

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

**FORM 10-Q**

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

For the quarterly period ended March 31, 2022

or

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

For the transition period from      to

Commission File Number: 0-24006

**NEKTAR THERAPEUTICS**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3134940  
(IRS Employer  
Identification No.)

455 Mission Bay Boulevard South  
San Francisco, California 94158  
(Address of principal executive offices)

415-482-5300  
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	NKTR	NASDAQ Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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.

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

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

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 186,274,156 on April 29, 2022.

**NEKTAR THERAPEUTICS  
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## **Forward-Looking Statements**

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q, including any projections of market size, earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements related to our strategic reorganization and cost restructuring plans, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates and our future research and development plans, any statements regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the initiation, formation, or success of our collaboration arrangements, commercialization activities and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, any statements related to potential, anticipated, or ongoing litigation and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “believe,” “may,” “will,” “expects,” “plans,” “anticipates,” “estimates,” “potential” or “continue,” or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part I, Item 1A “Risk Factors” below and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, the “Company,” “Nektar,” “we,” “us,” and “our” refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

## **Trademarks**

The Nektar brand and product names, including but not limited to Nektar<sup>®</sup>, contained in this document are trademarks and registered trademarks of Nektar Therapeutics in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

## Summary of Risks

We are providing the following cautionary discussion of risk factors, uncertainties and assumptions that we believe are relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Exchange Act and Section 27A of the Securities Act. Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this section to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time, and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations.

Risks to our business are more fully described below in Item IA in this Form 10-Q, which risks include, among others:

- **Risks Related to our Research and Development Efforts:**

- clinical drug development is a lengthy and uncertain process and we may not be able to generate and develop successful drug candidates for commercial use;
- we are highly dependent on the success of NKTR-358 and NKTR-255 and our business will be significantly harmed if either NKTR-358 or NKTR-255 does not continue to advance in clinical studies;
- the outcomes from competitive oncology and immunology therapy clinical trials, and the discovery and development of new potential oncology and immunology therapies could have a material and adverse impact on the value of our pipeline;
- significant competition for our polymer conjugate chemistry technology platforms and our products and drug candidates could make our technologies, drug products or drug candidates obsolete or uncompetitive;
- preliminary and interim data from our clinical studies are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available; and
- clinical trials for any of our drug candidates could be delayed for a variety of reasons.

- **Risks Related to our Financial Condition and Capital Requirements:**

- we are implementing a new strategic reorganization plan focused on prioritizing key research and development efforts, as well as a cost restructuring plan, and our business will be significantly harmed if either of these plans is unsuccessful;
- we have substantial future capital requirements and there is a risk we may not have access to sufficient capital to meet our current business plan;
- our revenue is exclusively derived from our collaboration agreements. If we are unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer; and
- we expect to continue to incur substantial net losses from operations and may not achieve or sustain profitability in the future.

- **Risks Related to our Collaboration Partners:**

- we are highly dependent on Eli Lilly and Company, our collaboration partner for NKTR-358, our lead drug candidate, to initiate, properly conduct and prioritize clinical trials for NKTR-358 and to perform important additional development and commercialization activities, and our business will be significantly harmed if our partner's actions deprioritize or otherwise harm the prospects of NKTR-358; and
- the operations of our collaboration partners have been affected by the COVID-19 pandemic in the past, and it is possible that the COVID-19 pandemic will affect the operations of our collaboration partners in the future, which would cause delays in initiating or completing one or more clinical trials involving our drug candidates.

- **Risks Related to the COVID-19 Pandemic:**

- our business could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic. While the COVID-19 pandemic has not had a material adverse effect on our current operations, the

ongoing challenges associated with the pandemic, including the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, and resurgences in number and rates of infections, and shortages in raw materials and equipment and other supply chain disruptions, could have a material negative impact on our business and our clinical trial timelines.

- **Risks Related to Supply and Manufacturing:**

- if we or our contract manufacturers are not able to manufacture drugs or drug substances in sufficient quantities that meet applicable quality standards, our business, financial condition and results of operations could be harmed; and
- we purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause delays, loss of revenue and contract liability.

- **Risks Related to Intellectual Property, Litigation and Regulatory Concerns:**

- we or our partners may not obtain regulatory approval for our drug candidates on a timely basis, or at all;
- patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required, which may not be available to us on commercially reasonable terms; and
- from time to time, we are involved in legal proceedings and may incur substantial litigation costs and liabilities that could adversely affect our business, financial condition and results of operations.

In addition to the above-mentioned risks, our business is subject to a number of additional risks faced by businesses generally.

## PART I: FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements—Unaudited:

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except par value)  
(Unaudited)

	March 31, 2022	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 67,993	\$ 25,218
Short-term investments	599,032	708,737
Accounts receivable	30,220	22,492
Inventory	15,379	15,801
Other current assets	20,831	23,333
Total current assets	733,455	795,581
Long-term investments	37,363	64,828
Property, plant and equipment, net	60,980	60,510
Operating lease right-of-use assets	114,296	117,025
Goodwill	76,501	76,501
Other assets	1,521	2,744
Total assets	\$ 1,024,116	\$ 1,117,189
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	12,617	9,747
Accrued compensation	22,653	15,735
Accrued clinical trial expenses	33,403	26,809
Other accrued expenses	17,011	15,468
Operating lease liabilities, current portion	19,597	17,441
Total current liabilities	105,281	85,200
Operating lease liabilities, less current portion	122,638	125,736
Development derivative liability	—	27,726
Liabilities related to the sales of future royalties, net	185,604	195,427
Other long-term liabilities	2,704	3,592
Total liabilities	416,227	437,681
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares designated or outstanding at March 31, 2022 or December 31, 2021, respectively	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized; 186,274 shares and 185,468 shares outstanding at March 31, 2022 or December 31, 2021, respectively	19	19
Capital in excess of par value	3,537,790	3,516,641
Accumulated other comprehensive loss	(6,532)	(4,157)
Accumulated deficit	(2,923,388)	(2,832,995)
Total stockholders' equity	607,889	679,508
Total liabilities and stockholders' equity	\$ 1,024,116	\$ 1,117,189

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

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share information)  
(Unaudited)

	<b>Three months ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product sales	\$ 5,688	\$ 4,795
Non-cash royalty revenue related to the sales of future royalties	17,561	18,798
License, collaboration and other revenue	1,573	54
<b>Total revenue</b>	<b>24,822</b>	<b>23,647</b>
Operating costs and expenses:		
Cost of goods sold	5,315	5,756
Research and development	107,253	95,604
General and administrative	27,339	31,679
Restructuring, impairment and other costs of terminated program	1,475	—
<b>Total operating costs and expenses</b>	<b>141,382</b>	<b>133,039</b>
Loss from operations	(116,560)	(109,392)
Non-operating income (expense):		
Change in fair value of development derivative liability	33,427	(1,599)
Non-cash interest expense on liabilities related to the sales of future royalties	(7,529)	(13,296)
Interest income and other income (expense), net	395	1,412
<b>Total non-operating income (expense), net</b>	<b>26,293</b>	<b>(13,483)</b>
Loss before provision for income taxes	(90,267)	(122,875)
Provision for income taxes	126	92
<b>Net loss</b>	<b>\$ (90,393)</b>	<b>\$ (122,967)</b>
Basic and diluted net loss per share	\$ (0.49)	\$ (0.68)
Weighted average shares outstanding used in computing basic and diluted net loss per share	185,848	181,370

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

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(In thousands)**  
**(Unaudited)**

	Three months ended March 31,	
	2022	2021
Net loss	\$ (90,393)	\$ (122,967)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale investments	(2,091)	(766)
Net foreign currency translation gain (loss)	(284)	(60)
Other comprehensive income (loss)	(2,375)	(826)
Comprehensive loss	\$ (92,768)	\$ (123,793)

