil, Canada, China, Hong Kong, the European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, and South Africa.

The issued U.S. patents, and the U.S. patent applications referenced above, if issued as patents, are expected to expire on various dates from 2033 through to 2041, in each case without taking into account any possible extension of patent term that may be available.

## [Table of Contents](#)

We have a pending U.S. provisional application related to IL-18. We intend to file a PCT application and national phase applications in the U.S. and various non-U.S. jurisdictions before applicable deadlines.

Our patent applications related to IL-12 include a pending U.S. non-provisional application and a corresponding application filed under the PCT. The pending U.S. non-provisional patent application, if issued as a patent, is expected to expire in 2042, without taking into account any possible extension of patent term that may be available. We intend to file additional patent applications in various non-U.S. jurisdictions based on the PCT application before applicable deadlines.

Our patent portfolio for each of our product candidates is summarized in further detail below.

### **Nemvaleukin**

We have 10 patent families related to nemvaleukin. One of the families includes two issued U.S. patents and one issued European patent with composition of matter claims directed to nemvaleukin, and pending patent applications in the U.S., Australia, New Zealand, Canada, the European Patent Office, Japan and Hong Kong that claim compositions of matter of nemvaleukin. The 20-year term for patents in this family runs through 2033, excluding any extension of patent term that may be available.

A second patent family has an issued U.S. patent directed to methods of treating cancer via subcutaneous dosing regimens of nemvaleukin alone or in combination with other therapeutic agents, and pending patent applications in the U.S., Australia, New Zealand, Brazil, Canada, China, Hong Kong, the European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, and South Africa. The 20-year term for patents in this family runs through 2040, excluding any extension of patent term that may be available.

A third patent family has an issued U.S. patent directed to methods of treating cancer with nemvaleukin in combination with a PD-1 inhibitor, and pending patent applications in the U.S., Australia, New Zealand, Brazil, Canada, China, Hong Kong, the European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, and South Africa. The 20-year term for patents in this family runs through 2040, excluding any extension of patent term that may be available.

The additional patent families include pending U.S. non-provisional applications and corresponding applications filed under the PCT to various nemvaleukin intravenous dosing regimens and combination therapies, combination therapies with TKIs, manufacturing processes and intravenous and subcutaneous formulations. Patent applications based on the PCT are filed in Australia, New Zealand, Brazil, Canada, China, Hong Kong, the European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, and South Africa. The 20-year term for patents in these families, if issued, runs from 2040 to 2043, excluding any extension of patent term that may be available.

### **IL-18**

We have a pending U.S. provisional application directed at IL-18 composition of matter. This pending U.S. provisional application, if issued as a patent, is expected to expire in 2043, without taking into account any possible extension of patent term that may be available. We intend to file a PCT application and national phase applications in the U.S. and various non-U.S. jurisdictions before applicable deadlines.

### **IL-12**

We have a pending U.S. non-provisional application and a corresponding PCT application to compositions of self-assembling tumor targeted split IL-12 subunits. The pending U.S. non-provisional application, if issued as a patent, is expected to expire in 2042, without taking into account any possible extension of patent term that may be available. We intend to file additional applications in various non-U.S. jurisdictions based on the PCT application before applicable deadlines.

## **Patent Term and Extensions**

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to compensate a patentee for administrative delays by the USPTO in examining and granting a patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for extension of patent term when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the extension of patent term is related to the length of time the drug is under regulatory review while the patent is in force.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”), permits an extension of patent term of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug are extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. We will, in general, pursue available extension of patent terms in the U.S. and in non-U.S. jurisdictions that provide for extension of patent terms, however, there is no guarantee that the applicable authorities, including the FDA in the U.S., will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

## **Trademarks, Trade Secrets and Know-How**

In connection with the ongoing development of our product candidates in the U.S. and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks where available and when appropriate.

In addition to patent and trademark protection, we rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our partners, collaborators, employees and consultants and contractors, as well as invention assignment agreements with our employees and selected consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary intellectual property of third parties to develop, manufacture and commercialize specific aspects of our future products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or future commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have a material adverse impact on us. If third parties file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

For more information regarding risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

## **Government Regulation**

In the U.S., biological products are subject to regulation under the U.S. Federal Food, Drug, and Cosmetic Act (“FD&C Act”) and the Public Health Service Act (“PHS Act”), and other U.S. federal, state, local and non-U.S. statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations

govern, among other things, the testing, manufacturing, quality control, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, post-approval monitoring and reporting, advertising and promotion, export and import of biological products. FDA clearance of an IND must be obtained before clinical testing of a biological product candidate in the U.S., and FDA approval of a BLA must be obtained before marketing of a biological product in the U.S. Similar laws and regulations are in place outside the U.S. The process of obtaining regulatory approvals and the subsequent compliance with appropriate U.S. federal, state, local and non-U.S. statutes and regulations require the expenditure of substantial time and financial resources.

### **U.S. Biological Products Development Process**

The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practice (“GLP”), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must receive FDA clearance before human clinical studies may begin;
- approval by an institutional review board (“IRB”) or independent ethics committee at each clinical trial site before each trial may be initiated;
- manufacture of drug substance and drug product in accordance with applicable regulations, including manufacturing activities performed in accordance with cGMP requirements;
- performance of adequate and well-controlled human clinical studies according to the FDA’s regulations commonly referred to as good clinical practices (“GCP”), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the biological product candidate for its intended use;
- submission to the FDA of a BLA for marketing approval that includes evidence of safety, purity, and potency from results of nonclinical testing and clinical studies;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biological product’s identity, strength, quality and purity;
- potential FDA inspection of the company and the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee.

Before testing any biological product candidate in humans, the product candidate is evaluated in preclinical tests, also referred to as nonclinical studies, that include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with applicable U.S. federal regulations and requirements including GLP.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical trial protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A clinical hold may either be a full clinical hold or a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. The FDA may also impose clinical holds on an IND or a clinical trial at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, clinical trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials generally involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's GCP regulations, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers factors such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each study subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information are collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness and safety of the product for its intended use, establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

In March 2022, the FDA released a final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by the FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual reports detailing the progress and results of preclinical studies and clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor receives the safety information and determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days

## [Table of Contents](#)

after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

### **U.S. Review and Approval Processes**

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product may begin. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the biological product candidate to the satisfaction of the FDA.

In addition, under the Pediatric Research Equity Act, as amended ("PREA"), a BLA and certain supplements to a BLA must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor that is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("iPSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The FDA and the sponsor must reach an agreement on the iPSP and any amendments to the iPSP. The FDA may grant deferrals of required pediatric assessments or reports or full or partial waivers. Unless otherwise required, PREA does not apply to any biological product for an indication for which orphan designation has been granted. For example, a sponsor who is planning to submit an original application for a new active ingredient that is subject to the molecularly targeted cancer drug provision of PREA (i.e., where the drug that is the subject of the application is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer) is also required to submit an iPSP, regardless of whether the drug is for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews a BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not

## [Table of Contents](#)

bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (“REMS”), is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without a REMS.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assess whether the clinical studies were conducted in compliance with GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval in its discretion. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve a BLA in its submitted form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor (e.g., requiring labeling changes) or major (e.g., requiring additional clinical studies). Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product receives regulatory approval, an approval letter authorizes commercial marketing of the biological product with specific prescribing information for specific indications. The approval may be significantly limited to specific conditions of use, or the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, which could restrict the commercial value of the product. The FDA may impose conditions on product distribution, prescribing, or dispensing in the form of a REMS, or may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical studies, designed to further assess a biological product’s safety and effectiveness, or surveillance programs to monitor the safety of an approved product.

One of the performance goals agreed to by the FDA under the Prescription Drug User Fee Act (“PDUFA”) is to review 90% of standard BLAs within 10 months of the 60-day filing date and 90% of priority BLAs within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

### **U.S. Orphan Drug Designation**

Under the Orphan Drug Act of 1983, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan designation to a drug or biological product, the FDA publicly discloses the orphan designation. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than its orphan designation, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union (“EU”) has similar, but not identical, benefits.

### **U.S. Expedited Development and Review Programs**

The FDA has a Fast Track program that is intended to expedite or facilitate the development and review of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for FTD if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. FTD applies to both the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product. One of the benefits of FTD is that the sponsor can submit completed sections of its BLA on a rolling basis for review by FDA rather than waiting until every section of the BLA is completed before the entire application can be reviewed, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

In addition, a product intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies may be eligible for Breakthrough Therapy designation. A product designated as a Breakthrough Therapy is eligible for all the benefits of the Fast Track program, as well as an organizational commitment by the FDA to involve senior management at the agency to provide timely advice to help the sponsor design and conduct an efficient development program.

Any product—including a product candidate that has received Fast Track and/or Breakthrough Therapy designation—may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product may be eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or if the product represents a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval if it treats a serious or life-threatening illness and has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit or on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies, and, under the Food and Drug Omnibus Reform Act of 2022 (“FDORA”) the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date accelerated approval is granted. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.



## **Post-Approval Requirements**

Maintaining compliance with applicable U.S. federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely on third parties for the production of clinical and future commercial quantities of any future products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Other post-approval requirements applicable to biological products include adverse event reporting, submitting annual reports and maintaining certain records. New safety or effectiveness data that emerge after approval may require changes to a drug's approved labeling, including the addition of new warnings and contraindications or implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue.

We also must comply with the FDA's and other jurisdictions' advertising and promotion regulations and rules, such as those related to direct-to-consumer advertising and promotion to healthcare professionals. Although physicians may prescribe a product for uses that are not in the product's FDA-approved prescribing information, manufacturers may not market or promote such unapproved uses. In addition, promotional materials for an FDA-approved product must be submitted to the FDA at the time of their first use.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. Consequences could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with healthcare professionals, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

## **U.S. Patent Term Restoration and Marketing Exclusivity**

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited extension of patent term under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of product approval. The USPTO, in consultation with the FDA, reviews and approves the application for any extension of patent term or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant BLA.

## [Table of Contents](#)

A biological product may also be eligible to obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, runs from the end of other regulatory exclusivity protection and may be granted based on the voluntary completion of a pediatric study that fairly responds to an FDA-issued “Written Request” for such a study.

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), created an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, a reference biological product is granted twelve years of exclusivity from the date of first licensure of the reference 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. “First licensure” typically means the initial date the reference biological product was approved in the U.S.; however, date of first licensure does not include the date of licensure of (and therefore, a new period of exclusivity is not available for) a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

### **Healthcare and Privacy Laws**

In addition to restrictions on marketing of pharmaceutical products, several other types of U.S. state/federal laws and trade association membership codes of conduct have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include Anti-Kickback and false claims statutes. The U.S. federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity need not have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from U.S. federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging healthcare professionals or patients as speakers or consultants, may be subject to scrutiny if they do not fit squarely within the exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs.

The U.S. federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or

## [Table of Contents](#)

concealing an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the U.S. federal government alleging violations of the False Claims Act and to share in any monetary recovery. In recent years, certain pharmaceutical and other healthcare companies have faced enforcement actions under the U.S. federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill U.S. federal programs for the product. Other companies have faced enforcement actions for causing false claims to be submitted because of the company’s marketing the product for unapproved, and thus non-reimbursable, uses. U.S. federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, the Affordable Care Act amended U.S. federal law to provide that the government, or a “whistleblower” bringing an action on behalf of the government, may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback statute constitutes a false or fraudulent claim for purposes of the U.S. federal civil False Claims Act. In addition to the civil False Claims Act, there is a U.S. federal criminal statute that prohibits making or presenting a false or fictitious or fraudulent claim to the U.S. federal government.

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), also created several new U.S. federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The U.S. federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to engage in extensive tracking of payments and other transfers of value to physicians, physician assistants, advanced practice nurses and teaching hospitals, including physician ownership and investment interests, and public reporting of such data. Pharmaceutical and biological manufacturers with products for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program are required to track such payments, and must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. A number of other countries, states and municipalities have also implemented additional payment tracking and reporting requirements, which if not done correctly may result in additional penalties.

In addition, the U.S. Foreign Corrupt Practices Act of 1977, as amended (“FCPA”), prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. In many other countries, healthcare professionals who prescribe pharmaceuticals are employed by government entities, and the purchasers of pharmaceuticals are government entities. Our dealings with these prescribers and purchasers may be subject to the FCPA.

Other countries, including a number of EU member states, have laws of similar application, including anti-bribery or anti-corruption laws such as the United Kingdom Bribery Act 2010 (the “UK Bribery Act”). The UK Bribery Act prohibits giving, offering, or promising bribes to any person, as well as requesting, agreeing to receive, or accepting bribes from any person. Under the UK Bribery Act, a company that carries on a business or part of a business in the United Kingdom (“UK”) may be held liable for bribes given, offered or promised to any person in any country by employees or other persons associated with the company in order to obtain or retain

## [Table of Contents](#)

business or a business advantage for the company. Liability under the UK Bribery Act is strict, but a defense of having in place adequate procedures designed to prevent bribery is available.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the U.S. federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing U.S. federal civil actions. In California the California Consumer Protection Act (“CCPA”), which went into effect on January 1, 2020 and was amended effective January 1, 2023, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and 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. While clinical trial data and information governed by HIPAA are 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. Other states, including Virginia (effective January 1, 2023), Colorado (effective July 1, 2023), Connecticut (effective July 1, 2023), and Utah (effective December 31, 2023) have passed privacy legislation and more states may do so in the future, including Iowa, where the Iowa state legislature passed a comprehensive privacy legislation on March 15, 2023. State and non-U.S. laws, including for example the EU General Data Protection Regulation, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The majority of states also have statutes or regulations similar to the U.S. federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states, to report gifts and payments to individual health care providers in those states, marketing expenditures, and drug pricing information. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. Certain state and local laws require the registration of pharmaceutical sales representatives.

Because of the breadth of these various healthcare and privacy laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare and privacy laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

## **Government Regulation Outside of the U.S.**

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application (“CTA”), much like the IND prior to the commencement of human clinical studies. In the EU, for example, a CTA must be submitted for each clinical trial to each country’s national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country’s requirements, the corresponding clinical study may proceed.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

The new Clinical Trials Regulation (Regulation (EU) No 536/2014) (the “Regulation”) in the EU replaced the previous Clinical Trials Directive 2001/20/EC on 31 January 2022 and overhauled the system of approvals for clinical trials in the EU. The transitory provisions of the new Regulation provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the new Regulation. Specifically, the new Regulation, which is directly applicable in all Member States (meaning that no national implementing legislation in each Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have also been established for the assessment of CTAs.

To obtain regulatory approval of a product under the EU regulatory systems, we must submit a marketing authorization application. A centralized marketing authorization is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and is valid throughout the EU, and in the additional Member States of the European Economic Area (Norway, Iceland and Liechtenstein). The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines), and medicinal products containing a new active substance indicated for the treatment of human immunodeficiency virus/acquired immunodeficiency syndrome, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. The EU also provides opportunities for data and market exclusivity. Upon receiving a marketing authorization in the EU, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator’s preclinical and clinical trial data contained in the dossier

of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity (and the grant of the relevant generic or biosimilar marketing authorization). The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan product if its sponsor can establish that (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication during which time no "similar medicinal product" for the same indication may be placed on the market, subject to certain limited exceptions. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for a marketing authorization. Orphan designation itself does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EU, the advertising and promotion of our products will also be subject to EU Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU Member State legislation that may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's approved labeling. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at the EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict communications concerning the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

The national laws of certain EU Member States require payments made to physicians by qualifying pharmaceutical companies to be publicly disclosed. In addition, agreements with physicians must often be submitted for prior notification and approval by the physician's employer, the competent professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States.

## [Table of Contents](#)

The above-mentioned EU rules are also generally applicable in the additional countries of the European Economic Area (Liechtenstein, Iceland and Norway).

The UK left the EU on January 31, 2020 and the UK and the EU concluded a trade and cooperation agreement (the “TCA”) which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework continues to apply in Northern Ireland for the time being). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain’s regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. The extent to which the regulation of clinical trials in the UK will mirror the new EU Clinical Trials Regulation in the long term is not yet certain, however, in March 2023 the Medicines and Healthcare products Regulatory Agency (“MHRA”) the UK’s medicines regulator, has published a detailed response to the consultation on a set of proposals designed to improve and strengthen the UK clinical trials legislation, which ran in early 2022. The MHRA has stated they will now take forward new legislation to update the UK clinical trials legislation in line with the detailed response to the consultation. The key purpose of the new legislation will be to provide a more flexible regime to make it easier to conduct trials in the UK, increase the transparency of clinical trials conducted in the UK and make trials more patient centered.

However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under the new framework which will be put in place by the MHRA, from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization. On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the “Windsor Framework”. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK Government and the EU will enact legislative measures to bring it into law.

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable non-U.S. regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

## **Pricing, Coverage and Reimbursement**

In the U.S. and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. If coverage and adequate reimbursement are not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a product price sufficient to realize a sufficient return on our investment.

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the U.S., the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payers may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. These third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety, efficacy, and overall value. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to incurring the costs required to obtain FDA approvals. Our product candidates may not be considered medically reasonable or necessary or cost-effective.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drug products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate systems under which products may be marketed only after a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of studies or analyses of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to set their own prices for medicines, but exert cost controls in other ways, including but not limited to, placing revenue caps on product sales, providing reimbursement for only a subset of eligible patients, mandating price negotiations after a set period of time, or mandating that prices not exceed an average basket of prices in other countries. The downward pressure on health care costs in general, particularly treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, European governments may periodically review and decrease prices based on factors, including but not limited to, years-on-market, price in other countries, competitive entry, new clinical data, lack of supporting clinical data, or other factors.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, the emphasis on managed care in the U.S. has increased and we expect will continue to exert downward pressure on pharmaceutical pricing and reimbursement. Coverage policies, third-party reimbursement rates and



pharmaceutical pricing regulations may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### **Healthcare Reform**

Payers, whether domestic or non-U.S., or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the U.S. and certain non-U.S. jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”) was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the U.S. federal government’s comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court. Additionally, the former Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices and the U.S. Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business, especially given the new administration.

The Inflation Reduction Act of 2022 (“IRA”) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from \$7,050 to \$2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under 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 at certain time points following FDA approval; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HSS rebate rule that would have limited 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 orphan designation and are approved for only that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’s Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general are not yet known.

U.S. federal, state and local governments in the U.S. and non-U.S. governments continue to consider other legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Specifically, there

have been several recent U.S. Congressional inquiries and proposed U.S. federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2011, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by the U.S. Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

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

The former Trump administration's budget proposal for fiscal year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to the U.S. Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the former Trump administration also previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain U.S. federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services ("HHS") has already solicited feedback on some of these measures and, at the same time, implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions.

In 2020, former President Trump announced several executive orders related to prescription drug pricing that sought to implement several of the former administration's proposals. In response, the FDA released a final rule, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S.

## Table of Contents

District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. Authorization of importation of drugs from Canada or implementation of the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The Inflation Reduction Act of 2022 delayed implementation of this rule to January 1, 2032.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted U.S. federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In addition, in February 2023, HHS issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, the U.S. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's motion for summary judgment invalidating the accumulator adjustment rule. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

## Human Capital Resources

Following the separation, we expect to have approximately \_\_\_\_\_ employees, \_\_\_\_\_ of whom hold M.D. or Ph.D. degrees. Approximately \_\_\_\_\_ employees are expected to be in discovery research, \_\_\_\_\_ in our drug development organization, \_\_\_\_\_ in our strategy and corporate development organizations and \_\_\_\_\_ in general and administrative functions. None of our employees are expected to be subject to a

---

[Table of Contents](#)

collective bargaining agreement or represented by a trade or labor union. We consider our employee relations to be good.

**Facilities**

Following the separation, our corporate offices will be located in \_\_\_\_\_, where we will occupy approximately \_\_\_\_\_ rentable square feet of office and laboratory space under a lease that expires in \_\_\_\_\_. In connection with the separation, we expect that Alkermes will assign to us the lease for the facility located at 850 and 852 Winter Street in Waltham, Massachusetts. We believe this facility is sufficient to meet our needs until the expiration of the lease and that suitable space will be available as and when needed.

**Legal Proceedings**

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims, which may have a material adverse effect on our financial position or results of operations.

## MANAGEMENT

### Directors and Executive Officers

The following table sets forth the names and ages, as of \_\_\_\_\_, 2023, and titles of the individuals we currently expect to serve as our executive officers and members of our board of directors upon completion of the separation. Certain biographical information with respect to those executive officers and directors follows the table.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Caroline Loew, Ph.D.		Chief Executive Officer
		Chief Financial Officer
		Director
		Director
		Director
		Director
		Director

### Executive Officers

Caroline Loew, Ph.D. will serve as our chief executive officer upon completion of the separation. Dr. Loew served as the president and chief executive officer of Glympse Bio, Inc. (“Glympse”) from November 2018 to August 2022 and as a strategic advisor to Glympse from August 2022 to October 2022. Prior to Glympse, Dr. Loew was vice president, head of research and development strategy and planning at Bristol-Myers Squibb Company from December 2015 to October 2018, where she led portfolio strategy and operations. Dr. Loew earned her Ph.D. in Organic Chemistry and B.Sc. in Chemistry from Imperial College London. We believe that Dr. Loew is qualified to serve as our chief executive officer and as a member of our board of directors because of her extensive scientific and industry knowledge with respect to the biotechnology and pharmaceutical industries.

We have not yet identified the individuals who will serve as our other executive officers upon completion of the separation, and will identify such executive officers in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part.

### Non-Management Directors

We expect to appoint non-management directors to serve on our board of directors upon completion of the separation, and will identify such directors in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part.

### Board Composition and Independence

Our business and affairs will be managed under the direction of our board of directors. Upon completion of the separation, our board of directors is expected to consist of \_\_\_\_\_ members. Our directors will hold office until their successors have been elected and qualified or until their earlier death, resignation or removal. It is anticipated that a majority of our board of directors will satisfy the independence standard established by the listing standards of Nasdaq Global Market as well as the corporate governance principles to be adopted by our board of directors.

We have applied to list our ordinary shares on The Nasdaq Global Market. Under the listing rules of the Nasdaq Stock Market (“Nasdaq”), independent directors must comprise a majority of a listed company’s board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under the Nasdaq listing rules, a director will only qualify as an “independent director” if, in the opinion of the company’s board of directors, that person does not have a relationship that would interfere with their exercise of independent judgment in carrying out the

## [Table of Contents](#)

responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in their capacity as a member of the audit committee, the board of directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (ii) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of any compensation to the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that members of our board of directors, except Dr. Loew, are independent directors, including for purposes of Nasdaq and U.S. Securities and Exchange Commission ("SEC") rules. In making that determination, our board of directors considered the relationships that each director has with us and all other facts and circumstances that the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each director, including directors that are affiliated with certain of our major shareholders. Upon completion of the separation, we expect that the composition and structure of our board of directors and each of its committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. There are no family relationships among any of our executive officers and directors.

We intend to adopt a policy, subject to and upon completion of the separation, that outlines a process for our securityholders to send communications to the board of directors.

### **Board Committees**

Upon the completion of the separation, our board of directors will have three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors.

Following the separation, the full text of our audit committee charter, compensation committee charter and nomination and corporate governance committee charter will be posted on the investor relations portion of our website at [www.mural.com](#). We do not incorporate the information contained on, or accessible through, our corporate website into this information statement, and you should not consider it a part of this information statement.

Each of our board committees will focus on their respective areas of responsibility, but the overall day-to-day management and decision making for Mural will be overseen by the full board of directors.

Our board of directors may also, from time to time, form new committees or subcommittees, based on our circumstances or where a desire for a more focused committee is identified. Our board of directors may also disband committees or subcommittees as it deems appropriate.

Our board of directors will be responsible for the appointment of committee members and will rely on the nominating and corporate governance committee to recommend candidates for such appointments, as well as candidates to serve as the chairs of the committees. Each committee of our board of directors will have the authority to engage outside experts, advisors and counsel, or to establish subcommittees, in each case to the extent it considers appropriate to assist the committee in its work.

### **Audit Committee**

The responsibilities of the audit committee will be more fully described in our Audit Committee Charter.

## Table of Contents

Upon completion of the separation, our audit committee will consist of \_\_\_\_\_ and will be chaired by \_\_\_\_\_. The purpose and responsibilities of the audit committee will include:

- appointing and approving the compensation, and assessing the independence of our independent registered public accounting firm;
- pre-approving audit services and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and the members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and our quarterly financial statements, related disclosures and critical accounting policies and practices;
- coordinating the oversight and reviewing the adequacy of our internal controls over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related and other compliance complaints and concerns;
- recommending, based upon its review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the report of the audit committee required by SEC rules to be included in our annual proxy statement; and
- reviewing all related person transactions for potential conflict of interest situations and approving any such transactions.

Upon completion of the separation, we expect that the audit committee will consist entirely of independent directors, and we intend that each committee member will meet the independence requirements set forth in the Nasdaq listing standards and Rule 10A under the Exchange Act. Each member of the audit committee will be financially literate and have accounting or related financial management expertise as such terms are interpreted by our board of directors in its business judgment. Additionally, upon completion of the separation, at least one member of the audit committee will be an “audit committee financial expert” as defined under SEC rules and the Nasdaq Global Market listing standards applicable to audit committees. The initial members of the audit committee will be determined prior to the completion of the separation. The responsibilities of the audit committee are without prejudice to the responsibilities of the board of directors.

### ***Compensation Committee***

The responsibilities of the compensation committee will be more fully described in our Compensation Committee Charter. Upon completion of the separation, our compensation committee will consist of \_\_\_\_\_, and will be chaired by \_\_\_\_\_. The purpose and responsibilities of the compensation committee will include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our chief executive officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and, based on such evaluation, reviewing and recommending to the board of directors the cash compensation of, and grants and awards to our chief executive officer under equity-based plans;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policies;

## Table of Contents

- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in applicable Nasdaq listing rules;
- reviewing and recommending to the board of directors our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our non-employee directors;
- preparing our compensation committee report if and when required by SEC rules for inclusion in our annual proxy statement and/or in our Annual Report on Form 10-K;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis,” if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Upon completion of the separation, we expect that the compensation committee will consist entirely of independent directors, and we intend that each committee member will meet the independence requirements set forth in the listing standards. We also intend the members of the compensation committee will qualify as “non-employee directors” (within the meaning of Rule 16b-3 of the Exchange Act). The initial members of the compensation committee will be determined prior to the completion of the separation.

### *Compensation Committee Interlocks and Insider Participation*

During the fiscal year ended December 31, 2022, Mural did not exist in its current form and did not have a compensation committee or any other committee serving a similar function. Prior to the separation, decisions as to the compensation of those who are expected to serve as our executive officers and our non-employee directors were made by the compensation committee of the Alkermes plc board of directors. Following the separation, our compensation committee will ratify the compensation of our executive officers and non-employee directors.

### *Nominating and Corporate Governance Committee*

The responsibilities of the nominating and corporate governance committee will be more fully described in our Nominating and Corporate Governance Committee Charter. Upon completion of the separation, our nominating and corporate governance committee will consist of and will be chaired by . The purpose and responsibilities of the nominating and corporate governance committee will include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating director candidates, including nominees recommended by shareholders;
- reviewing the composition of the board of directors to assess whether it is composed of members containing the appropriate skills and expertise to advise the company;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors, including its committees.

Upon completion of the separation, we expect that the nominating and corporate governance committee will consist entirely of independent directors, and we intend that each committee member will meet the independence requirements set forth in the Nasdaq listing standards. The initial members of the nominating and corporate governance committee will be determined prior to the completion of the separation.



**Code of Business Conduct and Ethics**

In connection with the separation, our board of directors is expected to adopt corporate governance principles that set forth the responsibilities of the board of directors and the qualifications and independence of its members and the members of its standing committees. In addition, in connection with the separation, our board of directors is expected to adopt, among other codes and policies, a code of conduct setting forth standards applicable to the company and our subsidiaries, and our directors, officers and employees. The corporate governance principles and code of conduct will be available on our website at . We expect that any amendments to the code of business conduct and ethics, or any waivers of its requirements, will be disclosed on our website.

## EXECUTIVE COMPENSATION

### Executive Compensation

We have not yet identified the individuals who will serve as our executive officers upon completion of the separation, other than our chief executive officer, Dr. Caroline Loew. None of our executive officers were serving as executive officers of Alkermes as of December 31, 2022, and as such, our executive officers do not have historical compensation information to be reported in this Form 10. We will provide information for our other executive officers as required in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part once they are identified. Compensation arrangements for our executive officers will be determined based on the compensation policies, programs and procedures to be established by our board of directors or the compensation committee that our board of directors will form in connection with the separation.

### Employment Agreements

In connection with the separation, we have entered into or will enter into employment agreements with our executive officers. Below is a description of the employment agreement with our chief executive officer. We will provide additional information regarding the employment agreements with our other executive officers as required in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part once they are identified.

*Caroline Loew, Ph.D.* On June 1, 2023, Alkermes and, effective as of the completion of the separation, Mural, entered into an employment agreement with Dr. Loew (the “Loew Employment Agreement”), which provides that Dr. Loew is to be employed by Alkermes as of June 5, 2023 as a strategic advisor to Alkermes and that, as of the completion of the separation, Dr. Loew will be employed by Mural as President and Chief Executive Officer. The Loew Employment Agreement provides for: (i) an initial annual base salary of \$585,000, which is subject to annual review, (ii) initial target annual cash incentive compensation of 55% of Dr. Loew’s base salary, with any annual cash incentive compensation for calendar year 2023 to be prorated based on Dr. Loew’s start date and (iii) a sign-on bonus in the aggregate amount of \$280,000, with the first installment of \$100,000 to be paid within 30 days of Dr. Loew’s start date with Alkermes and the second installment of \$180,000 to be paid within 30 days of the effective date of the separation (with any previously paid installment of the sign-on bonus subject to repayment in the event that Dr. Loew voluntarily separates from employment without “good reason” (as defined in the Loew Employment Agreement) or Dr. Loew’s employment is terminated without “cause” (as defined in the Loew Employment Agreement) within six months following the date such installment of the sign-on bonus is paid). The Loew Employment Agreement also provides for an initial equity award with respect to Alkermes ordinary shares with an aggregate grant date fair value equal to 2.0% of the estimated overall value of Mural as of the effective date of the separation, 65% of which will be in the form of an option to purchase Alkermes ordinary shares that vests as to 25% of the underlying shares on the one-year anniversary of the date of grant, with the remainder to vest in 12 equal quarterly installments on each quarterly anniversary of Dr. Loew’s start date thereafter, and 35% of which will be in the form of restricted stock unit awards that vest in four equal annual installments, with the first installment to vest on the first anniversary of the date of grant and the remaining three installments to vest on each of the next three anniversaries of Dr. Loew’s start date, assuming that she remains employed by Mural on each such date. On the effective date of the separation, these awards will be converted into equity awards for Mural ordinary shares, subject to substantially the same terms. The Loew Employment Agreement also provides that, following the separation, Mural will grant Dr. Loew an equity award such that Dr. Loew holds equity awards covering Mural ordinary shares equal to 3.5% of the aggregate outstanding equity of Mural, which award will be 65% in the form of an option to purchase Mural ordinary shares that vests as to 25% of the underlying shares on the one-year anniversary of the effective date of the separation, with the remainder to vest in 12 equal quarterly installments on each quarterly anniversary of the effective date of the separation thereafter, and 35% in the form of restricted stock unit awards that vest in four equal annual installments following the effective date of the separation.

Pursuant to the Loew Employment Agreement, in the event that Alkermes terminates Dr. Loew’s employment without cause on or prior to September 30, 2024 in connection with Alkermes’ public announcement that the proposed separation will not move forward or the separation is not completed prior to September 30, 2024 and Dr. Loew terminates her employment within 60 days thereafter, Dr. Loew will be entitled to the following severance payments and benefits, subject to her execution and the effectiveness of a

## Table of Contents

general release of claims against Alkermes and/or Mural (the “Release”): (i) one times the sum (A) of Dr. Loew’s then-current base salary plus (B) the higher of Dr. Loew’s target bonus for the fiscal year in which the termination occurs or the actual amount of the annual bonus earned by Dr. Loew with respect to the calendar year prior to the year in which the date of termination occurs (the “Prior Year’s Bonus”), (ii) subject to Dr. Loew’s copayment of premium amounts at the applicable active employees’ rate and proper election to continue COBRA health coverage, payment of the portion of the premiums equal to the amount that we would have paid to provide health insurance to Dr. Loew had she remained employed with us until the earliest of (A) 12 months following termination, (B) Dr. Loew’s eligibility for group medical plan benefits under any other employer’s group medical plan or (C) the end of Dr. Loew’s COBRA health continuation period, (iii) Dr. Loew shall not be required to repay any portion of the sign-on bonus paid to her and (iv) an amount equal to Dr. Loew’s target bonus for the fiscal year in which the termination occurs, pro-rated for the number of days Dr. Loew is employed in the year of termination (the “Pro-Rated Target Bonus”).

Pursuant to the Loew Employment Agreement, in the event that Dr. Loew’s employment is terminated by Alkermes or Mural, as applicable, without cause or Dr. Loew terminates her employment for good reason, and such termination occurs outside the Change in Control Period (as defined below), Dr. Loew will be entitled to the following severance payments and benefits, subject to her execution and the effectiveness of the Release: (i) an amount equal to the sum of (A) 15 months of Dr. Loew’s then-current base salary plus (B) 1.25 times the higher of Dr. Loew’s target bonus for the fiscal year in which the termination occurs or the Prior Year’s Bonus, (ii) subject to Dr. Loew’s copayment of premium amounts at the applicable active employees’ rate and proper election to continue COBRA health coverage, payment of the portion of the premiums equal to the amount that we would have paid to provide health insurance to Dr. Loew had she remained employed with us until the earliest of (A) 15 months following termination, (B) Dr. Loew’s eligibility for group medical plan benefits under any other employer’s group medical plan or (C) the end of Dr. Loew’s COBRA health continuation period, (iii) the Pro-Rated Target Bonus, (iv) if not paid prior to the date of termination, the second installment of the sign-on bonus, and (v) Dr. Loew shall not be required to repay any portion of the sign-on bonus paid to her.

In the event that Dr. Loew’s employment is terminated after the separation by Mural without cause or if Dr. Loew resigns for good reason, in each case within the 24 months following a “change in control” (as defined in the Loew Employment Agreement) (the “Change in Control Period”), Dr. Loew will be entitled to the following severance payments and benefits, (i) a lump-sum payment equal to the sum of (A) two times Dr. Loew’s then-current annual base salary and (B) two times the higher of the target bonus for the year in which the termination occurs or the Prior Year’s Bonus, (ii) subject to Dr. Loew’s copayment of premium amounts at the applicable active employees’ rate and proper election to continue COBRA health coverage, payment of the portion of the premiums equal to the amount that we would have paid to provide health insurance to Dr. Loew had she remained employed with us until the earliest of (A) 18 months following termination, (B) Dr. Loew’s eligibility for group medical plan benefits under any other employer’s group medical plan or (C) the end of Dr. Loew’s COBRA health continuation period, (iii) all outstanding Mural equity-based awards held by Dr. Loew shall immediately vest and become fully exercisable or nonforfeitable as of the date of termination, (iv) if not yet paid prior to the date of termination, Mural shall pay the second installment of the Mural sign-on bonus and (v) Dr. Loew shall not be required to repay any portion of the sign-on bonus. If the payments or benefits payable to Dr. Loew in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Internal Revenue Code of 1986, as amended, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to Dr. Loew.

### **Director Compensation**

While we expect Dr. Loew to serve on our board of directors, we have not yet appointed Dr. Loew to the board of directors or identified the other members of our board of directors. We will provide information regarding the proposed compensation of our non-employee directors in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part.

### **Limitation on Liability and Indemnification Matters**

Each of our directors and executive officers is entitled to indemnification under our amended and restated memorandum and articles of association (together, our “Constitution”). In addition, we will enter into indemnification agreements with each of our current directors and executive officers.

## [Table of Contents](#)

Our Constitution will provide that our directors and secretary(ies) may only be indemnified to the extent permitted by the Irish Companies Act 2014 (the “Irish Companies Act”), which limits indemnification of directors and secretaries of Irish companies to circumstances in which the indemnified party receives a favorable judgment in respect of the liability, or where an Irish court determines that the director or the secretary acted honestly and reasonably and ought fairly to be excused. This restriction in the Irish Companies Act does not apply to executives who are not directors or the secretary of Mural. Any provision for indemnification by Mural to a greater extent to the directors or secretaries of Mural is void under Irish law, whether contained in our Constitution or any contract between such individual and Mural.

Our Constitution will also contain indemnification and expense advancement provisions for current or former executives who are not directors or the secretary of Mural.

The directors of Mural may, on a case-by-case basis, decide at their discretion that it is in the best interests of Mural to indemnify an individual director from any liability arising from his or her position as a director of Mural. However, this discretion must be exercised bona fide in the best interests of Mural as a whole.

Irish companies may obtain directors’ and officers’ liability insurance, as well as other types of insurance, for their directors and officers.