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



**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands)  
(Unaudited)

	Common Shares	Par Value	Capital in Excess of Par Value	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	180,091	\$ 18	\$ 3,388,730	\$ (2,295)	\$ (2,309,158)	\$ 1,077,295
Shares issued under equity compensation plans	2,199	—	17,106	—	—	17,106
Stock-based compensation	—	—	23,898	—	—	23,898
Comprehensive income (loss)	—	—	—	(826)	(122,967)	(123,793)
Balance at March 31, 2021	<u>182,290</u>	<u>18</u>	<u>3,429,734</u>	<u>(3,121)</u>	<u>(2,432,125)</u>	<u>994,506</u>

	Common Shares	Par Value	Capital in Excess of Par Value	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	185,468	\$ 19	\$ 3,516,641	\$ (4,157)	\$ (2,832,995)	\$ 679,508
Shares issued under equity compensation plans	806	—	188	—	—	188
Stock-based compensation	—	—	20,961	—	—	20,961
Comprehensive income (loss)	—	—	—	(2,375)	(90,393)	(92,768)
Balance at March 31, 2022	<u>186,274</u>	<u>19</u>	<u>3,537,790</u>	<u>(6,532)</u>	<u>(2,923,388)</u>	<u>607,889</u>

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

**NEKTAR THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (90,393)	\$ (122,967)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to the sales of future royalties	(17,561)	(18,798)
Non-cash interest expense on liabilities related to the sales of future royalties	7,529	13,296
Change in fair value of development derivative liability	(33,427)	1,599
Non-cash research and development expense	4,951	2,248
Stock-based compensation	20,961	23,898
Depreciation and amortization	3,730	3,543
Amortization of premiums (discounts), net and other non-cash transactions	1,276	2,345
Changes in operating assets and liabilities:		
Accounts receivable	(7,728)	9,733
Inventory	422	(1,516)
Operating leases, net	1,787	1,541
Other assets	2,864	6,183
Accounts payable	2,998	779
Accrued compensation	6,918	8,981
Other accrued expenses	7,249	(7,950)
Net cash used in operating activities	<u>(88,424)</u>	<u>(77,085)</u>
<b>Cash flows from investing activities:</b>		
Purchases of investments	(93,493)	(295,314)
Maturities of investments	227,974	303,612
Sales of investments	—	5,036
Purchases of property, plant and equipment	(4,203)	(2,876)
Net cash provided by investing activities	<u>130,278</u>	<u>10,458</u>
<b>Cash flows from financing activities:</b>		
Proceeds from shares issued under equity compensation plans	188	17,106
Cash receipts from development derivative liability	750	750
Net cash provided by financing activities	<u>938</u>	<u>17,856</u>
Effect of foreign exchange rates on cash and cash equivalents	(17)	(20)
Net increase (decrease) in cash and cash equivalents	<u>42,775</u>	<u>(48,791)</u>
Cash and cash equivalents at beginning of period	25,218	198,955
Cash and cash equivalents at end of period	<u>\$ 67,993</u>	<u>\$ 150,164</u>
<b>Supplemental disclosures of cash flow information:</b>		
Operating lease right-of-use asset recognized in exchange for lease liabilities	<u>\$ —</u>	<u>\$ 1,057</u>

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

**NEKTAR THERAPEUTICS**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2022**  
**(Unaudited)**

**Note 1 — Organization and Summary of Significant Accounting Policies**

**Organization**

We are a research-based biopharmaceutical company headquartered in San Francisco, California and incorporated in Delaware. We are developing a pipeline of drug candidates that utilize our advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. Our research and development pipeline of new investigational drugs includes investigational treatments in oncology and immunology.

Our research and development activities have required significant ongoing investment to date and are expected to continue to require significant investment. As a result, we expect to continue to incur substantial losses and negative cash flows from operations in the future. We have financed our operations primarily through cash generated from licensing, collaboration and manufacturing agreements and financing transactions. As of March 31, 2022, we had approximately \$704.4 million in cash and investments in marketable securities.

**Restructuring, Impairment and Other Costs of Terminated Program**

In March and April 2022, we announced the unsuccessful results from our clinical trials studying bempegaldesleukin in combination with Opdivo® under our Strategic Collaboration Agreement with Bristol-Myers Squibb Company (BMS). Based on these results, we decided to discontinue all of our ongoing clinical trials of bempegaldesleukin in combination with checkpoint inhibitors. In April 2022, we also announced new strategic reorganization and cost restructuring plans for the Company's future:

- On March 14, 2022, BMS and we announced that the registrational trial for bempegaldesleukin in combination with Opdivo® in metastatic melanoma did not meet its primary endpoints and that BMS and we decided to discontinue the registrational trials in metastatic melanoma and adjuvant melanoma. See Note 7 for additional information on our BMS Collaboration Agreement.
- On April 14, 2022, we announced that each of our registrational trials for bempegaldesleukin in combination with Opdivo® in renal cell carcinoma and in cisplatin-ineligible, locally advanced or metastatic urothelial cancer did not meet their respective primary endpoints. Due to these results, BMS and we decided to discontinue these studies and all other ongoing studies for bempegaldesleukin in combination with Opdivo®.
- On April 14, 2022, we announced that, in consultation with SFJ Pharmaceuticals and based upon a recommendation from an independent Data Monitoring Committee, we made the decision to discontinue our Phase 2/3 study in bempegaldesleukin in combination with Keytruda® in patients with metastatic or unresectable recurrent squamous cell cancer of the head and neck under our Co-Development Agreement with SFJ Pharmaceuticals. See Note 4 for additional information regarding our Co-Development Agreement with SFJ Pharmaceuticals. In addition to announcing the decision to discontinue this Phase 2/3 study, we also announced on April 14, 2022, the discontinuation of our Phase 1/2 PROPEL study of bempegaldesleukin in combination with Keytruda® in locally advanced or metastatic solid tumors, including non-small cell lung cancer. With these announcements on April 14, 2022, there are no ongoing clinical development activities of bempegaldesleukin.
- On April 25, 2022, we announced our strategic reorganization and cost restructuring plans (together, the Reorganization and Restructuring Plans), which were reviewed and approved by our Board of Directors on April 14, 2022. On April 26, 2022, our duly authorized officers approved certain strategic, operational and organizational steps to undertake in connection with the Reorganization and Restructuring Plans. Under the Reorganization and Restructuring Plans, we are prioritizing key research and development efforts and continuing to evaluate our early stage drug candidate pipeline. We are also reducing our workforce by approximately 70%. See Note 10 for additional information regarding our reorganization and restructuring plans.

For the three months ended March 31, 2022, restructuring, impairment and other costs for terminated programs primarily include cancellation fees for certain manufacturing activities for bempegaldesleukin which were scheduled to support our efforts at securing potential FDA approval and commercial launch of bempegaldesleukin in metastatic melanoma in 2022.

### ***Basis of Presentation and Principles of Consolidation***

Our Condensed Consolidated Financial Statements include the financial position, results of operations and cash flows of Nektar Therapeutics and our wholly-owned subsidiaries. We have eliminated all intercompany accounts and transactions in consolidation.

We prepared our Condensed Consolidated Financial Statements following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, we may condense or omit certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles (GAAP) for annual periods. In the opinion of management, these financial statements include all normal and recurring adjustments that we consider necessary for the fair presentation of our financial position and operating results.

Our Condensed Consolidated Financial Statements are denominated in U.S. dollars. Accordingly, changes in exchange rates between the applicable foreign currency and the U.S. dollar will affect the translation of each foreign subsidiary's financial results into U.S. dollars for purposes of reporting our consolidated financial results. We include translation gains and losses in accumulated other comprehensive loss in the stockholders' equity section of our Condensed Consolidated Balance Sheets. To date, such cumulative currency translation adjustments have not been significant to our consolidated financial position.

Our comprehensive loss consists of our net loss plus our foreign currency translation gains and losses and unrealized gains and losses on available-for-sale securities. There were no significant reclassifications out of accumulated other comprehensive loss to the statements of operations during the three months ended March 31, 2022 and 2021.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2021 was derived from the audited consolidated financial statements which are included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and the accompanying notes to those financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Revenue, expenses, assets, and liabilities can vary during each quarter of the year. The results and trends in these interim Condensed Consolidated Financial Statements are not necessarily indicative of the results to be expected for the full year or any other period.

### ***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Accounting estimates and assumptions are inherently uncertain.

Actual results could differ materially from those estimates and assumptions. As appropriate, we assess estimates each period, update them to reflect current information, and generally reflect any changes in estimates in the period first identified.

### ***Significant Concentrations***

Our customers are primarily pharmaceutical and biotechnology companies that are located in the U.S. and Europe and with whom we have multi-year arrangements. Our accounts receivable balance contains billed and unbilled trade receivables from product sales, milestones (to the extent that they have been achieved and are due from the counterparty), and other contingent payments, as well as reimbursable costs from collaborative research and development agreements. As of March 31, 2022 and December 31, 2021, our accounts receivable includes \$26.9 million and \$21.4 million, respectively, for unbilled net expense reimbursements from BMS. The remaining accounts receivable relate primarily to product sales. We generally do not require collateral from our customers. We perform a regular review of our customers' credit risk and payment histories, including payments made after period end. Historically, we have not experienced credit losses from our accounts receivable and recorded no bad debt expense for the three months ended March 31, 2022 and 2021. We have not recorded a reserve for credit losses at March 31, 2022 or December 31, 2021.

We are dependent on our suppliers and contract manufacturers to provide raw materials and drugs of appropriate quality and reliability and to meet applicable contract and regulatory requirements. In certain cases, we rely on single sources of supply of one or more critical materials. Consequently, in the event that supplies are delayed or interrupted for any reason, including as a result of the COVID-19 pandemic, our ability to develop and produce our drug candidates, our ability to supply comparator drugs for our clinical trials, or our ability to meet our supply obligations could be significantly impaired, which could have a material adverse effect on our business, financial condition and results of operations.

For our available-for-sale securities, we have significant concentrations of issuers in the banking and financial services industries. While our investment policy requires that we only invest in highly-rated securities and limit our exposure to any single issuer, the COVID-19 pandemic or other factors may materially affect the financial condition of issuers. Additionally, pursuant to our investment policy, we may sell securities before maturity if the issuer's credit rating has been downgraded below our minimum credit rating requirements, which may result in a loss on the sale. Accordingly, if the COVID-19 pandemic or other factors result in downgrades below our minimum credit rating requirements and if we decide to sell these securities, we may experience losses on such sales.

### ***Collaborative Arrangements***

We enter into collaboration arrangements with pharmaceutical and biotechnology collaboration partners, under which we may grant licenses to our collaboration partners to further develop and commercialize one of our drug candidates, either alone or in combination with the collaboration partners' compounds, or grant licenses to partners to use our technology to research and develop their own drug candidates. We may also perform research, development, manufacturing and supply activities under our collaboration agreements. Consideration under these contracts may include an upfront payment, development and regulatory milestones and other contingent payments, expense reimbursements, royalties based on net sales of approved drugs, and commercial sales milestone payments. Additionally, these contracts may provide options for the customer to purchase our proprietary PEGylation materials, drug candidates or additional contract research and development services under separate contracts.

When we enter into collaboration agreements, we assess whether the arrangements fall within the scope of ASC 808, *Collaborative Arrangements* (ASC 808) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards of the arrangement. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our collaboration partner fall within the scope of other accounting literature. If we conclude that payments from the collaboration partner to us represent consideration from a customer, such as license fees and contract research and development activities, we account for those payments within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606). However, if we conclude that our collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, we present such payments as a reduction of research and development expense or general and administrative expense, based on where we present the underlying expense.

### ***Revenue Recognition***

For elements of those arrangements that we determine should be accounted for under ASC 606, we assess which activities in our collaboration agreements are performance obligations that should be accounted for separately and determine the transaction price of the arrangement, which includes the assessment of the probability of achievement of future milestones and other potential consideration. For arrangements that include multiple performance obligations, such as granting a license or performing contract research and development activities or participation on joint steering or other committees, we allocate upfront and milestone payments under a relative standalone selling price method. Accordingly, we develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include revenue forecasts, clinical development timelines and costs, discount rates and probabilities of clinical and regulatory success.

### ***Product Sales***

Product sales are primarily derived from manufacturing and supply agreements with our customers. We have assessed our current manufacturing and supply arrangements and have generally determined that they provide the customer an option to purchase our proprietary PEGylation materials. Accordingly, we treat each purchase order as a discrete exercise of the customer's option (i.e. a separate contract) rather than as a component of the overall arrangement. The pricing for the manufacturing and supply is generally at a fixed price and may be subject to annual producer price index (PPI) adjustments. We invoice and recognize product sales when title and risk of loss pass to the customer, which generally occurs upon shipment. Customer payments are generally due 30 days from receipt of invoice. We test our products for adherence to technical specifications before shipment; accordingly, we have not experienced any significant returns from our customers. We recognize costs related to shipping and handling of product to customers in cost of goods sold.

### ***Non-cash royalty revenue***

Generally, for our collaboration arrangements that include sales-based royalties, we have granted our collaboration partner a license to our intellectual property. Pursuant to these arrangements, our collaboration partners are typically obligated to pay a royalty that is based on the net sales of their approved drugs that are sold in the countries where we have intellectual property rights covering their drugs. As of December 30, 2020, we have sold our rights to receive sales-based royalties for

CIMZIA®, MIRCERA®, MOVANTIK®, ADYNOVATE® and REBINYN® as further described in Note 5. For collaboration arrangements that include sales-based royalties, we have concluded that the license is the predominant item to which the royalties relate. Accordingly, we recognize royalty revenue when the underlying sales occur based on our best estimates of sales of the drugs. Our non-cash royalty revenue of \$17.6 million and \$18.8 million for the three months ended March 31, 2022 and 2021, respectively, represents revenue for granting licenses which we had satisfied in prior periods. Our partners generally pay royalties after the end of the calendar quarter in accordance with contractual terms.

#### ***License, collaboration and other revenue***

***License Grants:*** For collaboration arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. Generally, we would conclude that the license is distinct if the customer is able to benefit from the license with the resources available to it. For licenses that are distinct, we recognize revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and we have provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

***Milestone Payments:*** At the inception of the arrangement and at each reporting date thereafter, we assess whether we should include any milestone payments or other forms of variable consideration in the transaction price, based on whether a significant reversal of revenue previously recognized is not probable upon resolution of the uncertainty. Since milestone payments may become payable to us upon the initiation of a clinical study, filing for or receipt of regulatory approval or the first commercial sale of a product, we review the relevant facts and circumstances to determine when we should update the transaction price, which may occur before the triggering event. When we do update the transaction price for milestone payments, we allocate it on a relative standalone selling price basis and record revenue on a cumulative catch-up basis, which results in recognizing revenue for previously satisfied performance obligations in such period. If we update the transaction price before the triggering event, we recognize the increase in the transaction price as a contract asset. Our partners generally pay development milestones subsequent to achievement of the triggering event.

***Research and Development Services:*** For amounts allocated to our research and development obligations in a collaboration arrangement, we recognize revenue over time using a proportional performance model, representing the transfer of goods or services as we perform activities over the term of the agreement.

#### ***Research and Development Expense***

Research and development costs are expensed as incurred and include salaries, benefits and other operating costs such as outside services, supplies and allocated overhead costs. We perform research and development activities for our drug candidates and technology development and for certain third parties under collaboration agreements. For our drug candidates and our internal technology development programs, we invest our own funds without reimbursement from a third party. Where we perform research and development activities under a joint development collaboration, such as our collaboration with BMS, we record the cost reimbursement from our partner as a reduction to research and development expense when reimbursement amounts are due to us under the agreement.