In addition, due to the more restrictive provisions of Irish law in relation to the indemnification of directors and the secretary as described above, in connection with the separation, Mural Oncology, Inc. will also enter into indemnification agreements with Mural’s directors and executive officers. Mural expects that the indemnification and expense advancement to be provided to the directors and executive officers of Mural under these indemnification agreements will, to the extent permitted by Irish law, be the same or substantially similar to that afforded in the current indemnification agreements between Alkermes and its officers and directors.

Under Irish law, a company may not exempt its directors from liability for negligence or a breach of duty. However, where a breach of duty has been established, directors may be statutorily exempted by an Irish court from personal liability for negligence or breach of duty if, among other things, the court determines that they have acted honestly and reasonably, and that they may fairly be excused as a result.

Under Irish law, shareholders may not agree to exempt a director or officer from any claim or right of action that the shareholder may have, whether individually or in the right of a company, on account of any action taken or the failure to take any action in the performance of his or her duties to the company.

The limitation of liability and indemnification provisions described above may discourage shareholders from bringing a lawsuit against directors for breaches of their fiduciary duties. These provisions may also have the effect of reducing the likelihood of derivative litigation against Mural’s directors and officers, even though such an action, if successful, might otherwise benefit Mural and its shareholders. However, these provisions will not limit or eliminate Mural’s rights, or those of any shareholder, to seek any non-monetary relief such as injunction or rescission in the event of a breach of a director’s duty of care, nor alter any liability of directors and officers under the U.S. federal securities laws. In addition, your investment may be materially adversely affected to the extent that, in a class action or direct suit, Mural pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. There is currently no pending material litigation or proceeding against any Mural director, officer or employee for which indemnification is being sought.

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

### **Relationship with Alkermes**

Prior to the completion of the separation, all of Mural's issued shares are held legally and beneficially by an Irish corporate services provider (which is not a subsidiary of Alkermes). Following the completion of the separation, it is not expected that Alkermes will own any of Mural's ordinary shares. See "Risk Factors—Risks Related to the Separation and Distribution" and "The Separation and Distribution."

Following the separation and distribution, Mural and Alkermes will operate separately, each as an independent public company. In connection with the separation, Mural and Alkermes, or their respective subsidiaries, have entered or will enter into certain agreements that will effectuate the separation and govern the relationship between Mural and Alkermes after the separation.

The following is a summary of the terms of the material agreements that Mural intends to enter into with Alkermes prior to or concurrently with the completion of the separation, which will be filed as exhibits in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part. These summaries set forth the terms of the agreements that we believe are material to Mural and are qualified in their entirety by reference to the full text of such agreements. The terms of the agreements described below that will be in effect following the separation and distribution have not yet been finalized. Changes to these agreements, some of which may be material, may be made prior to the separation and distribution.

### **Agreements with Alkermes**

Unless the context requires otherwise, references to "Mural," "we," "us," "our," "our company" and "the company" in this section refer to Mural Oncology Limited, an Irish limited company and its subsidiaries, and references to "Alkermes" refer to Alkermes plc, an Irish public limited company, and its consolidated subsidiaries, in each case as they will exist, assuming the completion of all the transactions referred to in this information statement in connection with the separation and the distribution.

#### Separation Agreement

We intend to enter into a separation agreement with Alkermes prior to the distribution of our ordinary shares to Alkermes shareholders. The separation agreement will set forth our agreements with Alkermes regarding the principal actions to be taken in connection with the separation, including the distribution. The separation agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of Mural and Alkermes as part of the separation, and it will provide for when and how these transfers, assumptions and assignments will occur.

*Transfer of Assets and Assumption of Liabilities.* The separation agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of Alkermes and us as part of an internal reorganization, and will describe when and how these transfers, assumptions and assignments will occur, though certain of the transfers, assumptions and assignments will have already occurred prior to the parties' entering into the separation agreement. The separation agreement will provide for those transfers of assets and assumptions of liabilities that are necessary in connection with the separation so that we and Alkermes receive or retain the assets necessary to operate our respective businesses and retain or assume the liabilities allocated in accordance with the separation. The separation agreement will also provide for the settlement or extinguishment of certain liabilities and other obligations between us and Alkermes.

Except as otherwise set forth in the separation agreement or any ancillary agreement, each party to the separation agreement will assume the liability for, and control of, all pending, threatened and future legal matters related to its own business or its assumed or retained liabilities. The allocation of liabilities with respect to taxes, except for payroll taxes and reporting and other tax matters expressly covered by the employee matters agreement, are solely covered by the tax matters agreement.

*Further Assurances.* Each party will agree to use commercially reasonable efforts to take, or to cause to be taken, all actions, and to do, or to cause to be done, all things reasonably necessary under applicable law or contractual obligations to consummate and make effective the transactions contemplated by the separation agreement and other transaction agreements.

## Table of Contents

*Employee Non-Solicit and Non-Hire.* Each of Alkermes and Mural will be subject to mutual obligations, subject to customary exceptions. employee non-solicitation and non-hire

*The Distribution.* The separation agreement will govern the rights and obligations of the parties with respect to the distribution and certain actions that must occur prior to the distribution. On the distribution date, Mural will issue its ordinary shares to Alkermes shareholders on a pro rata basis, with each Alkermes shareholder receiving ordinary shares of Mural for every ordinary shares of Alkermes held of record as of close of business on , 2023, the record date for the distribution. Alkermes shareholders will receive cash in lieu of any fractional ordinary shares. Alkermes will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date for the distribution, the distribution date and the distribution ratio.

*Intellectual Property License.* Under the terms of the separation agreement, Alkermes will grant Mural a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property controlled by Alkermes as of the distribution date to allow Mural to use such intellectual property for the oncology business, and Mural will grant Alkermes a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to intellectual property transferred to Mural as part of the separation for use outside of the oncology business.

*Conditions.* The separation agreement will provide that the distribution is subject to several conditions that must be satisfied (or waived by Alkermes, in its sole discretion). Alkermes may, in its sole discretion, determine the record date, the distribution date and the distribution ratio or other terms of the distribution and may at any time prior to the completion of the distribution decide to abandon or modify the distribution. For further information regarding these conditions, see “The Separation and Distribution—Conditions to the Distribution.”

*Indemnification.* The separation agreement will provide for releases, with respect to pre-distribution claims, and cross-indemnities, with respect to post-distribution claims, that, except as otherwise provided in the separation agreement, 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 Alkermes under the separation agreement with Alkermes. The separation agreement will also specify procedures with respect to claims subject to indemnification and related matters. Indemnification with respect to taxes will be governed by the tax matters agreement described below.

*Term/Termination.* Prior to the distribution, Alkermes will have the unilateral right to terminate, modify or amend the terms of the separation agreement and amend, modify or abandon the distribution. After the effective time of the distribution, the term of the separation agreement is indefinite and it may only be terminated with the prior written consent of both Alkermes and Mural.

*Other Matters Governed by the Separation Agreement.* Other matters governed by the separation agreement include, without limitation, access to financial and other information, insurance, confidentiality and access to, and provision of, records.

### Transition Services Agreements

*Alkermes Transitional Services.* Mural and Alkermes will enter into a transition services agreement in connection with the separation pursuant to which Alkermes and its affiliates’ will provide, on an interim, transitional basis, various services to Mural and its subsidiaries. Historically, Alkermes has provided our business with significant corporate and shared services and resources related to corporate functions such as finance, human resources, internal audit, research and development, financial reporting, and information technology, which we refer to collectively as the “Alkermes Services.” This transition services agreement will become operative as of the completion of the separation and each of the Alkermes Services will continue for an initial term of , unless earlier terminated or extended according to the terms of the transition services agreement. We will pay Alkermes fees for the Alkermes Services, to be mutually agreed upon by us and Alkermes as provided under the transition services agreement, which fees will be based on Alkermes’ cost of providing the Alkermes Services.

## Table of Contents

*Mural Transitional Services.* We also intend to enter into a second transition services agreement whereby we will provide certain services to Alkermes, which we refer to collectively as the “Mural Services.” This second transition services agreement will become operative as of the completion of the separation and the Mural Services will continue for an initial term of \_\_\_\_\_, unless earlier terminated or extended according to the terms of the transition services agreement. Alkermes will pay us fees for the Mural Services, to be mutually agreed upon by us and Alkermes as provided under this transition services agreement, which fees will be based on our cost of providing the Mural Services.

### Tax Matters Agreement

We intend to enter into a tax matters agreement with Alkermes prior to or concurrently with the completion of the separation that will govern Alkermes’ and Mural’s respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, 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 of tax matters.

In addition, the tax matters agreement will impose certain restrictions on us and our subsidiaries (including restrictions on share issuances, business combinations, sales of assets and similar transactions) that will be designed to preserve the tax-free status of the distribution, together with certain related transactions. The tax matters agreement will provide special rules that allocate tax liabilities in the event the distribution, together with certain related transactions, is not tax-free. In general, under the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is 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 “Code”), and if and to the extent that such failure results from certain actions, omissions or failures to act by Alkermes, including a prohibited change of control in Alkermes under Section 355(e) of the Code or an acquisition of Alkermes shares or assets, then Alkermes will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from certain actions, omissions or failures to act by us, including a prohibited change of control in Mural under Section 355(e) of the Code or an acquisition of our shares or assets, then we will indemnify Alkermes for any resulting taxes, interest, penalties and other costs. If such failure does not result from a prohibited change of control in Alkermes or Mural under Section 355(e) of the Code and both we and Alkermes are responsible for such failure, liability will be shared according to relative fault. If neither we nor Alkermes is responsible for such failure, Alkermes will bear any resulting taxes, interest, penalties and other costs.

### Employee Matters Agreement

We intend to enter into an employee matters agreement with Alkermes prior to or concurrently with the completion of the separation. The employee matters agreement will govern Alkermes’, our and the parties’ respective subsidiaries’ and affiliates’ rights, responsibilities and obligations after the separation with respect to the following matters:

- employment, benefits and compensation matters relating to employees and former employees (and their respective dependents and beneficiaries) who are or were associated with Alkermes, including those who will become employees of Mural following the separation;
- the allocation of assets and liabilities generally relating to employees, employment or service-related matters and employee benefit plans; and
- other human resources, employment and employee benefits matters.

**Related Party Transactions Policy**

In connection with the separation, we plan to adopt a related party transactions policy that will govern the review and approval of related party transactions following the separation. Pursuant to this policy, if we want to enter into a transaction with a related party or an affiliate of a related party, our audit committee will review the proposed transaction to determine, based on applicable rules of the Nasdaq Global Market and the U.S. Securities and Exchange Commission, whether such transaction requires pre-approval by our audit committee or our board of directors. If pre-approval is required, the proposed transaction will be reviewed at the next regular or special meeting of our audit committee or our board of directors, as applicable. We may not enter into a related party transaction unless our audit committee has specifically confirmed in writing that either no further reviews are necessary or that all requisite corporate reviews have been obtained.

Each of the agreements between us and our subsidiaries and Alkermes and its subsidiaries that have been entered into prior to or concurrently with the completion of the separation, and any transactions contemplated thereby, will be deemed to be approved and not subject to the terms of such policy.



## SECURITY OWNERSHIP BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Prior to the distribution, all of our outstanding ordinary shares will be owned beneficially and of record by an Irish corporate services provider (which is not a subsidiary of Alkermes). The following tables set forth information with respect to the expected beneficial ownership of our ordinary shares immediately following the distribution, including: (i) each person who we believe will be a beneficial owner of more than five percent of our ordinary shares, (ii) each of our expected directors and named executive officers and (iii) all of our expected directors and executive officers as a group. Except as noted below, we based the share amounts on each person's beneficial ownership of Alkermes ordinary shares as of [redacted], 2023, after giving effect to a distribution ratio of [redacted] Mural ordinary shares for every [redacted] Alkermes ordinary shares. Immediately following the distribution, we estimate that [redacted] of our ordinary shares will be issued and outstanding based on the number of Alkermes ordinary shares outstanding as of [redacted], 2023. The actual number of our outstanding ordinary shares issued in the distribution will be determined on [redacted], 2023, the record date. Unless otherwise indicated, the address of each beneficial owner is in care of Alkermes plc, Connaught House, 1 Burlington Road, Dublin 4, Ireland, D04 C5Y6.

### Security Ownership of Certain Beneficial Owners

Based solely on the information publicly available reporting beneficial ownership of Alkermes ordinary shares, we anticipate the following shareholders will beneficially own more than five percent of our ordinary shares following the distribution.

<u>Name of Beneficial Owner</u>	<u>Number of Ordinary Shares</u>	<u>Percent of Ordinary Shares Outstanding</u>
---------------------------------	----------------------------------	---

### Security Ownership of Directors and Executive Officers

The following table provides information regarding beneficial ownership of our expected named executive officers, our expected directors and all of our expected directors and executive officers as a group as of [redacted], 2023.

<u>Name of Beneficial Owner</u>	<u>Number of Ordinary Shares <sup>(1)</sup></u>	<u>Percent of Ordinary Shares Outstanding</u>
---------------------------------	---	---

Directors and Officers as a Group (persons)

\* Less than one percent

(1) Does not include Mural ordinary shares that may be issued upon exercise or settlement of Mural equity awards that will be converted from Alkermes equity awards in connection with the distribution, as the conversion ratio is not currently calculable and such shares will not affect the beneficial ownership of our expected directors and named executive officers at the time of the distribution unless the equity awards are exercised or settled prior to the record date of the distribution.

## THE SEPARATION AND DISTRIBUTION

### Overview

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore separation of its neuroscience business and oncology business. Alkermes intends to effect the separation through the distribution of the ordinary shares of Mural to Alkermes' shareholders. The distribution is intended to be tax-free for U.S. federal income tax and Irish tax purposes to Alkermes' shareholders. See "The Separation and Distribution—Conditions to the Distribution" and "Material Irish Tax Consequences" for more information.

Mural is an Irish incorporated limited company established in May 2017 as a shelf company and was recently de-shelved to hold Alkermes' oncology business in connection with the separation. Prior to completion of the separation and distribution, we intend to alter the legal status of Mural under Irish law to that of a public limited company by re-registering it as a public limited company and changing its name to Mural Oncology Public Limited Company. Prior to the separation, the oncology business was held and conducted within Alkermes.

On \_\_\_\_\_, 2023, Alkermes' board of directors approved the transfer of the oncology business to us in return for which we will issue Mural ordinary shares to Alkermes shareholders on the basis of \_\_\_\_\_ Mural ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares issued and outstanding on the record date, subject to the satisfaction (or waiver) of all conditions to the distribution.

Currently, all of Mural's issued shares are held legally and beneficially by an Irish corporate services provider (which is not a subsidiary of Alkermes). Immediately prior to the distribution, Alkermes will transfer the oncology business to us in return for which we will issue Mural ordinary shares to Alkermes shareholders, pro rata to their respective holdings in Alkermes. Prior to the transfer by Alkermes to us of the oncology business, we will have no business operations.

On \_\_\_\_\_, 2023, the expected distribution date, each person who held Alkermes ordinary shares at the close of business on \_\_\_\_\_, 2023, the record date for the distribution, will receive \_\_\_\_\_ Mural ordinary shares for every \_\_\_\_\_ Alkermes ordinary shares held at the close of business on such date. You will receive cash in lieu of any fractional Mural ordinary shares which you would have received after the application of the above ratio. Immediately following the distribution, the persons entitled to receive Mural ordinary shares in the distribution will own all of the outstanding Mural ordinary shares. You will neither be required to pay anything for the Mural ordinary shares nor be required to surrender any Alkermes ordinary shares to participate in the distribution. In connection with these transactions, we will acquire by surrender all shares currently held by the Irish corporate services provider referred to above for no consideration, following which we will cancel such shares.

The distribution of Mural ordinary shares as described in this information statement is subject to the satisfaction or waiver of certain conditions by Alkermes. For a more detailed description of these conditions, see below in this section under "—Conditions to the Distribution."

### Reasons for the Separation

Alkermes' board of directors determined that separating its neuroscience business and oncology business would be in the best interests of Alkermes and its shareholders. A wide variety of factors were considered by Alkermes' board of directors in evaluating the separation. Among other things, Alkermes' board of directors considered the following potential benefits of the separation, including that the separation is expected to:

- allow each business to pursue its own operational and strategic priorities and respond to trends, developments and opportunities in its respective markets;

## Table of Contents

- create two separate and distinct management teams focused on each business' unique strategic priorities, target markets and corporate development opportunities;
- reduce competition for capital allocation between the neuroscience business and oncology business of revenues generated by Alkermes prior to the separation;
- create two independent companies that are expected to have well-capitalized financial structures and direct access to the debt and equity capital markets to fund each company's respective growth strategy;
- increase flexibility for each business to pursue its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- enable the board and management team of each business to better align corporate goals with the specific vision, strategy, and objectives of their respective businesses and establish compensation programs designed to attract and retain skilled employees; and
- allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

Alkermes' board of directors also considered a number of potentially negative factors in evaluating the separation, including the following factors that may impact Mural:

- some or all of the anticipated benefits of the separation to Alkermes and Mural may not be achieved for a variety of reasons, including: (i) the separation has required, and will continue to require, significant amounts of time and effort from Alkermes' management team, which may divert Alkermes' management team's attention from operating and growing the Alkermes and Mural businesses prior to the separation and (ii) following the separation, each business will be less diversified than Alkermes' business prior to the separation;
- costs and liabilities that were less significant to Alkermes as a whole will be more significant for Mural as a standalone company, and after the distribution, as a separate, independent entity, Mural may be unable to obtain goods, services, and technologies at prices or on terms as favorable as those Alkermes obtained prior to the separation;
- Mural and Alkermes will incur one-time costs related to the separation, including financial advisor, accounting, legal and other advisor costs;
- Mural will incur costs in connection with the transition to being a standalone public company that will include establishment of accounting, tax, auditing, legal and other professional services costs, recruiting and potential relocation costs associated with hiring personnel new to Mural and costs to separate information systems;
- under the terms of the tax matters agreement that Mural intends to enter into with Alkermes, for a period of two years following the distribution, Mural will be restricted from taking certain actions that could cause the distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes, which will limit Mural's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that might increase the value of its business; and
- the trading prices of Mural and Alkermes ordinary shares following the separation, and whether the combined market value of Mural ordinary shares and Alkermes ordinary shares will be less than, equal to, or greater than the market value of Alkermes ordinary shares prior to the separation, cannot be predicted with certainty.

Alkermes' board of directors concluded that the potential benefits of the separation outweighed these potentially negative factors. However, neither Alkermes nor Mural can be sure that, following the separation, any of the benefits described above or otherwise will be realized to the extent anticipated or at all. For more information on the risks involved in the separation process, see "Risk Factors—Risks Related to the Separation and Distribution."