We record an accrued expense for the estimated unbilled costs of our clinical study activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients and completion of certain clinical trial activities. We generally recognize costs associated with the start-up and reporting phases of the clinical trials as incurred. We generally accrue costs associated with the treatment phase of clinical trials based on the estimated activities performed by our third party vendors, including our contract research organizations. We may also accrue expenses based on the total estimated cost of the treatment phase on a per patient basis and expense the per patient cost ratably over the estimated patient treatment period. In specific circumstances, such as for certain time-based costs, we recognize clinical trial expenses ratably over the service period, as we believe that this methodology may be more reflective of the timing of costs incurred.

We record an accrued expense for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether we consider the production process to be sufficiently defined such that the resulting product can be considered the delivery of a good, as evidenced by predictive or contractually required yields in the production process or payment terms based on the actual yield, or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize expense when the drug product is delivered, or we otherwise bear risk of loss. If we consider the process to be the delivery of a service, we recognize expense based on our best estimates of

the contract manufacturer's progress towards completion of the stages in the contracts. We recognize and amortize upfront payments and accrue liabilities based on the specific terms of each arrangement. Certain arrangements may provide upfront payments for certain stages of the arrangement and milestone payments for the completion of certain stages, and, accordingly, we may record advance payments for services that have not been completed or goods not delivered and liabilities for stages where the contract manufacturer is entitled to a milestone payment.

We capitalize advance payments for goods or services that will be used or rendered for future research and development activities and recognize expense as the related goods are delivered or services performed. We base our estimates on the best information available at the time. However, additional information may become available to us in the future which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. We generally consider such increases or decreases in cost as changes in estimates and reflect them in research and development expenses in the period identified.

## Note 2 — Cash and Investments in Marketable Securities

Cash and investments in marketable securities, including cash equivalents, are as follows (in thousands):

	Estimated Fair Value at	
	March 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 67,993	\$ 25,218
Short-term investments	599,032	708,737
Long-term investments	37,363	64,828
Total cash and investments in marketable securities	\$ 704,388	\$ 798,783

We invest in liquid, high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in securities with maturities of two years or less and maintain a weighted average maturity of one year or less. As of March 31, 2022 and December 31, 2021, all of our long-term investments had maturities between one and two years.

Our portfolio of cash and investments in marketable securities includes (in thousands):

	Fair Value Hierarchy Level	March 31, 2022				December 31, 2021	
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Fair Value	
Corporate notes and bonds	2	\$ 196,643	\$ 4	\$ (1,270)	\$ 195,377	\$ 278,121	
Corporate commercial paper	2	439,280	—	(1,479)	437,801	478,629	
Obligations of U.S. government agencies	2	4,880	—	(9)	4,871	5,875	
Available-for-sale investments		\$ 640,803	\$ 4	\$ (2,758)	\$ 638,049	\$ 762,625	
Money market funds	1				43,523	23,968	
Certificates of deposit	2				10,894	10,940	
Cash	N/A				11,922	1,250	
Total cash and investments in marketable securities					\$ 704,388	\$ 798,783	

For the three months ended March 31, 2022 and 2021, there were no transfers between Level 1 and Level 2 of the fair value hierarchy. At December 31, 2021, our gross unrealized losses totaled \$0.7 million, and our gross unrealized gains were insignificant.

**Note 3 — Inventory**

Inventory consists of the following (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	\$ 2,084	\$ 3,166
Work-in-process	9,420	9,342
Finished goods	3,875	3,293
Total inventory	<u>\$ 15,379</u>	<u>\$ 15,801</u>

We manufacture finished goods inventory upon receipt of firm purchase orders, and we may manufacture certain intermediate work-in-process materials and purchase raw materials based on purchase forecasts from our collaboration partners. We include direct materials, direct labor, and manufacturing overhead in inventory and determine cost on a first-in, first-out basis for raw materials and on a specific identification basis for work-in-process and finished goods. We value inventory at the lower of cost or net realizable value, and we write down defective or excess inventory to net realizable value based on historical experience or projected usage. We expense inventory related to our research and development activities as manufactured by us or when purchased.

**Note 4 — Co-Development Agreement with SFJ Pharmaceuticals and Development Derivative Liability**

On February 12, 2021, we entered into a Co-Development Agreement (the SFJ Agreement) with SFJ Pharmaceuticals XII, L.P., a SFJ Pharmaceuticals Group company (SFJ), pursuant to which SFJ would pay up to \$150.0 million in committed funding to support a Phase 2/3 study of bempegaldesleukin in combination with Keytruda® (pembrolizumab) for first-line treatment of patients with metastatic or unresectable recurrent squamous cell carcinoma of the head and neck (the SCCHN Clinical Trial) whose tumors express PD-L1 (the SCCHN Indication). SFJ has primary responsibility for the clinical trial management of the SCCHN Clinical Trial, and we are the sponsor of the SCCHN Clinical Trial. The SFJ Agreement provided for us to pay up to \$637.5 million in Success Payments in the event of FDA approval of bempegaldesleukin for the metastatic melanoma, the SCCHN Indication, or both, and in the event of FDA approval of one additional bempegaldesleukin indication.

As discussed in Note 1, on March 14, 2022, we announced that the metastatic melanoma trial did not meet its primary endpoints and that we and BMS decided to discontinue the registrational trials in metastatic melanoma trial and adjuvant melanoma. On April 14, 2022, BMS and we announced that, due to the negative results of our trials for bempegaldesleukin in each of renal cell carcinoma and cisplatin-ineligible, locally advanced or metastatic urothelial cancer, BMS and we decided to end the development for bempegaldesleukin in combination with Opdivo® and that these studies and all other ongoing studies in the bempegaldesleukin program will be discontinued. On April 14, 2022, due to these results, SFJ and we agreed to discontinue the SCCHN Clinical Trial. Accordingly, SFJ will not be entitled to any Success Payments, and SFJ has the responsibility to wind down the SCCHN Clinical Trial at its sole cost. SFJ has no right to seek reimbursement from us for any costs incurred for the SCCHN Clinical Trial.

We presented the SFJ Agreement as a Development derivative liability in our Condensed Consolidated Balance Sheets, which we remeasured to fair value at each reporting date. As SFJ conducted the SCCHN Clinical Trial, we recorded non-cash research and development expense with a corresponding increase to the development derivative liability, and as SFJ remitted funding to us to support our internal costs of conducting the trial, we also recorded a corresponding increase to the development derivative liability. We presented the gain (loss) from the remeasurement as change in fair value of development derivative liability in our Condensed Consolidated Statements of Operations. As of March 31, 2022, due to the negative results of the metastatic melanoma trial and initial discussions with SFJ, we concluded that it was remote that SFJ and we would continue the SCCHN Clinical Trial. Accordingly, the fair value of the development derivative liability was reduced to \$0 as of March 31, 2022, and we recognized a corresponding gain in the Change in fair value of development derivative liability.



The following table presents the changes in the development derivative liability for the three months ended March 31, 2022 and 2021:

	Fair Value Hierarchy Level	Three months ended March 31,	
		2022	2021
Fair value as of December 31, 2021 and February 12, 2021 (inception), respectively	3	\$ 27,726	\$ —
Non-cash research and development expense		4,951	2,248
Cash receipts from SFJ		750	750
Change in the fair value of development derivative liability		(33,427)	1,599
Fair value at end of period	3	\$ —	\$ 4,597

#### Note 5 — Liabilities Related to Sales of Future Royalties

In 2012 and 2020, we sold to RPI Finance Trust (RPI) and entities managed by Healthcare Royalty Management, LLC (collectively, HCR), respectively, our rights to receive royalties under our license and manufacturing agreements with certain pharmaceutical partners as summarized below under the 2012 Purchase and Sale Agreement and the 2020 Purchase and Sale Agreement, respectively:

Drug	Manufacturer	Counterparty under Purchase and Sale Agreement	Date Sold
ADYNOVATE <sup>®</sup> and ADYNOVI <sup>®</sup> (brand name for ADYNOVATE <sup>®</sup> in Europe)	Takeda Pharmaceutical Company Limited	Healthcare Royalty Management, LLC	December 16, 2020
MOVANTIK <sup>®</sup> (naloxegol tablets) and MOVENTIG <sup>®</sup> (brand name for MOVANTIK <sup>®</sup> in Europe)	AstraZeneca AB	Healthcare Royalty Management, LLC	December 16, 2020
REBINYN <sup>®</sup>	Novo Nordisk Inc., Novo Nordisk A/S and Novo Nordisk A/G	Healthcare Royalty Management, LLC	December 16, 2020
CIMZIA <sup>®</sup> (certolizumab pegol)	UCB Pharma	RPI Finance Trust	February 24, 2012
MIRCERA <sup>®</sup> (Continuous Erythropoietin Receptor Activator)	F. Hoffmann-La Roche Ltd	RPI Finance Trust	February 24, 2012

Due to our ongoing manufacturing obligations in both arrangements, we account for the proceeds as debt (Royalty Obligations) and therefore continue to recognize these non-cash royalties as revenue. As royalties are remitted to RPI and HCR by our licensees, the balances of the respective Royalty Obligations will be effectively repaid over the lives of the agreements. To determine the amortization of the Royalty Obligations, we are required to estimate the total amount of future royalty payments to be received by RPI and HCR, respectively. The sum of these amounts less the net proceeds we received will be recorded as non-cash interest expense over the lives of the respective Royalty Obligations. The following table shows the activity within the liability account of each arrangement (in thousands):

	Period from inception to March 31, 2022		
	2012 Purchase and Sale Agreement	2020 Purchase and Sale Agreement	Total
Royalty monetization proceeds	\$ 124,000	\$ 150,000	\$ 274,000
Non-cash royalty revenue	(289,655)	(61,357)	(351,012)
Non-cash interest expense	226,506	25,296	251,802
Payments to RPI	(10,000)	—	(10,000)
Loss on revaluation of liability related to the sale of future royalties (1)	23,522	—	23,522
Liabilities related to the sales of future royalties – ending balance	74,373	113,939	188,312
Less: unamortized transaction costs	—	(2,708)	(2,708)
Liabilities related to the sales of future royalties, net	\$ 74,373	\$ 111,231	\$ 185,604

(1) Loss recognized from Settlement Agreement to resolve UCB’s challenges to our patents, as agreed to by UCB, RPI and us, on October 13, 2021.

We periodically assess the estimated royalty payments to RPI and HCR from our licensees and to the extent the amount or timing of such payments is materially different from our original estimates, we will prospectively adjust the imputed interest rate and the related amortization of the applicable Royalty Obligation. As of March 31, 2022, our imputed interest rates for the arrangements with RPI and HCR were 16% and 15%, respectively.

## Note 6 — Commitments and Contingencies

### Legal Matters

From time to time, we are involved in lawsuits, arbitrations, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters, which arise in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. If any unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of our operations for that period and on our cash flows and liquidity.

In October 2018, we and certain of our executives were named in a putative securities class action complaint filed in the U.S. District Court for the Northern District of California (Case No. 18-cv-06607, which we refer to as the Mulquin action). The Mulquin plaintiffs have challenged public statements Nektar made, between January 2017 and June 2018, about the clinical trials of bempegaldesleukin. The Mulquin complaint was amended in May 2019. The defendants moved to dismiss and the court granted the motion without prejudice in July 2020. The Mulquin plaintiffs again amended their complaint and the defendants again moved to dismiss. In December 2020, the court dismissed the action with prejudice. The plaintiffs filed a notice of appeal in January 2021 and appellate briefing in the U.S. Court of Appeals for the Ninth Circuit was completed in September 2021. Oral argument occurred on December 10, 2021, and the matter remains pending with the court.

A second putative securities class action was filed against the Company and certain of our executives in the U.S. District Court for the Northern District of California in August 2019 (Case No. 4-19-cv-05173, which we refer to as the Damiba action). The Damiba plaintiffs challenged public statements Nektar made, between February 2019 and May 2019, about its bempegaldesleukin clinical trials and collaboration with Bristol-Myers Squibb. After the Damiba plaintiffs filed an amended complaint and the defendants moved to dismiss, the court dismissed the action without prejudice in January 2021. The Damiba plaintiffs subsequently voluntarily dismissed the action, with prejudice, in March 2021.

In addition to the two securities actions (the Mulquin action and the Damiba action), three additional sets of derivative actions have been filed against certain of the Company’s current and former officers and directors, purportedly on the Company’s behalf. These derivative actions are based on the allegations in the securities actions and on the premise that the Company’s officers and directors breached their fiduciary duties by exposing the Company to one or both of the securities actions. The first derivative action was filed in the U.S. District Court for the District of Delaware in February 2019 (Case No. 1:19-cv-00322-MN-JLH). After amending their complaint several times, the plaintiffs in that action voluntarily dismissed their claims without prejudice in April 2021.

A second set of derivative actions was filed in February 2020 in the U.S. District Court for the Northern District of California (Case No. 4:20-cv-01088-JSW). The derivative actions in California were consolidated and the Company moved to

dismiss on the basis that the plaintiffs had neither made a demand on the Company's board of directors nor shown that a demand would be futile. On September 1, 2021, the court dismissed the action with prejudice.

A third derivative complaint was filed in February 2021 in the Court of Chancery of the State of Delaware (C.A. No. 2021-0118-PAF). The parties agreed to stay further proceedings in this action until thirty days after the U.S. Court of Appeals for the Ninth Circuit's final resolution of the appeal in the Mulquin action.

Given the nature and status of these securities class action lawsuits and derivative complaints, we cannot reasonably estimate a potential future loss or a range of potential future losses. However, an unfavorable resolution could potentially have a material adverse effect on our business, financial condition, and results of operations or prospects, and potentially result in paying monetary damages. We have recorded no liability for these matters in our Consolidated Balance Sheets at either March 31, 2022 or December 31, 2021.

#### ***Indemnifications in Connection with Commercial Agreements***

As part of our collaboration agreements with our partners related to the license, development, manufacture and supply of drugs and PEGylation materials based on our proprietary technologies and drug candidates, we generally agree to defend, indemnify and hold harmless our partners from and against third party liabilities arising out of the agreement, including product liability (with respect to our activities) and infringement of intellectual property to the extent the intellectual property is developed by us and licensed to our partners. The term of these indemnification obligations is generally perpetual commencing after execution of the agreement. There is generally no limitation on the potential amount of future payments we could be required to make under these indemnification obligations.

From time to time, we enter into other strategic agreements such as divestitures and financing transactions pursuant to which we are required to make representations and warranties and undertake to perform or comply with certain covenants. For example, we made certain intellectual property representations in connection with our RPI and HCR transactions, however, the time limitation we have to indemnify RPI with respect to any breach of these intellectual property-based representations and warranties has passed. In the event it is determined that we breached certain of the representations and warranties or covenants made by us in any such agreements or certain express indemnification provisions are applicable, we could incur substantial indemnification liabilities depending on the timing, nature, and amount of any such claims.

To date, we have not incurred any costs to defend lawsuits or settle claims related to these indemnification obligations, nor any breaches of representations or warranties or covenants. Because the aggregate amount of any potential indemnification obligation is not a stated amount, we cannot reasonably estimate the overall maximum amount of any such obligations.