## **When and How You Will Receive Mural Ordinary Shares in the Distribution**

With the assistance of \_\_\_\_\_, as distribution agent, Mural expects to issue its ordinary shares on \_\_\_\_\_, 2023, the distribution date, to all holders of outstanding Alkermes ordinary shares as of the close of business on \_\_\_\_\_, 2023, the record date. \_\_\_\_\_ will serve as the distribution agent in connection with the distribution and as transfer agent and registrar for Mural's ordinary shares.

If you own Alkermes ordinary shares as of the close of business on the record date, Mural ordinary shares that you are entitled to receive in the distribution will be issued electronically, as of the distribution date, to you in direct registration form or to your bank, broker or other nominee on your behalf. If you are a registered holder, the distribution agent or the transfer agent will then mail you a direct registration account statement that reflects your Mural ordinary shares. "Direct registration form" refers to a method of recording share ownership when no physical share certificates are issued to shareholders, as will be the case in the distribution.

Commencing on or shortly after the distribution date, if you are the registered holder of Alkermes ordinary shares, the distribution agent will mail to you an account statement that indicates the number of Mural ordinary shares that have been registered in book-entry form in your name, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive.

Most Alkermes shareholders beneficially own their ordinary shares through a bank or brokerage firm. In such cases, the bank or brokerage firm would be said to hold the shares in "street name" and ownership would be recorded on the bank or brokerage firm's books. If you beneficially own your Alkermes ordinary shares through a bank or brokerage firm, your bank or brokerage firm will credit your account for the Mural ordinary shares that you are entitled to receive in the distribution. If you have any questions concerning the mechanics of having shares held in "street name," please contact your bank or brokerage firm.

If you sell Alkermes ordinary shares in the "regular way" market up to and including the distribution date, you will also be selling your right to receive Mural ordinary shares in the distribution. See "—Trading Between the Record Date and Distribution Date" for more information.

## **Results of the Separation and Distribution**

After its separation from Alkermes, Mural will be an independent, publicly traded company. The actual number of ordinary shares to be distributed will be determined on \_\_\_\_\_, 2023, the record date for the distribution, and will reflect any exercise of Alkermes options or the vesting of Alkermes restricted stock units between the date the Alkermes board of directors declares the distribution and the record date for the distribution. The distribution will not affect the number of outstanding Alkermes ordinary shares or any rights of Alkermes' shareholders. No fractional ordinary shares of Mural will be distributed.

Prior to the distribution, Mural intends to enter into a separation agreement with Alkermes. Additionally, Mural and Alkermes, or their respective subsidiaries, also intend to enter into various other agreements, including a transition services agreement under which Mural will temporarily receive certain services from Alkermes, a second transition services agreement under which we will temporarily provide Alkermes with certain services, a tax matters agreement and an employee matters agreement. These agreements will effectuate the separation and distribution and will provide for the allocation between Alkermes and Mural, or their respective subsidiaries, of Alkermes' assets, employees, liabilities and obligations (including employee benefits, intellectual property and tax-related assets and liabilities) attributable to periods prior to, at and after Mural's separation from Alkermes. These agreements will also govern certain relationships between Alkermes and Mural, or their respective subsidiaries, after the separation. For a more detailed description of these agreements, see "Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes."

### **The Number of Mural Ordinary Shares You Will Receive**

For every \_\_\_\_\_ ordinary shares of Alkermes that you own at the close of business on \_\_\_\_\_, 2023, the record date for the distribution, you will receive \_\_\_\_\_ ordinary shares of Mural on the distribution date. Fractional ordinary shares of Mural will not be distributed to Alkermes shareholders. Instead, the distribution agent will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds (net of discounts and commissions) of the sales pro rata (based on the fractional share such holder would otherwise have been entitled to receive) to each holder who otherwise would have been entitled to receive a fractional share in the distribution. The distribution agent, in its sole discretion, without any influence by Alkermes or Mural, will determine when, how, through which broker-dealer and at what price to sell the whole shares. \_\_\_\_\_ is not an affiliate of either Alkermes or Mural and any broker-dealer used by \_\_\_\_\_, as distribution agent, will not be an affiliate of either Alkermes or Mural. Neither Mural nor Alkermes will be able to guarantee any minimum sale price in connection with the sale of these shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The aggregate net cash proceeds distributed to Alkermes shareholders in lieu of fractional shares will be taxable for U.S. federal income tax purposes. See “Material U.S. Federal Income Tax Consequences” for an explanation of the material U.S. federal income tax consequences of the distribution. If you are a holder of record of Alkermes ordinary shares, you will receive a check from the distribution agent in an amount equal to your pro rata share of the aggregate net cash proceeds of the sales. Mural estimates that it will take approximately \_\_\_\_\_ from the distribution date for the distribution agent to complete the distributions of the aggregate net cash proceeds. If you beneficially own your Alkermes ordinary shares through a bank or brokerage firm, your bank or brokerage firm will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales and will distribute to your account your share of such proceeds.

### **Transferability of Ordinary Shares You Receive**

Mural ordinary shares distributed to holders through the distribution will be transferable without registration under the Securities Act of 1933, as amended (the “Securities Act”), except for shares received by persons who may be deemed to be Mural affiliates. Persons who may be deemed to be Mural’s affiliates after the distribution generally include individuals or entities that control, are controlled by or are under common control with Mural, which may include certain of Mural’s executive officers, directors or principal shareholders. Securities held by Mural affiliates will be subject to resale restrictions under the Securities Act. Mural affiliates will be permitted to sell Mural ordinary shares only pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act, such as the exemption afforded by Rule 144 promulgated under the Securities Act.

### **Market for Mural Ordinary Shares**

There is currently no public trading market for Mural ordinary shares. Mural has applied to have its ordinary shares authorized for listing on the Nasdaq Global Market under the symbol “MURA” in connection with the distribution. No assurance can be given that Mural’s listing application will be approved.

Mural has not and will not set the initial price of its ordinary shares. The initial price will be established by the public markets. Mural cannot predict the price at which its ordinary shares will trade after the distribution. In fact, the combined trading prices, after the distribution, of the Mural ordinary shares that each Alkermes shareholder will receive in the distribution and Alkermes ordinary shares held at the record date may not equal the “regular way” trading price of an Alkermes ordinary share immediately prior to the distribution. The price at which Mural ordinary shares trade may fluctuate significantly, particularly until an orderly public market develops. Trading prices for Mural ordinary shares will be determined in the public markets and may be influenced by many factors. See “Risk Factors—Risks Related to Ownership of Our Ordinary Shares.”

### **Trading Between the Record Date and Distribution Date**

Beginning on or shortly before the record date and continuing up to and including through the distribution date, we expect that there will be two markets in Alkermes ordinary shares: a “regular way” market and an “ex-distribution” market. Alkermes ordinary shares that trade on the “regular way” market will trade with an entitlement to Mural ordinary shares distributed pursuant to the separation. Alkermes ordinary shares that trade on the “ex-distribution” market will trade without an entitlement to Mural ordinary shares distributed pursuant to the distribution. Therefore, if you sell Alkermes ordinary shares in the “regular way” market up to and including through the distribution date, you will also be selling your right to receive Mural ordinary shares in the distribution. If you own Alkermes ordinary shares at the close of business on the record date and sell those shares on the “ex-distribution” market up to and including through the distribution date, you will receive the Mural ordinary shares that you are entitled to receive pursuant to your ownership as of the record date of Alkermes ordinary shares.

Furthermore, Mural anticipates that trading in its ordinary shares will begin on a “when issued” basis on or shortly before the record date for the distribution and will continue up to and including the distribution date. “When issued” trading in the context of a separation refers to a sale or purchase made conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. The “when issued” trading market will be a market for Mural ordinary shares that will be distributed to holders of Alkermes ordinary shares on the distribution date. If you owned Alkermes ordinary shares at the close of business on the record date, you would be entitled to Mural ordinary shares distributed pursuant to the distribution. You may trade this entitlement to Mural ordinary shares, without impacting your ownership of Alkermes ordinary shares, on the “when issued” market. On the first trading day following the distribution date, “when issued” trading with respect to Mural ordinary shares will end, and “regular way” trading will begin.

### **Conditions to the Distribution**

Mural expects that the distribution will be effective at 12:01 a.m., Eastern Time, on \_\_\_\_\_, 2023, the distribution date, provided that certain conditions, including those listed below, shall have been satisfied or waived by Alkermes in its sole discretion:

- the receipt by Alkermes of a private letter ruling from the Internal Revenue Service (“IRS”) and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes’ board of directors and each continuing to be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended (the “Code”), except for cash received in lieu of fractional ordinary shares;
- the internal restructuring transactions and the transfer of assets to, and assumption of liabilities by, Mural contemplated by the separation agreement to be completed prior to the distribution shall have been completed;
- the U.S. Securities and Exchange Commission (“SEC”) declaring effective the registration statement on Form 10 of which this information statement forms a part, with no order suspending the effectiveness of the registration statement in effect and no proceedings for such purposes pending before or threatened by the SEC;
- the mailing (or delivery by electronic means) of this information statement to the holders of Alkermes ordinary shares as of the record date for the distribution;
- the approval for listing on the Nasdaq Global Market of Mural ordinary shares to be delivered to the Alkermes shareholders in the distribution having been obtained, subject to official notice of issuance;
- the receipt by Alkermes of an opinion from an independent appraisal firm, which opinion is satisfactory to Alkermes’ board of directors and continuing to be valid, with respect to the capital adequacy and solvency of Mural and Alkermes;

## Table of Contents

- all permits, registrations and consents required under applicable U.S. federal, U.S. state or other securities laws in connection with the distribution shall have been received and be in full force and effect;
- no order, injunction or decree issued by any governmental authority or other legal restraint or prohibition preventing the consummation of the distribution or any of the related transactions shall be pending, threatened, issued or in effect, and no other event outside the control of Alkermes shall have occurred or failed to occur that prevents the consummation of all or any portion of the distribution;
- the Alkermes' board of directors shall have declared the distribution and approved all related transactions (and such declaration or approval) shall not have been withdrawn;
- the transaction agreements relating to the separation shall have been duly executed and delivered by the parties; and
- no events or developments shall have occurred or shall exist that, in the sole and absolute judgment of Alkermes' board of directors, make it inadvisable to effect the distribution or would result in the distribution and related transactions not being in the best interest of Alkermes or its shareholders.

Neither Alkermes, Mural nor Goodwin Procter LLP can assure you that any or all of these conditions will be met and, to the extent permissible under applicable law, Alkermes in its sole discretion may waive any of the conditions to the distribution. In addition, Alkermes will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date, the distribution date and the distribution ratio for the distribution. Alkermes does not intend to notify its shareholders of any modifications to the terms of the separation that, in the judgment of its board of directors, are not material. For example, the Alkermes board of directors might consider material such matters as significant changes to the distribution ratio, the assets to be contributed or the liabilities to be assumed in the separation. To the extent that the Alkermes board of directors determines that any modifications by Alkermes materially change the material terms of the distribution or to abandon the distribution, Alkermes will notify Alkermes shareholders in a manner reasonably calculated to inform them about the modification as may be required by law, by, for example, publishing a press release, filing a Current Report on Form 8-K, or circulating a supplement to this information statement.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a discussion of material U.S. federal income tax consequences of (i) the distribution of Mural ordinary shares to “U.S. holders” (as defined below) of Alkermes ordinary shares and (ii) the ownership and disposition of Mural ordinary shares that are received in the distribution by U.S. holders. This summary is based on the Internal Revenue Code of 1986, as amended (the “Code”), U.S. Treasury Regulations promulgated thereunder, rulings and other administrative pronouncements issued by the Internal Revenue Service (“IRS”), judicial decisions, and the income tax treaty between Ireland and the U.S., all as in effect on the date of this information statement, and all of which are subject to differing interpretation and change at any time, possibly with retroactive effect. This discussion applies only to U.S. holders of ordinary shares of Alkermes who hold such shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment) and who will receive Mural ordinary shares in the distribution and hold such Mural ordinary shares as capital assets within the meaning of Section 1221 of the Code. Except where otherwise stated, this discussion is based upon the assumption that the separation and distribution, in relevant part and together with certain related transactions, will be consummated in accordance with the separation agreement and the other separation-related agreements and as described in this information statement. This summary is for general information only and is not tax advice. It does not discuss all aspects of U.S. federal income taxation that may be relevant to particular holders in light of their particular circumstances or to holders subject to special rules under the Code (including, but not limited to, insurance companies, tax-exempt organizations, governments or agencies or instrumentalities thereof, regulated investment companies, real estate investment trusts, expatriates or former long-term residents of the U.S., financial institutions or financial services entities, broker-dealers, partners in partnerships (or entities or arrangements treated as partnerships for U.S. federal income tax purposes) that hold Alkermes ordinary shares, pass-through entities (or investors therein), U.S. holders whose functional currency is not the U.S. dollar, traders in securities who elect to apply a mark-to-market method of accounting, shareholders who hold Alkermes ordinary shares as part of a “hedge,” “straddle,” “conversion,” “synthetic security,” “integrated investment” or “constructive sale transaction,” individuals who receive Alkermes or Mural ordinary shares upon the exercise of employee stock options or otherwise as compensation, and holders who are liable for the alternative minimum tax or any holders who actually or constructively own 5% or more of Alkermes’ ordinary shares). This discussion also does not address any tax consequences arising under the unearned Medicare contribution tax pursuant to Section 1411 of the Code, nor does it address any tax considerations under state, local or non-U.S. laws or U.S. federal laws other than those pertaining to the U.S. federal income tax. The distribution may be taxable under such other tax laws and all holders should consult their tax advisors with respect to the applicability and effect of any such tax laws.

If a partnership, including for this purpose any entity or arrangement that is treated as a partnership for U.S. federal income tax purposes, holds Alkermes ordinary shares, the tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Holders of Alkermes ordinary shares that are partnerships and partners in such partnerships should consult their tax advisors about the U.S. federal income tax consequences of the distribution and the ownership and disposition of Mural ordinary shares that are received in the distribution by U.S. holders.

For purposes of this discussion, a “U.S. holder” is any beneficial owner of Alkermes ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or a resident of the U.S.;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the U.S., any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, (i) if a court within the U.S. is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (ii) that has a valid election in place under applicable U.S. Treasury Regulations to be treated as a U.S. person.



**THE FOLLOWING DISCUSSION IS A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION AND THE OWNERSHIP AND DISPOSITION OF MURAL ORDINARY SHARES THAT ARE RECEIVED IN THE DISTRIBUTION BY U.S. HOLDERS UNDER CURRENT LAW AND IS FOR GENERAL INFORMATION ONLY. ALL HOLDERS SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF THE DISTRIBUTION AND THE OWNERSHIP AND DISPOSITION OF MURAL ORDINARY SHARES THAT ARE RECEIVED IN THE DISTRIBUTION BY U.S. HOLDERS, INCLUDING THE APPLICATION AND EFFECT OF U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX LAWS.**

#### **Material U.S. Federal Income Tax Consequences of the Distribution**

The following discussion summarizes material U.S. federal income tax consequences of the distribution.

It is a condition to the distribution that Alkermes receives a private letter ruling from the IRS and an opinion from Goodwin Procter LLP, each satisfactory to Alkermes' board of directors and each continuing to be valid, together confirming that the separation and distribution, in relevant part and together with certain related transactions, and subject to certain caveats, are tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, except for cash received in lieu of fractional ordinary shares. Any opinion of Goodwin Procter LLP and any IRS private letter ruling will be based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings from us and Alkermes (including those relating to our past and future conduct and the past and future conduct of Alkermes), and will be subject to certain caveats. If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or Alkermes breach any of our respective covenants relating to the separation, any IRS private letter ruling and any tax opinion may be invalid. Accordingly, notwithstanding receipt of an IRS private letter ruling and an opinion of Goodwin Procter LLP, the IRS could determine that the separation and distribution, in relevant part and together with certain related transactions, should be treated as taxable transactions for U.S. federal income tax purposes if it determines that any of the facts, assumptions, representations, statements or undertakings that were included in the request for any 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, and any IRS private letter ruling will not address all of the issues that are relevant to determining whether the separation and distribution, in relevant part and together with certain related transactions, qualify as transactions that are tax-free for U.S. federal income tax purposes, except for cash received in lieu of fractional ordinary shares. Accordingly, notwithstanding receipt by Alkermes of the tax opinion referred to above and an IRS private letter ruling, the IRS could assert that the separation and distribution, in relevant part and together with certain related transactions, do not qualify for tax-free treatment for U.S. federal income tax purposes. If the IRS were successful in taking this position, Alkermes, Mural and Alkermes shareholders could be subject to significant U.S. federal income tax liability. See “—Material U.S. Federal Income Tax Consequences if the Distribution is Taxable” below.

#### ***Material U.S. Federal Income Tax Consequences if the Distribution, Together with Certain Related Transactions, Qualifies as a Transaction that is Tax-Free Under Sections 355 and 368(a)(1)(D) of the Code***

If, as is expected and in accordance with the private letter ruling and opinion described above, the distribution, together with certain related transactions, qualifies as a transaction that is tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, the U.S. federal income tax consequences of the distribution generally are as follows:

- no gain or loss will be recognized by, and no amount will be includible in the income of Alkermes and its subsidiaries as a result of the distribution;
- no gain or loss will be recognized by (and no amount will be included in the income of) U.S. holders of Alkermes ordinary shares, upon the receipt of Mural ordinary shares in the distribution, except with respect to any cash received in lieu of fractional Mural ordinary shares (as described below);

## [Table of Contents](#)

- the aggregate tax basis of the Alkermes ordinary shares and Mural ordinary shares received in the distribution (including any fractional share interest in Mural ordinary shares for which cash is received) in the hands of each U.S. holder of Alkermes ordinary shares immediately after the distribution will equal the aggregate basis of Alkermes ordinary shares held by the U.S. holder immediately before the distribution, allocated between the Alkermes ordinary shares and the Mural ordinary shares (including any fractional share interest in Mural ordinary shares for which cash is received) in proportion to the relative fair market value of each on the date of the distribution; and
- the holding period of the Mural ordinary shares received by each U.S. holder of Alkermes ordinary shares in the distribution (including any fractional share interest in Mural ordinary shares for which cash is received) will generally include the holding period at the time of the distribution for the Alkermes ordinary shares with respect to which the distribution is made.

A U.S. holder who receives cash in lieu of fractional Mural ordinary shares in the distribution will be treated as having sold such fractional share for cash, and will recognize capital gain or loss in an amount equal to the difference between the amount of cash received and such U.S. holder's adjusted tax basis in such fractional share. Such gain or loss will be long-term capital gain or loss if the U.S. holder's holding period for its Alkermes ordinary shares exceeds one year at the time of distribution.