#### **Note 7 — License and Collaboration Agreements**

We have entered into various collaboration agreements including license agreements and collaborative research, development and commercialization agreements with various pharmaceutical and biotechnology companies. Under these collaboration arrangements, we are entitled to receive license fees, upfront payments, milestone and other contingent payments, royalties, sales milestone payments, and payments for the manufacture and supply of our proprietary PEGylation materials and/or reimbursement for research and development activities. We generally include our costs of performing these services in research and development expense, except for costs for product sales to our collaboration partners which we include in cost of goods sold. We analyze our agreements to determine whether we should account for the agreements within the scope of ASC 808, and, if so, we analyze whether we should account for any elements under ASC 606.

There have been no material changes to our collaboration agreements in the three months ended March 31, 2022, other than as described below for our Strategic Collaboration Agreement with BMS.

#### ***Bristol-Myers Squibb Company (BMS): Bempegaldesleukin, also referred to as NKTR-214***

On February 13, 2018, we entered into a Strategic Collaboration Agreement (the BMS Collaboration Agreement) and a Share Purchase Agreement with BMS, both of which became effective on April 3, 2018. Pursuant to the BMS Collaboration Agreement, we and BMS have jointly developed bempegaldesleukin in combination with BMS's Opdivo®. The parties share the internal and external development costs for bempegaldesleukin in combination regimens based on each party's relative ownership interest in the compounds included in the regimens. In accordance with the agreement, the parties share development costs for bempegaldesleukin in combination with Opdivo®, 67.5% of costs to BMS and 32.5% to Nektar. The parties share costs for the manufacturing and commercialization of bempegaldesleukin, 35% of the costs to BMS and 65% to Nektar.

Upon the effective date of the BMS Collaboration Agreement in April 2018, BMS paid us a non-refundable upfront cash payment of \$1.0 billion and purchased 8,284,600 shares of our common stock pursuant to the Share Purchase Agreement for total additional cash consideration of \$850.0 million. In 2020, we received non-refundable milestone payments of \$50.0 million in aggregate for the first patient, first visit in the registrational trials in muscle-invasive bladder cancer and adjuvant melanoma.

As discussed in Note 1, on March 14, 2022, we announced our registrational trial in metastatic melanoma did not meet its primary endpoints and that BMS and we decided to discontinue the trials in metastatic melanoma and adjuvant melanoma. On April 14, 2022, we announced that our registrational trials in each of renal cell carcinoma and cisplatin-ineligible, locally advanced or metastatic urothelial cancer did not meet their respective primary endpoints. Due to these results, BMS and we decided that these studies and all other ongoing studies in the program will be discontinued. The decision to terminate the program does not affect the cost-sharing provisions under the BMS Collaboration Agreement. However, without further development of bempegaldesleukin, we will no longer be eligible for the development, regulatory and sales milestones under the arrangement.

We determined that the BMS Collaboration Agreement falls within the scope of ASC 808. As mentioned above, BMS shares certain percentages of development costs incurred by us and we share certain percentages of development costs incurred by BMS. We consider these activities to represent collaborative activities under ASC 808 and we recognize such cost sharing proportionately with the performance of the underlying services. We recognize BMS' reimbursement of our expenses as a reduction of research and development expense and our reimbursement of BMS' expenses as research and development expense. During the three months ended March 31, 2022 and March 31, 2021, we recorded \$24.9 million and \$26.7 million, respectively, as reductions of research and development expense for BMS' share of our expenses, net of our share of BMS' expenses. As of March 31, 2022, we have recorded an unbilled receivable of \$26.9 million from BMS in accounts receivable in our Condensed Consolidated Balance Sheet.

***Eli Lilly and Company (Lilly): NKTR-358***

On July 23, 2017, we entered into a worldwide license agreement (the Lilly Agreement) with Eli Lilly and Company (Lilly) to co-develop NKTR-358, a novel immunological drug candidate that we invented, pursuant to which we received an initial payment of \$150.0 million and are eligible for up to \$250.0 million in additional development and regulatory milestones. We are currently in Phase 1B and Phase 2 development, where we share costs with 75% of the costs borne by Lilly and 25% of the costs borne by us. Lilly is responsible for the costs of Phase 3 development, but we retain the option to contribute up to 25% of the costs of Phase 3 development on an indication-by-indication basis in order for us to achieve maximum royalty level under the Lilly Agreement, and further, if approved, we will have the opportunity to receive a royalty rate up to the low twenties based upon our Phase 3 development cost contribution and the level of annual global product sales. Lilly will be responsible for all costs of global commercialization, and we will have an option to co-promote in the U.S. under certain conditions. A portion of the development milestones may be reduced by 50% under certain conditions, related to the final formulation of the approved product and the timing of prior approval (if any) of competitive products with a similar mechanism of action, which could reduce these milestone payments by 75% if both conditions occur.

The Lilly Agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. The Lilly Agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

Although we are entitled to significant development milestones under this arrangement, through March 31, 2022, we have excluded such milestones from the transaction price due to the significant uncertainties involved with clinical development. We re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

***Other***

We have other collaboration agreements that have resulted in commercialized products for our collaborations partners. Under these agreements, we may sell our proprietary PEGylation materials for use in these products, and we are entitled to receive royalties based on net sales of these products as well as sales milestones. As discussed in Note 5, we have sold our rights to receive royalties from these other collaboration agreements.

Additionally, we have a collaboration agreement for a product under development, under which we are entitled to up to a total of \$40.0 million of regulatory milestones, as well as sales milestones upon achievement of annual sales targets and royalties based on net sales of commercialized products, if any. However, given the current phase of development of the potential product under this collaboration agreement, we cannot estimate the probability or timing of achieving these milestones, and, therefore, have excluded all development milestones from the transaction price for this agreement.

**Note 8 — Stock-Based Compensation**

We recognized total stock-based compensation expense in our Condensed Consolidated Statements of Operations as follows (in thousands):

	Three months ended March 31,	
	2022	2021
Cost of goods sold	\$ 669	\$ 727
Research and development	12,041	14,162
General and administrative	8,251	9,009
Total stock-based compensation	<u>\$ 20,961</u>	<u>\$ 23,898</u>

We issued stock-based awards of our common stock as follows (shares in thousands):

	Three months ended March 31,	
	2022	2021
Options granted	22	121
Weighted-average grant-date fair value of options granted	\$ 6.61	\$ 10.82
RSUs granted	405	367
Weighted-average grant-date fair value of RSUs granted	\$ 9.39	\$ 20.63

**Note 9 — Net Loss Per Share**

We calculate basic net loss per share based on the weighted-average number of common shares outstanding during the periods presented and calculate diluted net loss per share based on the weighted-average number of shares of common stock outstanding, including potentially dilutive securities. For all periods presented in the accompanying Condensed Consolidated Statements of Operations, our net loss available to common stockholders equals the reported net loss.

For the three months ended March 31, 2022 and 2021, basic and diluted net loss per share are the same due to our net losses and the requirement to exclude potentially dilutive securities which would have an antidilutive effect on net loss per share. During the three months ended March 31, 2022 and 2021, potentially dilutive securities consisted of weighted-average common shares underlying outstanding stock options and RSUs as follows (in thousands):

	Three months ended March 31,	
	2022	2021
Potentially dilutive securities	22,338	19,393

**Note 10 — Subsequent Event**

As discussed in Note 1, on April 25, 2022, we announced our Reorganization and Restructuring Plans, pursuant to which we are prioritizing key research and development efforts and reducing our workforce by approximately 70% from approximately 735 to approximately 225 employees. We will recognize all costs of the Reorganization and Restructuring Plans, including severance and benefits for employees laid off and employee compensation and third-party costs for the wind down of the bempegaldesleukin program, net of BMS' reimbursement of our costs, in the restructuring, impairment and other costs of terminated program line in our Condensed Consolidated Statement of Operations. We expect to recognize approximately \$30.0 to \$35.0 million for severance and related benefits for employees laid off under the Reorganization and Restructuring Plans, primarily in the three months ending June 30, 2022.

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

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to those discussed in this section as well as factors described in Part II, Item 1A "Risk Factors."