If a U.S. holder of Alkermes ordinary shares holds different blocks of Alkermes ordinary shares (generally Alkermes ordinary shares acquired on different dates or at different prices), such holder should consult its tax advisor regarding the determination of the basis and holding period of Mural ordinary shares received in the distribution in respect of particular blocks of Alkermes ordinary shares.

### ***Material U.S. Federal Income Tax Consequences if the Distribution is Taxable***

As discussed above, notwithstanding receipt by Alkermes of a private letter ruling from the IRS and an opinion of Goodwin Procter LLP, the IRS could assert that the distribution does not qualify for tax-free treatment for U.S. federal income tax purposes. If the IRS were successful in taking this position, the consequences described above would not apply and Alkermes, Mural and Alkermes shareholders could be subject to a significant U.S. federal income tax liability. In addition, certain events that may or may not be within the control of Alkermes or Mural could cause the distribution and certain related transactions to not qualify for tax-free treatment for U.S. federal income tax purposes. Depending on the circumstances, Mural may be required to indemnify Alkermes for taxes (and certain related losses) resulting from the distribution and certain related transactions not qualifying as tax-free for U.S. federal income tax purposes.

If the distribution were to fail to qualify as a tax-free transaction for U.S. federal income tax purposes, in general, certain U.S. subsidiaries that are owned indirectly by Alkermes would recognize taxable gain and Alkermes shareholders who receive Mural 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.

Even if the distribution were otherwise to qualify as tax-free, for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) of the Code, it may result in taxable gain to certain U.S. subsidiaries that are owned indirectly by Alkermes under Section 355(e) of the Code if the distribution were later deemed to be part of a plan (or series of related transactions) pursuant to which one or more persons acquire, directly or indirectly, shares representing a 50% or greater interest (by vote or value) in Alkermes or Mural. For this purpose, any acquisitions of Alkermes or Mural shares within the period beginning two years before the distribution and ending two years after the distribution are presumed to be part of such a plan, although Alkermes or Mural may be able to rebut that presumption.

In connection with the distribution, Mural and Alkermes will enter into a tax matters agreement pursuant to which Mural will be responsible for certain liabilities and obligations following the distribution. In general, under

## [Table of Contents](#)

the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is 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 a prohibited change of control in Alkermes under Section 355(e) of the Code or an acquisition of Alkermes shares or assets or certain actions, omissions or failures to act, by Alkermes, then Alkermes will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from a prohibited change of control in Mural under Section 355(e) of the Code or an acquisition of Mural shares or assets or certain actions by Mural, then Mural will indemnify Alkermes for any resulting taxes, interest, penalties and other costs. If such failure does not result from a prohibited change of control in Alkermes or Mural under Section 355(e) of the Code and both Mural and Alkermes are responsible for such failure, liability will be shared according to relative fault. If neither Mural nor Alkermes is responsible for such failure, Alkermes will bear any resulting taxes, interest, penalties and other costs. For a discussion of the tax matters agreement, see “Certain Relationships and Related Person Transactions—Relationship with Alkermes—Agreements with Alkermes—Tax Matters Agreement.” The indemnification obligations of Mural to Alkermes under the tax matters agreement are not expected to be limited in amount or subject to any cap. If Mural is required to pay any taxes or indemnify Alkermes and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, Mural may be subject to substantial liabilities.

### ***Backup Withholding and Information Reporting***

Payments of cash to U.S. holders of Alkermes ordinary shares in lieu of fractional Mural ordinary shares may be subject to information reporting and backup withholding (currently, at a rate of 24%), unless such U.S. holder delivers a properly completed IRS Form W-9 certifying such U.S. holder’s correct taxpayer identification number and certain other information, or otherwise establishes an exemption from backup withholding. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be refunded or credited against a U.S. holder’s U.S. federal income tax liability provided that the required information is timely furnished to the IRS.

**THE FOREGOING DISCUSSION IS A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION UNDER CURRENT LAW AND IS FOR GENERAL INFORMATION ONLY. ALL HOLDERS SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES OF THE DISTRIBUTION TO THEM, INCLUDING THE APPLICATION AND EFFECT OF U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX LAWS.**

### **Material U.S. Federal Income Tax Consequences of the Ownership and Disposition of Our Ordinary Shares**

The following discussion summarizes material U.S. federal income tax consequences generally applicable to the ownership and disposition of Mural ordinary shares that are received in the distribution by U.S. holders.

### ***Taxation of Distributions***

We do not expect to pay any cash dividends in the foreseeable future. The payment of any dividends in the future, and the timing and amount thereof, is within the discretion of our board of directors. See the discussion above under “Dividend Policy.”

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” any distributions paid on ordinary shares, other than certain pro rata distributions of ordinary shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). We have not made a determination as to whether we will calculate our earnings and profits under U.S. federal income tax principles; assuming we do not, we expect that distributions generally will be reported to U.S. holders as dividends. Subject to applicable limitations, dividends paid to certain

non-corporate U.S. holders may be taxable at preferential rates applicable to “qualified dividend income” if we are a “qualified foreign corporation” and certain other requirements are met. However, the qualified dividend income treatment may not apply if we are treated as a passive foreign investment company (a “PFIC”) with respect to the U.S. holder. The amount of a dividend will include any amounts withheld by us in respect of Irish income taxes. The amount of the dividend will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. holder’s income on the date of the U.S. holder’s receipt of the dividend. The amount of any dividend income paid in non-U.S. currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. holder should not be required to recognize non-U.S. currency gain or loss in respect of the dividend income. A U.S. holder may have non-U.S. currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of ordinary shares or rights to acquire ordinary shares) will be the fair market value of such property on the date of distribution.

For foreign tax credit purposes, dividends will generally be treated as passive category income and, except if we are treated as a “U.S. owned foreign corporation,” foreign source income. If (a) Mural is 50% or more owned, by vote or value, by U.S. persons and (b) at least 10% of Mural’s earnings and profits are attributable to sources within the U.S. (such as, generally, dividends received from a U.S. corporation), then for foreign tax credit purposes, a portion of Mural’s dividends would be treated as derived from sources within the U.S. With respect to any dividend paid for any taxable year, the U.S. source ratio of our dividends for foreign tax credit purposes would be equal to the portion of Mural’s earnings and profits from sources within the U.S. for such taxable year divided by the total amount of Mural’s earnings and profits for such taxable year. Mural is a holding company that will hold, immediately after the distribution, shares of a wholly owned U.S. subsidiary.

The rules governing foreign tax credits are complex and U.S. holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. holders may, at their election, deduct foreign taxes, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

#### ***Taxable Exchange or Other Taxable Disposition of Ordinary Shares***

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” gain or loss realized on the sale or other taxable disposition of ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder’s holding period for the ordinary shares will have been more than one year at the time of sale or other taxable disposition.

The amount of the gain or loss will equal the difference between the U.S. holder’s tax basis in the ordinary shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Subject to the PFIC rules described below, long-term capital gains recognized by certain non-corporate U.S. holders (including individuals) will generally be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares are treated as traded on an “established securities market” and the U.S. holder is either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), the U.S. holder will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If a U.S. holder is

an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, the U.S. holder will recognize non-U.S. currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

### ***Passive Foreign Investment Company Rules***

If we are classified as a PFIC in any taxable year, a U.S. holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); and
- at least 50% of its gross assets (determined on the basis of a quarterly weighted average under applicable U.S. Treasury Regulations) is attributable to assets that produce passive income or are held for the production of passive income.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation, the equity of which we own, directly or indirectly, 25% or more (by value). It is uncertain whether we will be treated as a PFIC for U.S. federal income tax purposes for the year that includes the distribution or any subsequent tax year. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test described above, our status as a PFIC depends on the composition of our income, which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering and the cash we have on our balance sheet as of immediately after the distribution. Because PFIC status is based on our income, assets and activities for the entire taxable year, we cannot make a final determination at this time as to whether we will be a PFIC for the current taxable year and our PFIC status may change from year to year.

If we are classified as a PFIC in any year with respect to which a U.S. holder owns the ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ordinary shares, regardless of whether we continue to meet the tests described above, unless (i) we cease to be a PFIC and the U.S. holder has made a “deemed sale” election under the PFIC rules, or (ii) the U.S. holder makes a “qualified electing fund” election under Section 1295 of the Code (a “QEF Election”), as discussed below, with respect to all taxable years during such U.S. holder’s holding period in which we are a PFIC. If the “deemed sale” election is made, a U.S. holder will be deemed to have sold the ordinary shares the U.S. holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. holder’s ordinary shares with respect to which such election was made will not be treated as shares in a PFIC and the U.S. holder will not be subject to the rules described below with respect to any “excess distribution” the U.S. holder receives from us or any gain from an actual sale or other disposition of the ordinary shares. U.S. holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to U.S. holders, U.S. holders will be subject to special tax rules with respect to any “excess distribution” such U.S. holder receives and any gain such U.S. holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of ordinary shares, unless (i) such U.S. holder makes a QEF Election as discussed below or (ii) our ordinary shares constitute “marketable” securities, and such U.S. holder makes a mark-to-market election as discussed below. Distributions

## [Table of Contents](#)

a U.S. holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. holder received during the shorter of the three preceding taxable years or the U.S. holder's holding period for the ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. holder's holding period for the ordinary shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares cannot be treated as capital, even if a U.S. holder holds the ordinary shares as capital assets.

If a U.S. holder makes a QEF Election with respect to a PFIC, it will be taxed currently on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is a PFIC, even if no distributions were received. Any distributions we make out of our earnings and profits that were previously included in such a U.S. holder's income under the QEF Election would not be taxable to such U.S. holder. Such U.S. holder's tax basis in its ordinary shares would be increased by an amount equal to any income included under the QEF Election and decreased by any amount distributed on the ordinary shares that is not included in its income. In addition, a U.S. holder will recognize capital gain or loss on the disposition of its ordinary shares in an amount equal to the difference between the amount realized and its adjusted tax basis in the ordinary shares, each as determined in U.S. dollars. Once made, a QEF Election remains in effect unless invalidated or terminated by the IRS or revoked by the shareholder. A QEF Election can be revoked only with the consent of the IRS. A U.S. holder will not be currently taxed on the ordinary income and net capital gain of a PFIC with respect to which a QEF Election was made for any taxable year of the non-U.S. corporation that such corporation does not satisfy the PFIC income test or asset test, as described above. We have not made a determination as to whether we would provide the information necessary for U.S. holders to make a QEF Election. There is also no assurance that we will have timely knowledge of our status as a PFIC in the future or of the required information to be provided.

U.S. holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares by making a mark-to-market election with respect to the ordinary shares, provided that the ordinary shares are "marketable." Ordinary shares will be marketable if they are "regularly traded" on certain U.S. stock exchanges or on a non-U.S. stock exchange that meets certain conditions. For these purposes, the ordinary shares will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Each U.S. holder should consult its tax advisor as to whether a mark-to-market election is available or advisable with respect to the ordinary shares.

A U.S. holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares at the close of the taxable year over the U.S. holder's adjusted tax basis in the ordinary shares. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. holder's adjusted basis in the ordinary shares over the fair market value of the ordinary shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ordinary shares cease to be marketable.

## [Table of Contents](#)

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves “marketable.” As a result, even if a U.S. holder validly makes a mark-to-market election with respect to our ordinary shares, the U.S. holder may continue to be subject to the PFIC rules (described above) with respect to any lower-tier PFICs that we may own. U.S. holders should consult their tax advisors to determine whether any of the elections described above would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are a PFIC in the current or any subsequent year and, at any time when we are a PFIC, have a non-U.S. subsidiary that is classified as a PFIC, U.S. holders generally would be deemed to own a portion of the shares of such lower-tier PFIC, and generally could incur liability for the deferred tax and interest charge described above if we receive a distribution from, or dispose of all or part of our interest in, the lower-tier PFIC or the U.S. holders otherwise were deemed to have disposed of an interest in the lower-tier PFIC. If we determine that we are a PFIC, to the extent appropriate, there is no assurance that we will cause any lower-tier PFIC that we control to provide to a U.S. holder the information necessary for U.S. holders to make or maintain a QEF Election with respect to the lower-tier PFIC. However, in the future, we may not hold a controlling interest in any such lower-tier PFIC and thus there can be no assurance that we will be able to cause the lower-tier PFIC to provide such required information. A mark-to-market election generally would not be available with respect to such lower-tier PFIC. U.S. holders are urged to consult their tax advisors regarding the tax issues raised by lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. holder’s failure to file the annual report will cause the statute of limitations for such U.S. holder’s U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. holder’s entire U.S. federal income tax return will remain open during such period. U.S. holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

**WE STRONGLY URGE ALL U.S. HOLDERS TO CONSULT THEIR TAX ADVISORS REGARDING THE IMPACT OF OUR PFIC STATUS ON THEIR OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES AS WELL AS THE APPLICATION OF THE PFIC RULES TO THEIR OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES.**

### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the U.S. or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. holder may be allowed as a credit against the U.S. holder’s U.S. federal income tax liability and may entitle the U.S. holder to a refund, provided that the required information is timely furnished to the IRS.

### ***Information with Respect to Foreign Financial Assets***

Certain U.S. holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their U.S. federal income tax return. Such U.S. holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. holder does not file

---

[Table of Contents](#)

the required information, the statute of limitations with respect to tax returns of the U.S. holder to which the information relates may not close until three years after such information is filed. U.S. holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares.

**THE FOREGOING DISCUSSION IS A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF MURAL ORDINARY SHARES UNDER CURRENT LAW AND IS FOR GENERAL INFORMATION ONLY. ALL HOLDERS SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF MURAL ORDINARY SHARES TO THEM, INCLUDING THE APPLICATION AND EFFECT OF U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX LAWS.**



## MATERIAL IRISH TAX CONSEQUENCES

The following is a summary of the material Irish tax consequences for certain beneficial owners of Alkermes ordinary shares who receive Mural ordinary shares pursuant to the separation and distribution and who are the beneficial owners of such Mural ordinary shares. The summary is based upon Irish tax laws, the practice of Irish Revenue Commissioners (“Irish Revenue”) in effect on the date of this information statement and subject to receipt of relevant clearances from the Irish Revenue with respect to stamp duty and dividend withholding tax matters.

Changes in law and/or administrative practice may result in alteration of the tax considerations described below. The summary does not constitute tax advice and is intended only as a general guide. The summary is not exhaustive and shareholders should consult their own tax advisors about the Irish tax consequences (and tax consequences under the laws of other relevant jurisdictions) of the separation and distribution of Mural ordinary shares.

The summary applies only to shareholders who will own Mural ordinary shares as capital assets and does not apply to other categories of shareholders, such as dealers in securities, trustees, insurance companies, collective investment schemes and shareholders who have, or who are deemed to have, acquired our ordinary shares by virtue of an Irish office or employment (performed or carried on in Ireland). The summary does not constitute tax advice and is intended only as a general guide.

### **Irish Tax on Chargeable Gains**

The rate of tax on chargeable gains (where applicable) in Ireland is 33%.

#### ***Non-resident Shareholders***

Alkermes shareholders that are not resident or ordinarily resident in Ireland for Irish tax purposes and that do not hold their shares in connection with a trade or business carried on by such shareholders through an Irish branch or agency will not be subject to Irish tax on chargeable gains on the receipt of Mural ordinary shares pursuant to the separation and distribution.

Mural shareholders that are not resident or ordinarily resident in Ireland for Irish tax purposes and do not hold their shares in connection with a trade or business carried on by such shareholders through an Irish branch or agency will not be liable for Irish tax on chargeable gains realized on a subsequent disposal of Mural ordinary shares.

#### ***Irish Resident Shareholders***

Alkermes shareholders that are resident or ordinarily resident in Ireland for Irish tax purposes, or shareholders that hold their shares in connection with a trade or business carried on by such persons through an Irish branch or agency, will not be subject to Irish tax on chargeable gains on the receipt of Mural ordinary shares pursuant to the separation and distribution but will rather be treated for Irish tax purposes as having acquired their shares in Mural at the same time and for the appropriate portion of the original base cost as they acquired their original shares in Alkermes.

Alkermes shareholders may, however, be subject to Irish tax on chargeable gains on the receipt of any cash in lieu of fractional shares received pursuant to the separation and distribution as they will be deemed to have made a part disposal of their shares in Alkermes.

Mural shareholders that are resident or ordinarily resident in Ireland for Irish tax purposes, or that hold their shares in connection with a trade or business carried on by such persons through an Irish branch or agency will, subject to the availability of any exemptions and reliefs, be subject to Irish tax on chargeable gains arising on a subsequent disposal of Mural ordinary shares.

## [Table of Contents](#)

There is an annual exemption from Irish tax on chargeable gains whereby the first €1,270 of a taxable gain in each calendar year is exempt from tax.

### **Stamp Duty**

The rate of stamp duty on transfers of shares of Irish incorporated companies is 1% of the price paid or the market value of the shares acquired, whichever is greater. Where Irish stamp duty arises, it is generally a liability of the transferee.

The separation and distribution will be exempt from the charge to Irish stamp duty on the basis that the reconstruction relief, which applies to qualifying reconstructions, is expected to be available.

Irish stamp duty may, depending on the manner in which the shares in Mural are held, be payable in respect of transfers of Mural ordinary shares after the separation and distribution.

### ***Shares held through DTC***

A transfer of Mural ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company (“DTC”) will not be subject to Irish stamp duty. On the basis that most of Mural ordinary shares are expected to be held through DTC, it is anticipated that most transfers of ordinary shares will be exempt from Irish stamp duty.

#### *Shares held outside of DTC or Transferred Into or Out of DTC*

A transfer of Mural ordinary shares where any party to the transfer holds such shares outside of DTC may be subject to Irish stamp duty. Shareholders wishing to transfer their shares into (or out of) DTC may do so without giving rise to Irish stamp duty provided that there is no change in the beneficial ownership of such shares and at the time of the transfer into DTC there is no agreement in place for the sale of the shares by the beneficial owner to a third party.

Due to the potential Irish stamp charge on transfers of Mural ordinary shares in the future, it is strongly recommended that any person who wishes to acquire Mural ordinary shares after the separation and distribution acquires such shares through DTC (or through a broker who in turn holds such shares through DTC).

### **Withholding Tax on Dividends**

The separation and distribution will not be subject to Irish dividend withholding tax (“DWT”) as it is Irish Revenue’s practice not to treat such transfers as a distribution where both entities involved are Irish tax resident and Irish domestic reconstruction reliefs will apply to the separation and distribution.