### Overview

#### *Strategic Direction of Our Business*

Nektar Therapeutics is a research-based biopharmaceutical company that discovers and develops innovative new medicines in areas of high unmet medical need. Our research and development pipeline of new investigational drugs includes potential therapies for oncology and immunology. We leverage our proprietary and proven chemistry platform to discover and design new drug candidates. These drug candidates utilize our advanced polymer conjugate technology platforms, which are designed to enable the development of new molecular entities that target known mechanisms of action. We continue to make significant investments in new drug discovery and advancing our pipeline of drug candidates as we believe that this is the best strategy to build long-term stockholder value.

In oncology, we focus on developing medicines in immuno-oncology (I-O), which is a therapeutic approach based on targeting biological pathways that stimulate and sustain the body's immune response in order to fight cancer. In the I-O area, we executed a broad clinical development program to develop bempedaldesleukin (previously referred to as NKTR-214) in combination with Opdivo® in collaboration with Bristol-Myers Squibb Company (BMS) under our Strategic Collaboration Agreement. We also conducted independent development work evaluating bempedaldesleukin in combination with other checkpoint inhibitors and agents with potential complementary mechanisms of action, including studies evaluating bempedaldesleukin combination with Keytruda® (pembrolizumab). In April 2022, we and BMS jointly announced that the companies would be ending the global clinical development program for bempedaldesleukin in combination with Opdivo® and discontinue all ongoing studies in our collaboration with BMS. We also decided to discontinue all studies of bempedaldesleukin in combination with Keytruda®, as well as our studies of NKTR 262, which was being evaluated in combination with bempedaldesleukin.

In April 2022, we announced new strategic reorganization and cost restructuring plans (together, the Reorganization and Restructuring Plans) focused on prioritizing key research and development efforts that will be most impactful to the Company's future, including our NKTR-255 and NKTR-358 programs and several core research programs.

NKTR-255 is a biologic that targets the IL-15 pathway in order to activate the body's innate and adaptive immunity. Activation of the IL-15 pathway enhances the survival and function of natural killer (NK) cells and induces survival of both effector and CD8+ memory T cells. Recombinant human IL-15 is rapidly cleared from the body and must be administered frequently and in high doses limiting its utility due to toxicity. Through optimal engagement of the IL-15 receptor complex, NKTR-255 is designed to enhance functional NK cell populations and formation of long-term immunological memory, which may lead to sustained and durable anti-tumor immune response. Preclinical findings suggest NKTR-255 has the potential to synergistically combine with antibody-dependent cellular cytotoxicity molecules as well as to enhance CAR-T therapies. We have initiated a Phase 1 dose escalation and expansion clinical study of NKTR-255 in adults with relapsed or refractory non-Hodgkin lymphoma or multiple myeloma, as well as a Phase 1/2 clinical study of NKTR-255 in patients with relapsed or refractory head and neck squamous cell carcinoma or colorectal cancer. We are also continuing our oncology clinical collaboration with Merck KGaA and Pfizer Inc. to evaluate the maintenance regimen of NKTR-255 in combination with avelumab, a PD-L1 inhibitor, in patients with locally advanced or metastatic urothelial carcinoma in the Phase II JAVELIN Bladder Medley study. We are also currently designing a Nektar-sponsored comparative study, which we aim to initiate in the second half of 2022.

In immunology, NKTR-358 targets the underlying immune system imbalance in the body that occurs in patients with autoimmune disease. NKTR-358 is designed to optimally target the IL-2 receptor complex in order to stimulate proliferation and growth of regulatory T cells. NKTR-358 is being developed as a once or twice monthly self-administered injection for a number of autoimmune diseases. In 2017, we entered into a worldwide license agreement with Eli Lilly and Company (Lilly) to develop and commercialize NKTR-358, pursuant to which we received an initial payment of \$150.0 million and are eligible for up to an additional \$250.0 million for development and regulatory milestones. We have completed our responsibilities for Phase 1 clinical development and certain drug product development and supply activities. We also share Phase 2 development costs with Lilly, with Lilly responsible for 75% and Nektar responsible for 25% of these costs. Lilly is responsible for the costs of Phase 3 development, but we retain the option to contribute up to 25% of the costs of Phase 3 development on an indication-by-indication basis in order for us to achieve maximum royalty level under the Lilly Agreement, and further, if approved, we will have the opportunity to receive a royalty rate up to the low twenties based upon our Phase 3 development cost contribution and the level of annual global product sales.

We have completed a Phase 1 dose-finding trial of NKTR-358 to evaluate single-ascending doses of NKTR-358 in approximately 100 healthy patients. We also completed treatment of a Phase 1 multiple-ascending dose trial to evaluate NKTR-358 in patients with systemic lupus erythematosus (SLE). Lilly is conducting two Phase 1b studies in patients with psoriasis and atopic dermatitis, and based on positive interim Phase 1b results in atopic dermatitis announced in December 2021, Lilly is planning to initiate a Phase 2 study in atopic dermatitis. Lilly also initiated a Phase 2 study in SLE in October 2020 and a Phase 2 study in ulcerative colitis in March 2021. In April 2022, we announced that Lilly had informed us that an interim analysis in the Phase 2 study in ulcerative colitis led to the discontinuation of further development in this indication. Lilly also plans to initiate another Phase 2 study in another immune-mediated disease to potentially start in 2023.

We have historically derived all of our revenue and substantial amounts of operating capital from our collaboration agreements. In addition to our collaborations with BMS and Lilly, we have received upfront and milestone payments under a number of other previous collaboration agreements, several of which have resulted in approved drugs, for which we may continue to manufacture the polymer reagents used in the production of the drug products and may be entitled to royalties for net sales of these approved drugs. As of December 31, 2020, however, we have sold the majority of our rights to receive royalties under these arrangements, including:

- 2012 Purchase and Sale Agreement: In 2012, we sold all of our rights to receive royalties from CIMZIA<sup>®</sup> (for the treatment of Chron's disease and other autoimmune indications) and MIRCERA<sup>®</sup> (for the treatment of anemia associated with chronic kidney disease) under our collaborations with UCB Pharma and F. Hoffmann-La Roche Ltd, respectively, to RPI Finance Trust (RPI), an affiliate of Royalty Pharma for \$124.0 million.
- 2020 Purchase and Sale Agreement: In December 2020, we sold our rights, subject to a cap, to receive royalties from MOVANTIK<sup>®</sup> / MOEVNTIG<sup>®</sup> (for the treatment of opioid-induced constipation), ADYNOVATE<sup>®</sup> / ADYNOVI<sup>®</sup> (a half-life extension product of Factor VIII) and other hemophilia products, under our arrangements with AstraZeneca AB, Baxalta, Inc. (a wholly owned-subsiidiary of Takeda Pharmaceutical Company Ltd.), and Novo Nordisk A/S, respectively, for \$150.0 million to entities managed by HealthCare Royalty Management (HCR) under a capped sale arrangement, such that all future royalties return to Nektar if HCR receives \$210.0 million in royalties by December 31, 2025 (the 2025 Threshold) or \$240.0 million if the 2025 Threshold is not met.

While in the near-term we continue to expect to generate substantially all of our revenue from collaboration arrangements, our longer-term plan is to generate significant commercial revenue from proprietary products. Over the next several years, we plan to continue to make significant investments to advance our early drug candidate pipeline. We have several drug candidates in earlier stage clinical development or are being explored in research that we are preparing to advance into the clinical trials in future years. We are cultivating several research programs, including a collaboration with Biologic Design to develop a unique bivalent antibody targeting TNFR2, as well as two Nektar-developed research programs focused in the areas of oncology and auto-immune disease. We believe that our substantial investment in research and development has the potential to create significant value if one or more of our drug candidates demonstrates positive clinical results, receives regulatory approval in one or more major markets and achieves commercial success.