#### *DWT on future dividends*

While Mural has no current plans to pay dividends, dividends on Mural ordinary shares will be subject to Irish DWT at 25%, unless an exemption applies. Dividends on Mural ordinary shares that are owned by residents of the U.S. and held beneficially through DTC will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the U.S.

Dividends on Mural ordinary shares that are owned by residents of the U.S. and held directly (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to Mural’s transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

## [Table of Contents](#)

If any shareholder who is resident in the U.S. receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue on the prescribed form.

Most Irish tax resident or ordinarily resident shareholders will be subject to DWT in respect of dividends paid on Mural ordinary shares. Shareholders that are residents of Ireland, but are entitled to receive dividends without DWT, must complete the appropriate DWT forms and provide them to their brokers (so that such brokers can further transmit the relevant information to a qualifying intermediary appointed by Mural) before the record date for the first dividend to which they are entitled (in the case of shares held through DTC), or to Mural's transfer agent at least seven business days before such record date (in the case of shares held outside of DTC).

Mural shareholders that are residents of "relevant territories," other than the U.S. (i.e., a Member State of the European Union other than Ireland or a territory with which Ireland has a double tax treaty in place) must meet one of Ireland's domestic law exemptions from DWT and provide a completed DWT form, in order to receive dividends without them being subject to DWT. Mural shareholders should provide completed DWT forms to their brokers (so that such brokers can further transmit the relevant information to a qualifying intermediary appointed by Mural) before the record date for the first dividend to which they are entitled (in the case of shares held through DTC), or to Mural's transfer agent at least seven business days before such record date (in the case of shares held outside of DTC). If any shareholder who is resident in a "relevant territory" and who meets the tests for an exemption from DWT receives a dividend from which DWT has been withheld, the shareholder may be entitled to a refund of DWT from Irish Revenue.

For shareholders that cannot avail of one of Ireland's domestic law exemptions from DWT, it may be possible for such shareholders to rely on the provisions of a double tax treaty to which Ireland is a party to reduce the rate of DWT.

### **Income Tax on Dividends**

Irish income tax, if any, may arise in respect of dividends paid by Mural.

Irish income tax will not arise on the separation and distribution on the basis of the Irish Revenue's practice not to treat such transfers as distributions subject to Irish income tax.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT generally has no liability for Irish income tax or to the universal social charge on a dividend from Mural, unless the shareholder holds the ordinary shares through a branch or agency in Ireland which carries out a trade.

A Mural shareholder that is not resident or ordinarily resident in Ireland and that is not entitled to an exemption from DWT generally has no additional Irish income tax liability (or liability for the universal social charge in the case of an individual). The DWT deducted by Mural discharges the liability to income tax (and the universal social charge if applicable). An exception to this position may apply where the shareholder holds the ordinary shares through a branch or agency in Ireland which carries out a trade.

Irish resident or ordinarily resident shareholders may be subject to Irish tax and (in the case of an individual, the universal social charge and/or Pay Related Social Insurance) on dividends received from Mural. Such Mural shareholders should consult their own tax advisors.

### **Capital Acquisitions Tax**

Irish Capital Acquisitions Tax ("CAT") could apply to a gift or inheritance of Irish situate shares irrespective of the place of residence, ordinary residence or domicile of the parties. Mural ordinary shares may be

regarded as property situated in Ireland as Mural's share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT. CAT is levied at a rate of 33% above certain tax-free thresholds.

There is also "small gift exemption" from CAT whereby the first €3,000 of the taxable value of all taxable gifts taken by a donee from any one donor, in each calendar year, is exempt from CAT and is also excluded from any future aggregation. This exemption does not apply to an inheritance. Further transfers of gifts and inheritances between spouses are exempt from CAT.

Mural shareholders should consult their tax advisors as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

## DESCRIPTION OF MURAL'S SHARE CAPITAL

### General

The following description of our ordinary shares is intended as a summary only and is qualified in its entirety by reference to our amended and restated memorandum and articles of association (together, our "Constitution") that will be in effect at the closing of the separation, which will be filed as an exhibit to the registration statement on Form 10 of which this information statement is a part, and to the applicable provisions of the Irish Companies Act 2014 (the "Irish Companies Act"). The description of our ordinary shares reflects changes to our capital structure that will occur upon the closing of the separation.

Upon the closing of the separation and the filing of our Constitution, our authorized share capital will consist of \_\_\_\_\_ ordinary shares with a nominal value of \$0.01 each, \_\_\_\_\_ deferred shares with a nominal value of €1.00 each and \_\_\_\_\_ undesignated non-voting preferred shares, with a nominal value of \$0.01 each.

As of \_\_\_\_\_, 2023, we had \_\_\_\_\_ ordinary shares and \_\_\_\_\_ preferred shares issued and outstanding and had one shareholder of record.

### Authorized Share Capital

We may issue shares subject to the maximum authorized share capital contained in our Constitution. Our authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes of our shareholders cast at a general meeting (referred to under Irish law as an "ordinary resolution"). As a matter of Irish law, the board of directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by the constitution or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, after which it must be renewed by the shareholders by an ordinary resolution.

The rights and restrictions applicable to our ordinary shares are prescribed in our Constitution. Our Constitution permits our board of directors, without shareholder approval, to determine the terms of any preferred shares issued by us. Our board of directors is authorized, without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, to provide from time to time for the issuance of other classes or series of preferred shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Irish law does not recognize fractional shares held of record. Accordingly, our Constitution does not provide for the issuance of fractional shares, and our official Irish register of members will not reflect any fractional shares.

### Pre-emption Rights, Share Warrants and Share Options

Under Irish law, certain statutory pre-emption rights apply automatically in favor of shareholders where shares are to be issued for cash. We have opted out of these pre-emption rights in our Constitution as permitted under Irish law. However, Irish law requires this opt-out to be renewed at least every five years by a resolution approved by not less than 75% of the votes of our shareholders cast at a general meeting (referred to under Irish law as a "special resolution"). If the opt-out is not renewed, shares issued for cash must be offered to our existing shareholders on a pro rata basis to their existing shareholding before the shares can be issued to any new shareholders. The statutory pre-emption rights do not apply where shares are issued for non-cash consideration (such as in a stock-for-stock acquisition) and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or where shares are issued to employees pursuant to a stock option and incentive plan or similar equity plan.

## [Table of Contents](#)

Our Constitution provides that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which we are subject, our board of directors is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as our board of directors deems advisable, options to purchase such number of shares of any class or classes or of any series of any class as our board of directors may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Irish Companies Act provides that a board of directors may issue share warrants or options without shareholder approval once authorized to do so by its constitution or an ordinary resolution of shareholders. We are subject to the applicable rules and regulations of the Internal Revenue Code of 1986, as amended that require shareholder approval of certain equity plan and share issuances. Our board of directors may issue shares upon exercise of warrants or options without shareholder approval or authorization (up to the relevant authorized share capital limit).

### **Dividends**

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless our net assets are equal to, or in excess of, the aggregate of our called-up share capital plus undistributable reserves and the distribution does not reduce our net assets below such aggregate. Undistributable reserves include: (i) our undenominated capital; (ii) the amount by which our accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed our accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital; and (iii) any other reserve we are prohibited, at law, from distributing.

The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our “relevant accounts.” The “relevant accounts” will be either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act, which give a “true and fair view” of our unconsolidated financial position and accord with accepted accounting practice. The relevant accounts must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Our Constitution authorizes our board of directors to declare dividends, out of funds lawfully available for distribution, without shareholder approval to the extent they appear justified by our profits. Our board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. Our board of directors may direct that the payment be made by distribution of assets, shares or cash and no dividend issued may exceed the amount recommended by our board of directors. Dividends may be declared and paid in the form of cash or non-cash assets and may be paid in U.S. Dollars or any other currency.

Our board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to us in relation to our shares.

Our board of directors may also authorize us to issue shares with preferred rights to participate in dividends we declare. The holders of preferred shares may, depending on their terms, rank senior to our ordinary shares in terms of dividend rights and/or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

### **Share Repurchases, Redemptions and Conversions**

#### **Overview**

Our Constitution provides that any ordinary share that we have agreed to acquire shall be deemed to be a redeemable share, unless our board of directors elects to treat such share acquisition otherwise. Accordingly, for Irish law purposes, a repurchase of ordinary shares by us would technically be effected as a redemption of those shares as described below under “—Our Repurchases and Redemptions.” If our Constitution did not contain such provision, our repurchases would be subject to many of the same rules that apply to purchases of our ordinary

shares by subsidiaries described below under “—Purchases by Our Subsidiaries” including the shareholder approval requirements described below and the requirement that any open-market purchases be effected on a “recognized stock exchange.” Except where otherwise noted, references elsewhere in this information statement to repurchasing or buying back our ordinary shares refer to our or one of our subsidiaries’ redemption of ordinary shares, in each case in accordance with our Constitution and Irish law as described below.

### ***Our Repurchases and Redemptions***

Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new issue of shares for that purpose. Please see also the “—Dividends” section above. We may only issue redeemable shares if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of our total issued share capital. All redeemable shares must also be fully-paid. Redeemable shares may, upon redemption, be canceled or held in treasury. Based on the provision of our Constitution described above, shareholder approval will not be required to redeem our shares.

We may also be given an additional general authority to purchase our own shares on-market which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below.

Our board of directors may also issue preferred shares that may be redeemed at our option or the option of the preferred shareholder, depending on the terms of such preferred shares. Please see “—Authorized Share Capital” above for additional information on preferred shares.

Under Irish law, repurchased and redeemed shares may be canceled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. Treasury shares may be canceled by us or re-issued subject to certain conditions.

### ***Purchases by Our Subsidiaries***

Under Irish law, a subsidiary may purchase our shares either on-market (an overseas market purchase) or off-market. For one of our subsidiaries to make on-market purchases of our ordinary shares, our shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on-market purchase by a subsidiary of our ordinary shares is required. For an off-market purchase by one of our subsidiaries, the proposed purchase contract must be authorized by special resolution of the shareholders before the contract is entered into. The person whose shares are to be bought back cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution being passed, the purchase contract must be on display or must be available for inspection by shareholders at our registered office.

In order for one of our subsidiaries to make an overseas market purchase of our shares, such shares must be purchased on a “recognized stock exchange.” The Nasdaq Global Market, on which we have applied to list our ordinary shares, is specified as a recognized stock exchange for this purpose by Irish law.

The number of shares held by our subsidiaries at any time will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of our issued share capital. While a subsidiary holds our shares, it cannot exercise any voting rights in respect of those shares. The acquisition of our shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

### ***Bonus Shares***

Under our Constitution, our board of directors may resolve to capitalize any amount standing to the credit of our reserves (including, but not limited to, the share premium account, capital redemption reserve, capital conversion reserve and profit and loss account), whether or not available for distribution, for any purpose, including, but not limited to, for the purposes of effecting any exchange of any rights and applying any such sum

arising from such capitalization to pay up any shares of the company and allot them, credited as fully paid, to any holders of such rights.

### **Lien on Shares, Calls on Shares and Forfeiture of Shares**

Our Constitution provides that we will have a first and paramount lien on every share that is not a fully paid up share for all amounts payable at a fixed time or called in respect of that share. Subject to the terms of their allotment, our board of directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are standard inclusions in the constitution of an Irish company limited by shares such as ours and will only be applicable to our shares that have not been fully paid up.

### **Consolidation and Division; Subdivision**

Under our Constitution, we may, by ordinary resolution, consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares or subdivide our shares into smaller amounts than is fixed by our Constitution.

### **Reduction of Share Capital**

We may, by ordinary resolution, reduce our authorized share capital in any way provided that such resolution does not reduce the authorized share capital to an amount less than the issued share capital at such time. We also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel our issued share capital in any way we think expedient.

### **Annual General Meetings of Shareholders**

We are required to hold annual general meetings at intervals of no more than 15 months, provided that an annual general meeting is held in each calendar year and no more than nine months after our fiscal year-end. Any annual general meeting may be held outside Ireland, provided that we make all necessary arrangements to ensure that shareholders can participate in such meeting by technological means without leaving Ireland.

Notice of each annual general meeting must be given to all our shareholders and to our auditors. Our Constitution provides for a minimum notice period of 21 days, which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish law, be transacted at an annual general meeting are: (i) the consideration of our statutory financial statements and the report of our board of directors and the report of the statutory auditors on those statements and that report; (ii) the review by the shareholders of the company's affairs; (iii) the authorization of our board of directors to approve the remuneration of the statutory auditors; and (iv) the election and/or re-election of members of our board of directors in accordance with our Constitution. If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

### **Extraordinary General Meetings of Shareholders**

Extraordinary general meetings of our shareholders may be convened by: (i) our board of directors; (ii) at the request of shareholders holding not less than 10% of our paid-up share capital carrying voting rights; or (iii) at the request of our auditors in certain circumstances in accordance with the Irish Companies Act. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time. At any extraordinary general meeting, only such business shall be conducted as is set forth in the notice thereof.



## [Table of Contents](#)

Notice of an extraordinary general meeting must be given to our shareholders and to our auditors. Under Irish law and our Constitution, the minimum notice periods are 21 days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting.

In the case of an extraordinary general meeting convened on the requisition of our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of this required notice, our board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the required notice. This meeting must be held within two months of the receipt of the requisition notice. If our board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of our receipt of the requisition notice.

If our board of directors becomes aware that our net assets are not greater than half of the amount of our called-up share capital, our board of directors must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact to consider how to address the situation.

### **Quorum for General Meetings**

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.

### **Voting**

Our Constitution provides that all resolutions to be voted on at a general meeting of shareholders shall be decided on a poll. Our board of directors or the chairperson of our board of directors may determine the manner in which the poll is to be taken and the manner in which the votes of such poll are to be counted.

Pursuant to the Irish Companies Act, where a vote is decided on a poll, each shareholder present in person or by proxy is entitled to one vote for each ordinary share that she or he holds as of the record date for the meeting. Voting rights may be exercised by holders of record registered in our share register as of the record date for the meeting or by a duly appointed proxy, which proxy need not be a shareholder. Where shares are beneficially owned, meaning that they are held by a bank, broker or other nominee, such bank, broker or other nominee may exercise the rights of the beneficial owners on their behalf as their proxy. All proxies must be appointed in the manner prescribed by our Constitution, which permit shareholders to notify us of their proxy appointments electronically in such manner as may be approved by our board of directors. Shareholders entitled to more than one vote in a poll do not need to cast all their votes or cast all votes in the same way.

Our Constitution provides that a poll relating to the election of the chairperson or the adjournment of a general meeting 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 poll was demanded, as the chairperson of the meeting directs. No notice is required in respect of a poll not taken immediately.

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

The result of the poll will be deemed to be a resolution of the meeting at which the poll was demanded.

## [Table of Contents](#)

In accordance with our Constitution, our board of directors may from time to time authorize us to issue preferred shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred shares (e.g., they may carry more votes per share than ordinary shares or may entitle their holders to a class vote on such matters as may be specified in the terms of the preferred shares). Treasury shares or shares of the company that are held by our subsidiaries will not be entitled to be voted at general meetings of shareholders.

Irish law requires special resolutions of the shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

- amending our Constitution;
- approving a change of our name;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or connected person;
- opting out of pre-emption rights on the issuance of new shares;
- creating a new class of shares;
- our re-registration from a public limited company to a private company;
- variation of class rights attaching to classes of shares (where the Constitution does not provide otherwise);
- purchase of our own shares off-market;
- reduction of issued share capital;
- sanctioning a compromise/scheme of arrangement;
- resolving that we be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up;
- re-designation of shares into different share classes; and
- setting the re-issue price of treasury shares.

### **Variation of Rights Attaching to a Class or Series of Shares**

Under our Constitution and the Irish Companies Act, any variation of class rights attaching to our issued shares must be approved by a special resolution of the shareholders of the affected class or with the consent in writing of the holders of three-quarters of all the votes of that class of shares.

The provisions of our Constitution relating to general meetings apply to general meetings of the holders of any class of shares except that the necessary quorum is determined by reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of shares, where there is more than one holder of that class, a quorum consists of two or more holders present in person or by proxy, representing not less than a majority of the issued shares of that class entitled to vote at the meeting.

### **Acquisitions**

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Irish Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

## [Table of Contents](#)

- through a tender or takeover offer by a third party for all of our shares. Where the holders of 80% or more of our shares have accepted an offer for such shares, the remaining shareholders may also be statutorily required to transfer their shares. If the bidder does not exercise its “squeeze out” right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If our shares were to be listed on Euronext Dublin or another regulated stock exchange in the EU, this threshold would be increased to 90%; and
- by way of a merger with a company incorporated in the European Economic Area (“EEA”) under the EU Cross-Border Mergers Directive (EU) 2017/1132 or with another Irish company under the Irish Companies Act. Such a merger must be approved by a special resolution of the shareholders. Under certain circumstances, shareholders also may be entitled to have their shares acquired for cash.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company’s property and assets.

### **Appraisal Rights**

Irish law generally does not provide for “appraisal rights”. However, it does provide for dissenters’ rights in certain situations, as described below.

Under a tender or takeover offer, the bidder may require any remaining shareholders to transfer their shares on the terms of the offer (i.e., a “squeeze out”) if it has acquired, pursuant to the offer, not less than 80% of the target shares to which the offer relates (in the case of a company that is not listed on an EEA regulated market). Dissenting shareholders have the right to apply to the Irish High Court for relief.

A scheme of arrangement which has been approved by the requisite shareholder majority and sanctioned by the Irish High Court will be binding on all shareholders. Dissenting shareholders have the right to appear at the Irish High Court hearing and make representations in objection to the scheme.

Under the European Communities (Cross-Border Mergers) Regulations 2008 governing the merger of an Irish company limited by shares such as we are, and a company incorporated in another EEA member state, a shareholder: (i) who voted against the special resolution approving the merger; or (ii) of a company in which 90% of the shares are held by the other party to the merger, has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Similar rights apply in the case of a merger of an Irish public limited company into another company to which the provisions of the Irish Companies Act apply.

### **Disclosure of Interests in Shares**

Under the Irish Companies Act, shareholders must notify us if, as a result of a transaction, the shareholder will become interested in 3% or more of our shares; or if as a result of a transaction a shareholder who was interested in more than 3% of our shares ceases to be so interested. Where a shareholder is interested in more than 3% of our shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital of (or any such class of share capital in issue). Where the percentage level of the shareholder’s interest does not amount to a whole percentage this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder’s interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder’s rights in respect of any shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

## [Table of Contents](#)

In addition to these disclosure requirements, we may, under the Irish Companies Act, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to: (i) indicate whether or not it is the case; and (ii) where such person holds or has during that time held an interest in our shares, to provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event that we are in an offer period pursuant to the Irish Takeover Rules made under the Irish Takeover Panel Act 1997 (the "Irish Takeover Rules"), accelerated disclosure provisions apply for persons holding an interest in our securities of 1% or more.

In addition, the beneficial ownership disclosures of the U.S. federal securities laws will apply with respect to beneficial ownership of our shares.

### **Anti-Takeover Provisions**

#### ***Irish Takeover Rules and Substantial Acquisition Rules***

A transaction in which a third party seeks to acquire 30% or more of our voting rights will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder and will be regulated by the Irish Takeover Panel. The "General Principles" of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

#### ***General Principles***

The Irish Takeover Rules are built on the following general principles (the "General Principles"), which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company should be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of the securities of the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of the target company must give its views on the effects of implementation of the offer on employment, conditions of employment and the locations of the target company's places of business;
- the board of the target company must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or of any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;

## Table of Contents

- a bidder must announce an offer only after ensuring that it can fulfill in full, any cash consideration, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company must not be hindered in the conduct of its affairs for longer than is reasonable by an offer for its securities; and
- a substantial acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

### ***Mandatory Bid***

Under certain circumstances, a person who acquires our shares may be required under the Irish Takeover Rules to make a mandatory cash offer for our remaining outstanding shares at a price not less than the highest price paid for the shares by that acquirer (or any parties acting in concert with the acquirer) during the previous twelve months. This mandatory bid requirement is triggered if an acquisition of shares would increase the aggregate holding of an acquirer (including the holdings of any parties acting in concert with the acquirer) to shares representing 30% or more of our voting rights, unless the Irish Takeover Panel otherwise consents. An acquisition of shares by a person holding (together with its concert parties) shares representing between 30% and 50% of our voting rights would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a twelve-month period. Any person (excluding any parties acting in concert with the holder) holding shares representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements.

### ***Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirements***

If a person makes a voluntary offer to acquire our outstanding ordinary shares, the offer price must be no less than the highest price paid for our ordinary shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the “look back” period to twelve months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired our ordinary shares: (i) during the period of twelve months prior to the commencement of the offer period which represent more than 10% of our total ordinary shares; or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period and, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

### ***Substantial Acquisition Rules***

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of our voting rights. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of our voting rights is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of our voting rights and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

### **Shareholder Rights Plan**

Under our Constitution, our board of directors is authorized to adopt a shareholder rights plan (a “Shareholder Rights Plan”), upon such terms and conditions as our board of directors deems expedient and in the best interests of the company, subject to applicable law, including the grant of rights (including approving the execution of any documents relating to the grant of such rights) to subscribe for ordinary shares or preferred shares in the share capital of the company in accordance with the terms of any Shareholder Rights Plan. Our board of directors or any duly appointed committee thereof may effect an exchange of rights in accordance with such Shareholder Rights Plan.

### **Frustrating Action**

Under the Irish Takeover Rules, our board of directors is not permitted to take any action which might frustrate an offer for our shares once our board of directors has received an approach which may lead to an offer or has reason to believe an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as: (i) the issue of shares, options or convertible securities; (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, are prohibited during the course of an offer or at any time during which our board of directors has reason to believe an offer is imminent. Exceptions to this prohibition are available where:

- the action is approved by our shareholders at a general meeting; or
- the Irish Takeover Panel has given its consent, where:
  - it is satisfied the action would not constitute frustrating action;
  - the holders of 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
  - the action is taken in accordance with a contract entered into prior to the announcement of the offer; or
  - the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Certain other provisions of Irish law or our Constitution may be considered to have anti-takeover effects, including those described under the following captions: “—Authorized Share Capital” (regarding issuance of preferred shares), “—Pre-emption Rights, Share Warrants and Share Options,” and “—Disclosure of Interests in Shares.”

### **Appointment of Directors to our Board of Directors**

The Irish Companies Act provides for a minimum of two directors. Our Constitution will provide that the number of directors on our board of directors will be determined by our board of directors from time to time at its discretion.

Unless a company’s constitution provides otherwise, the Irish Companies Act provides for majority voting for the election of directors, which could result in the number of directors falling below the authorized number of directors due to the failure of nominees to be elected by a majority of the votes cast. Our Constitution will provide that if the number of directors is reduced below the prescribed minimum number of directors, the remaining director or directors shall appoint an additional director or additional directors to make up such prescribed minimum as soon as practicable or shall convene a general meeting of the company for the purpose of making such appointment. The Constitution will also provide that if, at any general meeting of shareholders, (i) the number of persons validly nominated to serve as directors exceeds the number of directors to be elected at such meeting, or (ii) the number of directors is reduced below the minimum number prescribed by our Constitution due to the failure of one or more director nominees to be elected or re-elected by a majority of the

## [Table of Contents](#)

votes cast at such meeting, then, in each case, of the persons properly nominated to be elected as directors at such meeting, those nominees receiving the highest number of votes in favor of election or re-election will be elected or re-elected as directors, so that the number of directors in office neither exceeds the maximum board size nor is less than the minimum number, respectively, prescribed by our Constitution.

No person shall be appointed director unless nominated as follows:

- by our board of directors or any authorized committee thereof;
- with respect to election at a general meeting, by any shareholder who holds ordinary shares or other shares carrying the general right to vote at general meetings of the company who is a shareholder at the time of the giving of the notice and at the time of the relevant general meeting and who timely complies with the notice procedures set out in our Constitution and is present, in person or by proxy, at the relevant general meeting to present their nominee; or
- with respect to election at an extraordinary general meeting requisitioned in accordance with section 1101 of the Irish Companies Act, by a shareholder or shareholders who hold ordinary shares or other shares carrying the general right to vote at general meetings of the company and who make such nomination in the written requisition of the extraordinary general meeting.

Directors shall be appointed as follows:

- by our board of directors in accordance with our Constitution; or
- so long as there is in office a sufficient number of directors to constitute a quorum of our board of directors, the directors shall have the power at any time and from time to time to appoint any person to be director, either to fill a vacancy in our board of directors or as an addition to the existing directors but so that the total number of directors shall not at any time exceed the maximum number authorized by the Board.

### **Duration; Dissolution; Rights upon Liquidation**

Our duration is unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding-up, a special resolution of shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where we have failed to file certain returns.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in our Constitution or the terms of any preferred shares issued by our board of directors from time to time. The holders of preferred shares in particular may have the right to priority in our dissolution or winding up. If the Constitution contains no specific provisions in respect of a dissolution or winding up then, subject to the priorities of any creditors, the assets will be distributed to shareholders in proportion to the paid-up nominal value of the shares held. Our Constitution provides that our ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

### **Uncertificated Shares**

Pursuant to the Constitution, the directors have the power to permit any class of shares to be held in uncertificated form and no shareholder is entitled to be issued a share certificate.

### **No Sinking Fund**

Our ordinary shares have no sinking fund provisions.

### **No Liability for Further Calls or Assessments**

The ordinary shares to be issued in the distribution will be duly and validly issued and fully-paid.

### **Transfer and Registration of Shares**

Our transfer agent, Computershare Trust Company, N.A., maintains our share register, which is determinative of ownership of our ordinary shares. Our shareholders who hold shares beneficially are not the holders of record of such shares. Instead, the depository (for example, Cede & Co., as nominee for Depository Trust Company) or other nominee is the holder of record of those shares. Accordingly, a transfer of ordinary shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depository or other nominee will not be registered in our official share register, as the depository or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on our official share register any transfer of ordinary shares: (i) from a person who holds such shares directly to any other person; (ii) from a person who holds such shares beneficially to a person who holds such shares directly; or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on our official Irish share register. However, a shareholder who directly holds ordinary shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares.

Any transfer of our ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped and provided to the transfer agent. Our Constitution allows us, in our absolute discretion, to create an instrument of transfer and pay (or procure the payment of) any stamp duty, which is the legal obligation of a buyer. In the event of any such payment, we are (on our behalf or on behalf of our affiliates) entitled to: (i) seek reimbursement from the buyer or seller (at our discretion); (ii) set-off the amount of the stamp duty against future dividends payable to the buyer or seller (at our discretion); and (iii) claim a lien against the ordinary shares on which we have paid stamp duty.

Our Constitution delegates to our secretary the authority to execute an instrument of transfer on behalf of a transferring party.

In order to help ensure that the official share register is regularly updated to reflect trading of our ordinary shares occurring through normal electronic systems, we intend to regularly produce any required instruments of transfer in connection with any transactions for which we pay stamp duty (subject to the reimbursement and set-off rights described above). In the event that we notify one or both of the parties to a share transfer that we believe stamp duty is required to be paid in connection with the transfer and that we will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from us for this purpose) or request that we execute an instrument of transfer on behalf of the transferring party in a form determined by us. In either event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to our transfer agent, the buyer will be registered as the legal owner of the relevant shares on our official Irish share register (subject to the matters described below).

Our board of directors may suspend registration of transfers from time to time, with such suspensions not to exceed 30 days in aggregate each year.



### **Sale of Unregistered Securities**

On May 31, 2017, we issued a total of 100 of our euro denominated ordinary shares to Andrew Lambe and Paula Horan for the purposes of incorporating the company. On March 24, 2023, these 100 euro denominated ordinary shares were transferred to an Irish corporate services provider. The company did not register the issuances of such shares in 2017 under the Securities Act of 1933, as amended (the “Securities Act”) because the issuances did not constitute public offerings and therefore were exempt from registration pursuant to Section 4(a)(2) of the Securities Act. Each share was issued for cash at nominal value of €1.00.

### **Exclusive Forum Provision**

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

Our Constitution will however also provide that unless we consent in writing to the selection of an alternative forum, the 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, and/or the Exchange Act of 1934, as amended (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 U.S. state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These provisions may limit or increase the difficulty of shareholders’ ability to bring a claim in a judicial forum that they find favorable for disputes with the company or our directors and officers under the Securities Act and Exchange Act, or may result in increased costs to bring a claim.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form 10 with the U.S. Securities and Exchange Commission (“SEC”) with respect to our ordinary shares being distributed as contemplated by this information statement. This information statement is a part of, and does not contain all of the information set forth in, the registration statement and the exhibits and schedules to the registration statement. For further information with respect to us and our ordinary shares, please refer to the registration statement, including its exhibits and schedules. Statements made in this information statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. You may review a copy of the registration statement, including its exhibits and schedules, on the Internet website maintained by the SEC at [www.sec.gov](http://www.sec.gov).

As a result of the separation and distribution, we will become subject to the information and reporting requirements of the Exchange Act of 1934, as amended (the “Exchange Act”) and, in accordance with the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC, which will be available at [www.sec.gov](http://www.sec.gov).

We intend to furnish holders of our ordinary shares with annual reports containing combined or consolidated financial statements prepared in accordance with accounting principles generally accepted in the U.S. and audited and reported on, with an opinion expressed, by an independent registered public accounting firm.

You should rely only on the information contained in this information statement or to which we have referred you. We have not authorized any person to provide you with different information or to make any representation not contained in this information statement.

**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**  
**Combined Financial Statements**  
**As of and for the Years Ended December 31, 2022 and 2021**

**Index to Combined Financial Statements**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
Combined Financial Statements:	
<a href="#">Combined Balance Sheets</a>	F-3
<a href="#">Combined Statements of Operations and Comprehensive Loss</a>	F-4
<a href="#">Combined Statements of Changes in Net Parent Investment</a>	F-5
<a href="#">Combined Statements of Cash Flows</a>	F-6
<a href="#">Notes to Combined Financial Statements</a>	F-7

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Alkermes plc

### **Opinion on the Financial Statements**

We have audited the accompanying combined balance sheets of Mural, a carve-out of the Oncology Business of Alkermes plc (the “Company”), as of December 31, 2022 and 2021, and the related combined statements of operations and comprehensive loss, of changes in net parent investment and of cash flows for the years then ended, including the related notes (collectively referred to as the “combined financial statements”). In our opinion, the combined financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### *Substantial Doubt About the Company’s Ability to Continue as a Going Concern*

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the combined financial statements, the Company is dependent on funding from Alkermes plc and has incurred recurring losses that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The combined financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These combined financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s combined financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these combined financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the combined financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the combined financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the combined financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the combined financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Boston, Massachusetts  
April 14, 2023

We have served as the Company’s auditor since 2023.

**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**  
**Combined Balance Sheets**

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
	(In thousands)	
<b>ASSETS</b>		
CURRENT ASSETS:		
Prepaid expenses	\$ 2,987	\$ 2,200
Other current assets	1,830	2,039
<b>Total current assets</b>	<u>4,817</u>	<u>4,239</u>
Property and equipment, net	10,617	6,646
Right-of-use assets	18,316	24,225
<b>TOTAL ASSETS</b>	<u>\$ 33,750</u>	<u>\$ 35,110</u>
<b>LIABILITIES AND NET PARENT INVESTMENT</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,966	\$ 10,586
Accrued expenses	32,750	16,741
Operating lease liabilities—short-term	5,844	5,920
<b>Total current liabilities</b>	<u>41,560</u>	<u>33,247</u>
Operating lease liabilities—long-term	13,542	19,386
Other long-term liabilities	304	356
<b>Total liabilities</b>	<u>55,406</u>	<u>52,989</u>
Commitments and contingencies (Note 8)		
Net parent investment	(21,656)	(17,879)
<b>Total net parent investment</b>	<u>(21,656)</u>	<u>(17,879)</u>
<b>TOTAL LIABILITIES AND NET PARENT INVESTMENT</b>	<u>\$ 33,750</u>	<u>\$ 35,110</u>

*See accompanying notes to the combined financial statements.*

**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**  
**Combined Statements of Operations and Comprehensive Loss**

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In thousands)</b>	
<b>Operating expenses</b>		
Research and development	\$ 167,191	\$ 159,817
General and administrative	17,732	15,548
<b>Total operating expenses</b>	<b>184,923</b>	<b>175,365</b>
<b>Operating loss</b>	<b>(184,923)</b>	<b>(175,365)</b>
<b>Income tax provision</b>	<b>4,884</b>	<b>68</b>
<b>Net loss and comprehensive loss</b>	<b><u>\$(189,807)</u></b>	<b><u>\$(175,433)</u></b>

*See accompanying notes to the combined financial statements.*

**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**  
**Combined Statements of Changes in Net Parent Investment**

	<b>Total Net Parent</b>
	<u>Investment</u>
	<u>(In thousands)</u>
<b>Balance, December 31, 2020</b>	<b>\$ (15,003)</b>
Net loss	(175,433)
Share-based compensation expense (Note 6)	11,504
Net transfers from parent	161,053
<b>Balance, December 31, 2021</b>	<b>\$ (17,879)</b>
Net loss	(189,807)
Share-based compensation expense (Note 6)	11,931
Net transfers from parent	174,099
<b>Balance, December 31, 2022</b>	<b>\$ (21,656)</b>

*See accompanying notes to the combined financial statements.*

**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**  
**Combined Statements of Cash Flows**

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(189,807)	\$(175,433)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	1,540	1,474
Share-based compensation expense	11,931	11,504
Changes in assets and liabilities:		
Prepaid expenses	(787)	(380)
Other current assets	209	(125)
Right-of-use assets	5,909	5,703
Accounts payable and accrued expenses	8,389	5,522
Operating lease liabilities	(5,920)	(4,758)
Other long-term liabilities	(52)	(175)
Cash flows used in operating activities	<u>(168,588)</u>	<u>(156,668)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions of property and equipment	(5,511)	(4,385)
Cash flows used in investing activities	<u>(5,511)</u>	<u>(4,385)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net transfers from parent	174,099	161,053
Cash flows provided by financing activities	<u>174,099</u>	<u>161,053</u>
Net increase in cash, cash equivalents and restricted cash	—	—
Cash, cash equivalents and restricted cash—Beginning of period	—	—
Cash, cash equivalents and restricted cash—End of period	<u>\$ —</u>	<u>\$ —</u>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 375	\$ 2,155

*See accompanying notes to the combined financial statements.*



**Mural**  
**(Carve-Out of Oncology Business of Alkermes plc)**

**Notes to Combined Financial Statements**  
**As of and for the Years Ended December 31, 2022 and 2021**

**1. Organization and Description of Business**

The accompanying carve-out financial statements present 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 subsidiaries' ("Alkermes" or the "Parent") oncology business (the "oncology business" or "Mural") as it was historically managed as part of Alkermes prior to the completion of the planned separation of Alkermes' oncology business from Alkermes' neuroscience business, and the creation, as a result of the distribution (as defined below) of an independent, publicly traded company (the "Public Company"), which will hold the assets, liabilities and operations associated with the oncology business. Mural 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, Mural has developed a portfolio of investigational cytokine therapies designed to address areas of unmet need for patients with a variety of cancers.

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

*The Separation*

On November 2, 2022, Alkermes announced its intent, as approved by its board of directors, to explore separation of its neuroscience business and oncology business. Alkermes intends to effect the separation through the distribution of the ordinary shares of the Public Company to Alkermes' shareholders (the "distribution").

As part of the planned separation, Alkermes intends to transfer the assets, liabilities and operations of the historical oncology business to the Public Company, pursuant to the terms of a separation agreement, to be entered into between the Public Company and Alkermes. On the distribution date, each Alkermes shareholder will receive a number of the Public Company's ordinary shares based on the distribution ratio. Registered shareholders will receive cash in lieu of any fractional Alkermes' ordinary shares that they would have received as a result of the application of the distribution ratio. Following the separation and distribution, the Public Company will operate as an independent, publicly traded company. The distribution is subject to the satisfaction or waiver by Alkermes of certain conditions.

*Going Concern*

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

Mural's ability to fund operations and capital needs will depend on funding from Alkermes through the date of separation that will be contributed to Mural immediately prior to or in connection with the separation to cover Mural's capital needs following the separation until it is able to access capital markets and other sources of capital, as further described below. Mural has incurred recurring losses, including net losses of \$189.8 million and \$175.4 million for the years ended December 31, 2022 and 2021, respectively.

## [Table of Contents](#)

As Alkermes manages Mural's cash and financing arrangements, excess cash generated, if any, is deemed remitted to Alkermes and all sources of cash are deemed funded by Alkermes. Mural expects to continue to generate operating losses for the foreseeable future. Mural's continued operations are dependent on continued funding by Alkermes and its ability to generate cash from operating activities and to raise additional capital to finance its future operations. Mural's failure to raise capital as and when needed will have a negative impact on its financial condition and its ability to continue to pursue its business strategies, which would adversely affect its business prospects, or it may be unable to continue its operations.

If Mural is unable to obtain funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of the planned research or development programs or be unable to expand or continue operations. There is no assurance that Mural will be successful in obtaining sufficient funding on terms acceptable to Mural to fund continuing operations, if at all. Based on Mural's recurring losses from operations incurred, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations, as of April 14, 2023, the issuance date of the combined financial statements for the year ended December 31, 2022, Mural has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that the combined financial statements are issued.

The accompanying combined financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the combined financial statements have been prepared on a basis that assumes Mural will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

## **2. Basis of Presentation and Summary of Significant Accounting Policies**

### *Basis of Presentation*

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

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

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

## [Table of Contents](#)

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

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

### *Use of Estimates*

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

### *Risks and Uncertainties*

The COVID-19 pandemic has impacted, and may continue to impact, many aspects of society, including the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide. The COVID-19 pandemic has caused, and Mural expects may continue to cause, varying degrees of disruption to its employees and business operations. While Mural has continued to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of its early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. Mural works with its internal teams, Parent personnel, its clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on its R&D activities.

The degree to which the COVID-19 pandemic may continue to impact Mural's employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic

## [Table of Contents](#)

and the manner in which it continues to evolve, including the emergence, prevalence and severity of new COVID-19 variants, and future developments in response thereto. Due to these and numerous other uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact of the pandemic on Mural's financial condition and operating results may differ from its current projections.

### *Cash and Cash Equivalents*

Mural considers cash equivalents only those investments that are highly liquid, readily convertible into cash and so near their maturity, generally three months from the date of purchase, that they present insignificant risk of change in value because of interest rate changes. There were no cash or cash equivalents specifically attributable to Mural for the historical periods presented; therefore, there are no cash or cash equivalents reflected in the combined financial statements.

### *Fair Value Measurements*

Mural's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. Financial assets and liabilities are classified within the fair value hierarchy as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amounts reflected in the combined balance sheets for prepaid expenses, other current assets, accounts payable, and accrued expenses approximate fair value due to their short-term nature. Other current assets consists of rebates from a clinical research organization of \$1.8 million and \$2.0 million as of December 31, 2022 and 2021, respectively.

### *Property and Equipment*

Property and equipment are recorded at cost, subject to assessment for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Expenditures for repairs and maintenance are charged to expense as incurred and major renewals and improvements are capitalized. Depreciation is calculated using the straight-line method over the following estimated useful lives of the assets:

<u>Asset group</u>	<u>Term</u>
Furniture, fixtures and equipment	3 - 10 years
Leasehold improvements	Shorter of useful life or lease term

### *Leases*

In accordance with Accounting Standards Codification ("ASC") 842, *Leases*, Mural determines if an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Mural classifies leases at the lease commencement date as operating or finance leases and records a right-of-use asset and a lease liability in the combined balance sheets for all leases with an initial lease term of greater than 12 months. Leases with an initial term of 12 months or less are not recorded in the balance sheet, but payments are recognized as expense on a straight-line basis over the lease term.

## [Table of Contents](#)

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

Operating lease liabilities and their corresponding right-of-use assets are initially recorded at the lease commencement date based on the present value of lease payments over the expected remaining lease term using the discount rate implicit in the lease. Certain adjustments to right-of-use assets may be required for items such as prepaid or accrued lease payments as well as incentives received. If the rate implicit is not readily determinable, Mural utilizes an incremental borrowing rate based upon the available information at the lease commencement date. The incremental borrowing rate is meant to reflect a rate of interest at which Mural could borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment. The historical incremental borrowing rate was utilized in the preparation of the carve-out financial statements. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. Mural's lease terms may include options to extend or terminate the lease when it is reasonably certain that Mural will exercise that option.

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

### *Impairment of Long-Lived Assets*

Mural reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset; a significant change in the extent or manner in which an asset is used; a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset; an accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset; a current-period operating or cash flow loss combined with a history of operating or cash-flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset; or a current expectation that, more likely than not, a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell them. The Business has not recorded any impairment charges for the years ended December 31, 2022 and 2021.

### *Research and Development Expenses*

For each of its R&D programs, Mural incurs both external and internal expenses. External R&D expenses include fees related to clinical and non-clinical activities performed by contract research organizations, consulting fees and costs related to laboratory services, purchases of drug product materials, and third-party manufacturing development costs. Internal R&D expenses include employee-related expenses, including share-based compensation, occupancy costs, depreciation, and general R&D overhead.

### *General and Administrative Expenses*

General and administrative expenses are primarily comprised of allocated expenses of Alkermes, including employee-related expenses associated with finance, human resources, legal, information technology and other

## [Table of Contents](#)

administrative personnel, and occupancy costs, depreciation and third-party expenses related to financial, legal and other general and administrative functions within Alkermes.

### *Share-Based Compensation*

Certain employees of Mural participate in the Parent's share-based compensation plans. Share-based compensation expense of Mural related to these plans is recognized through allocations based on methodologies that management believes are consistent and reasonable, utilizing headcount or proportional hours worked supporting Mural and other organizational activities, as appropriate. Share-based compensation expense for time-based awards issued under the Parent's plan is recognized over the requisite service period of the awards, which is generally the vesting period. Time-based awards granted to employees generally vest in four equal annual installments, commencing on the first anniversary of the date of grant, provided the employee remains continuously employed with the Parent during the applicable vesting period. Time-based awards granted to non-employee directors generally vest over a one-year period, provided that the director continues to serve on the Parent's board of directors through the vesting date. Share-based compensation expense for awards with performance conditions is recognized from the date the Parent determines the performance criteria are probable of being achieved to the date the award, or relevant portion of the award, is expected to vest. Cumulative adjustments to share-based compensation expense for awards with performance conditions are recorded on a quarterly basis to reflect subsequent changes to the estimated outcome of the performance criteria until the date results are determined. See Note 6, *Share-Based Compensation*, for more information.

### *Income Taxes*

Mural has historically been included in the Parent's income tax returns, and all income taxes have been paid by the Parent. Income tax expense and other income tax related information contained in these combined financial statements are presented on a separate return approach as if Mural filed its own tax returns for the years ended December 31, 2022 and 2021. Under this approach, the provision for income taxes represents income tax paid or payable (or received or receivable) for the current year plus the change in deferred taxes during the year calculated as if Mural were a standalone taxpayer filing hypothetical income tax returns, where applicable. Current income tax liabilities are assumed to be immediately settled with the Parent and are relieved through "Net parent investment" account and are reflected as "Net transfers from Parent" within financing activities in the combined statements of cash flows.

Mural recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In evaluating Mural's ability to recover its deferred tax assets, Mural considers all available positive and negative evidence including its past operating results, the existence of cumulative losses in the most recent fiscal years, changes in the business in which Mural operates and its forecast of future taxable income. In determining future taxable income, Mural is responsible for assumptions utilized, including the amount of Irish and non-Irish pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that Mural is using to manage the underlying business.

Mural accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. Mural also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

## [Table of Contents](#)

### *Comprehensive Loss*

Comprehensive loss is comprised of net loss and other comprehensive loss. Mural has no components of other comprehensive loss. Therefore, net loss equals comprehensive loss for all periods presented.

### *Segment Information*

Mural operates as one business segment, which is the business of developing medicines designed to address unmet medical needs of patients in the area of oncology. Mural's chief operating decision maker, which prior to the separation from Alkermes is the Chairman and Chief Executive Officer of Alkermes, reviews Mural's operating results on an aggregate basis and manages operations as a single operating unit. Upon separation and distribution, the expectation is that a new chief operating decision maker will be identified. All of Mural's long-lived assets are held in Massachusetts.

### *401(k) Plan*

The Parent maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees, and includes employees of the Parent who will become employees of Mural. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain IRS limitations. The Parent matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Parent contributions are fully vested when made. During the years ended December 31, 2022 and 2021, expenses related to the 401(k) Plan that were allocated to Mural totaled \$1.6 million and \$1.6 million, respectively.

### *Recently Issued Accounting Pronouncements*

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

## **3. Property and Equipment, Net**

Property and equipment, net consisted of the following:

<b>(In thousands)</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Furniture, fixtures and equipment	\$ 17,470	\$ 13,604
Leasehold improvements	22,510	20,884
Construction in progress	1,989	1,970
Subtotal	41,969	36,458
Less: accumulated depreciation and amortization	(31,352)	(29,812)
Total property and equipment, net	<u>\$ 10,617</u>	<u>\$ 6,646</u>

Depreciation and amortization expense was \$1.5 million and \$1.5 million for the years ended December 31, 2022 and 2021, respectively.

#### 4. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31,	December 31,
	2022	2021
Accrued external research and development services	\$ 25,298	\$ 10,215
Accrued compensation	7,104	6,297
Accrued general and administrative	302	204
Accrued other	46	25
Total accrued expenses	<u>\$ 32,750</u>	<u>\$ 16,741</u>

#### 5. Leases

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

As of December 31, 2022, the incremental borrowing rate and the remaining lease term for the operating lease held by Mural were 3.52% and 3.8 years, respectively. As of December 31, 2021, the incremental borrowing rate and the remaining lease term for the operating lease held by Mural were 3.52% and 4.8 years, respectively. During the years ended December 31, 2022 and 2021, cash paid by the Parent for amounts included for the measurement of lease liabilities was \$6.2 million and \$4.9 million, respectively, and are included within cash flows from operating activities.

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

(In thousands)	Year Ended	
	December 31,	
	2022	2021
Operating lease cost	\$6,202	\$5,894
Variable lease cost	3,618	3,812
Total lease cost	<u>\$9,820</u>	<u>\$9,706</u>



## [Table of Contents](#)

Future lease payments under non-cancelable leases as of December 31, 2022 consisted of the following:

(In thousands)	December 31,	
	2022	
2023	\$	6,353
2024		6,496
2025		6,642
2026		2,484
2027		—
Thereafter		—
Total operating lease payments	\$	21,975
Less: imputed interest		(2,589)
Total operating lease liabilities	\$	19,386

## 6. Share-Based Compensation

The Parent has share-based compensation plans which provide for granting equity awards, including non-qualified and incentive stock options, restricted stock, restricted stock unit awards, cash-based awards, and performance shares to employees, officers and directors of, and consultants to, the Parent. All share-based compensation plans are managed on a consolidated basis by the Parent. Share-based compensation expense allocated to Mural relates to stock options, time-based restricted stock unit awards and performance-based restricted stock unit awards issued by the Parent. Accordingly, the amounts presented are not necessarily indicative of future share-based compensation and do not necessarily reflect the amount that Mural would have issued as an independent company for the periods presented.

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

(In thousands)	Year Ended December 31,	
	2022	2021
Research and development	\$ 9,515	\$ 9,184
General and administrative	2,416	2,320
Total share-based compensation expense	\$ 11,931	\$ 11,504

## 7. Income Taxes

Mural has historically been included in the income tax returns filed by Alkermes. In preparing the combined financial statements for Mural, Alkermes has determined the tax provision for those operations on a separate return basis. The tax provision and the related tax disclosures set out below are not necessarily representative of the tax provision and the related tax disclosures that may arise in the future.

The distribution of Mural's loss before the provision for income taxes by geographical area consists of the following:

(In thousands)	Year Ended December 31,	
	2022	2021
Ireland	\$(178,693)	\$(171,796)
U.S.	(6,230)	(3,569)
Loss before the provision for income taxes	\$(184,923)	\$(175,365)

## [Table of Contents](#)

The provision for income taxes consists of the following:

(In thousands)	Year Ended December 31,	
	2022	2021
<b>Current income tax provision:</b>		
U.S. federal	\$ 4,858	\$ 67
U.S. state	26	1
Ireland	—	—
<b>Deferred income tax provision:</b>		
U.S. federal	—	—
U.S. state	—	—
Ireland	—	—
<b>Total tax provision</b>	<b>\$ 4,884</b>	<b>\$ 68</b>

The income tax provision in 2022 was primarily due to the capitalization and amortization of R&D expenses in accordance with Section 174 of the Internal Revenue Code of 1986 (the "Code"). The income tax provision in 2021 was primarily due to taxes on U.S. taxable income.

No provision for income tax has been provided on undistributed earnings of the U.S. subsidiary because such earnings are indefinitely reinvested in the U.S. operations. Cumulative unremitted earnings of the U.S. subsidiary from January 1, 2021 to December 31, 2022 totaled approximately \$144.9 million. In the event of a repatriation of those earnings in the form of dividends or otherwise, Mural may be liable for income taxes, subject to adjustment, if any, for U.S. tax credits and U.S. withholding taxes payable to U.S. tax authorities. Mural estimates that approximately \$7.2 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

The components of the net deferred tax assets (liabilities) of Mural consist of the following:

(In thousands)	December 31,	December 31,
	2022	2021
<b>Deferred tax assets:</b>		
Net operating losses	\$ 72,973	\$ 50,733
Tax credits	7,074	17,531
Accrued expenses	4,436	5,700
Research and development expenses	31,866	—
Other	6,021	5,386
Less: valuation allowance	(117,475)	(74,131)
Total deferred tax assets	4,895	5,219
<b>Deferred tax liabilities:</b>		
Right-of-use assets	(3,851)	(5,095)
Property and equipment	(1,044)	(124)
Total deferred tax liabilities	(4,895)	(5,219)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

Note that the net deferred tax assets presented in the table above and the tax attributes referred to below were calculated based on the separate return method and do not represent the net deferred tax assets or tax attributes that will transfer with Mural on separation.

## [Table of Contents](#)

The activity in the valuation allowance associated with deferred taxes consists of the following:

(In thousands)	Balance at Beginning of Period	Additions <sup>(1)</sup>	Balance at End of Period
Deferred tax asset valuation allowance for the year ended December 31, 2021	\$ (47,526)	\$ (26,605)	\$ (74,131)
Deferred tax asset valuation allowance for the year ended December 31, 2022	\$ (74,131)	\$ (43,344)	\$ (117,475)

- (1) The additions in the year ended December 31, 2021 relate primarily to Irish NOLs and the additions in the year ended December 31, 2022 relate primarily to Irish NOLs and capitalized research and development expenses in the U.S.

At December 31, 2022, Mural maintained a valuation allowance of \$41.1 million against U.S. federal and state deferred tax assets and \$76.4 million against Irish deferred tax assets as Mural has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If Mural demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets could change and the valuation allowance may be released in part or in whole.

As of December 31, 2022, Mural had \$583.8 million of Irish NOL carryforwards, \$4.6 million of federal R&D credits and \$5.9 million of state R&D credits which will either expire on various dates through 2042 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish taxable income and foreign tax respectively. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities and may be subject to limitations based upon changes in the ownership of our ordinary shares.

A reconciliation of Mural statutory tax rate to its effective tax rate is as follows:

(In thousands, except percentage amounts)	Year Ended December 31,	
	2022	2021
Statutory tax rate	12.5%	12.5%
Income tax provision at statutory rate	\$(23,115)	\$(21,921)
Foreign rate differential <sup>(1)</sup>	(4,885)	(42)
Change in valuation allowance	43,344	26,605
U.S. state income taxes, net of U.S. federal benefit	(11)	—
Foreign derived intangible income	(6,750)	(22)
R&D credit	(4,489)	(5,506)
Other permanent items <sup>(2)</sup>	790	954
Income tax provision	<u>\$ 4,884</u>	<u>\$ 68</u>
Effective tax rate	(2.64)%	(0.04)%

- (1) Represents income or losses of Mural's U.S. subsidiary, subject to tax at a rate other than the Irish statutory rate.

- (2) Other permanent items include, but are not limited to, non-deductible employee compensation and uncertain tax positions of Mural.

## [Table of Contents](#)

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

(In thousands)	Unrecognized Tax Benefits
Balance, December 31, 2020	\$ 1,301
Additions based on tax positions related to prior periods	—
Additions based on tax positions related to the current period	483
Balance, December 31, 2021	\$ 1,784
Additions based on tax positions related to prior periods	—
Additions based on tax positions related to the current period	348
Balance, December 31, 2022	\$ 2,132

The unrecognized tax benefits at December 31, 2022, if recognized, would affect Mural's effective tax rate prior to taking its valuation allowance into consideration. Mural does not anticipate that the amount of existing unrecognized tax benefits will materially increase or decrease within the next 12 months. Note that the unrecognized tax benefits presented in the table above were calculated based on the separate return method and do not represent the unrecognized tax benefits that will transfer with Mural on separation.

The taxing jurisdictions for Mural include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2019 through 2022 fiscal years remain subject to examination by the respective tax authorities, however, some states have longer statutes of limitation and additional fiscal years remain subject to examination. In Ireland, the 2018 through 2022 fiscal years remain subject to examination by the Irish tax authorities. Additionally, because of the R&D credit carryforwards, certain tax returns from fiscal years 2012 onward may also be examined. These years generally remain open for three to four years after the credit carryforwards have been utilized.

### **8. Commitments and Contingencies**

Mural, from time to time, may be involved with lawsuits arising in the ordinary course of business. In the opinion of Mural's management, any liability resulting from such litigation would not be material in relation to Mural's combined financial position, results of operations and cash flows. At December 31, 2022, there is no pending or threatened litigation against Alkermes that is related to the operations of Mural or employees of Mural.

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

Mural has open purchase orders for equipment as part of its normal course of business. At December 31, 2022 and 2021, Mural's open purchase orders for capital commitments were \$0.8 million and \$0.4 million, respectively.

### **9. Related Parties**

Corporate expenses represent shared costs of Alkermes that have been allocated to Mural based on a systematic and rational methodology and are reflected as expenses in these combined financial statements. These amounts include, but are not limited to, items such as general management and executive oversight, costs to support Mural's information technology infrastructure, facilities, compliance, human resources, legal and finance functions, risk management, and share-based compensation administration, all of which support the operations of Alkermes as a whole. Corporate expense allocations are generally allocated to Mural based on proportional cost

## [Table of Contents](#)

allocation methods using headcount, square footage, or proportional hours worked supporting Mural and other organizational activities, as applicable, which are considered to be reasonable reflections of the utilization of services provided or benefit received by Mural during the periods presented. Total corporate expense allocations in general and administrative were \$12.1 million and \$11.2 million during the years ended December 31, 2022 and December 31, 2021, respectively.

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

See Note 1, *Organization and Description of Business*, for details of Mural's cash and financing arrangements. As of the date these combined financial statements were available for issuance, there were no existing intercompany debt or other financing agreements in place with the Parent. See Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, for additional information on the preparation and basis of presentation of these combined 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) expenses.

### **10. Subsequent Events**

These combined financial statements were derived from the financial statements of Alkermes, which issued its annual consolidated financial statements for the year ended December 31, 2022 on February 16, 2023. Accordingly, Mural has evaluated subsequent events for consideration as recognized subsequent events in these combined financial statements through the date of February 16, 2023. Additionally, Mural has evaluated subsequent events that occurred through April 14, 2023, the date these combined financial statements were available for issuance, for the purposes of unrecognized subsequent events.