Our business is subject to significant risks, including the risks inherent in our development efforts, the results of our clinical trials, our dependence on the marketing efforts by our collaboration partners, uncertainties associated with obtaining and enforcing patents, the lengthy and expensive regulatory approval process and competition from other products. Drug research and development is an inherently uncertain process with a high risk of failure at every stage prior to approval. The timing and outcome of clinical trial results are extremely difficult to predict. Clinical development successes and failures can have a disproportionately positive or negative impact on our scientific and medical prospects, financial condition and prospects, results of operations and market. For a discussion of these and some of the other key risks and uncertainties affecting our business, see Item 1A "Risk Factors."

#### ***Effects of the COVID-19 Pandemic***

We continue to actively monitor the ongoing COVID-19 pandemic and applicable government recommendations in light of new developments. In particular, the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, and local resurgences in number and rates of infections, and the further spread of the virus may result in the return of prior restrictions or the institution of restrictions in the affected areas, which could have an adverse effect on our business, including our clinical trial timelines. Currently, our operations in research, manufacturing and maintenance that occur within our facilities are continuing in accordance with applicable guidelines and orders. Across all our locations, we have instituted a temporary work from home policy for office personnel who do not need to work on site to maintain productivity and we allow employees to voluntarily return to work on site with appropriate health and safety measures. The safety and well-being of our employees, and the patients and healthcare providers in our clinical trial programs, are of first and foremost importance to us. We believe that the safety measures we are taking and instructing our contractors to take in response to the COVID-19 pandemic meet or exceed the guidance and requirements issued from government and public health officials. We also continue to monitor our supply chains for

any disruptions or constraints caused by the COVID-19 pandemic. To date, we have not experienced any significant impacts on our supply, but ongoing global shortages in labor, raw materials and equipment could limit our ability to manufacture our products or to supply drug candidates for our clinical trials, or delay our research and development efforts.

We and our partners are currently engaged in the clinical testing of our drug candidates and the COVID-19 pandemic introduces challenges to our clinical development programs which are central to our business. The evolving situation around the COVID-19 pandemic, along with the resulting public health guidance measures that have been put into place, have thus far had varying impacts on the clinical testing of our drug candidates depending on the therapeutic indication, geographic distribution of clinical trial sites, the clinical trial stage, and, in certain cases, our partners' general corporate approach to the COVID-19 pandemic. Nektar's Phase 1 clinical study of NKTR-255 in patients with relapsed/refractory hematologic malignancies has enrolled slower than anticipated due to the challenges caused by the COVID-19 pandemic, and the dose-escalation monotherapy portion of the study is currently expected to be completed in 2022. While we are not currently aware of significant delays by our partners and collaborators caused the COVID-19 pandemic on clinical trials involving our drug candidates, the fluidity of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect this disease will have on these clinical trials. Any current assessments of the effects of the COVID-19 pandemic on our clinical programs are difficult to predict and subject to change and, with regard to individual clinical trial sites within these studies, will likely vary by the geographic region in which they are located.

In an effort to mitigate the negative effects of the COVID-19 pandemic on our clinical trials (both in terms of clinical trial timelines and integrity of clinical study data), we have taken steps to help our clinical trial investigators and their teams continue to provide care and uninterrupted access to their patients. Particularly, in the context of our clinical trials directed to investigational cancer treatments, for example, we are actively working with our study sites to implement measures to prevent study protocol violations, to minimize any disruption of treatment visits, to accommodate for patient visit delays caused by limited access to healthcare facilities, to leverage alternative methods for maintaining clinical trial integrity, and to properly record patient event data that may be influenced by the COVID-19 pandemic. In addition, to the extent that the integrity of individual patient data is negatively affected by the COVID-19 pandemic, we will consider measures to maintain the integrity of the clinical study overall (such as over-enrolling patients into the study and removing all patients originating from an affected study site when performing statistical analyses of study endpoints). Although these measures may have the benefit of preserving the overall integrity of a clinical study, implementing these measures could result in a delay in completing the study.

With respect to financing our near-term business needs, as set forth below in "Key Developments and Trends in Liquidity and Capital Resources," we estimate we have working capital to fund our current business plans through at least the next twelve months.

#### **Key Developments and Trends in Liquidity and Capital Resources**

We estimate that we have working capital to fund our current business plans for at least the next twelve months from the date of filing. At March 31, 2022, we had approximately \$704.4 million in cash and investments in marketable securities.

#### **Results of Operations**

*Three Months Ended March 31, 2022 and 2021*

*Revenue (in thousands, except percentages)*

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Product sales	\$ 5,688	\$ 4,795	\$ 893	19 %
Non-cash royalty revenue related to sales of future royalties	17,561	18,798	(1,237)	(7)%
License, collaboration and other revenue	1,573	54	1,519	>100%
Total revenue	\$ 24,822	\$ 23,647	\$ 1,175	5 %

Our revenue is derived from our collaboration agreements, under which we may receive product sales revenue, royalties, and license fees, as well as development and sales milestones and other contingent payments. We recognize revenue when we transfer promised goods or services to our collaboration partners. The amount of upfront fees received under our license and collaboration agreements allocated to continuing obligations, such as development or manufacturing and supply commitments, is generally recognized as we deliver products or provide development services. As a result, there may be significant variations in the timing of receipt of cash payments and our recognition of revenue. We make our best estimate of the timing and amount of



products and services expected to be required to fulfill our performance obligations. Given the uncertainties in research and development collaborations, significant judgment is required to make these estimates.

### **Product Sales**

Product sales include predominantly fixed price manufacturing and supply agreements with our collaboration partners and are the result of firm purchase orders from those partners. The timing of shipments is based solely on the demand and requirements of our collaboration partners and is not ratable throughout the year.

Product sales increased for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 primarily due to an increase in product demand from our collaboration partners. We expect product sales for the full year of 2022 to increase compared to 2021 due to increased demand from our collaboration partners.

### **Non-cash Royalty Revenue Related to Sales of Future Royalties**

For a discussion of our Non-cash royalty revenue, please see our discussion below “Non-Cash Royalty Revenue and Non-Cash Interest Expense.”

### **License, Collaboration and Other Revenue**

License, collaboration and other revenue includes the recognition of upfront payments, milestone and other contingent payments received in connection with our license and collaboration agreements and certain research and development activities. The level of license, collaboration and other revenue depends in part upon the estimated recognition period of the upfront payments allocated to continuing performance obligations, the achievement of milestones and other contingent events, the continuation of existing collaborations, the amount of research and development work, and entering into new collaboration agreements, if any. During the three months ended March 31, 2022, we recognized \$1.5 million for a license agreement, under which we are entitled to no further consideration. As a result of the recognition of this revenue in the three months ended March 31, 2022, we expect license, collaboration and other revenue for 2022 to increase compared to 2021.

The timing and future success of our drug development programs and those of our collaboration partners are subject to a number of risks and uncertainties. See Item 1A. Risk Factors for discussion of the risks associated with the complex nature of our collaboration agreements.

### **Cost of Goods Sold and Product Gross Margin (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Cost of goods sold	\$ 5,315	\$ 5,756	\$ (441)	(8)%
Product gross profit (1)	373	(961)	1,334	>100%
Product gross margin	7 %	(20)%		

(1) Percentage change represents an improvement in the gross margin.

Our strategy is to manufacture and supply polymer reagents to support our proprietary drug candidates or our third-party collaborators where we have a strategic development and commercialization relationship or where we derive substantial economic benefit. We have elected to only enter into and maintain those manufacturing relationships associated with long-term collaboration agreements which include multiple sources of revenue, which we view holistically and in aggregate. We have a predominantly fixed cost base associated with our manufacturing activities. As a result, our product gross profit and margin are significantly impacted by the mix and volume of products sold in each period.

Our product gross margin improved from the three months ended March 31, 2021 to the three months ended March 31, 2022 due to the mix of manufacturing orders from our customers. Product gross margin was negative for the three months ended March 31, 2021. We have a manufacturing arrangement with a partner that includes a fixed price which is less than the fully burdened manufacturing cost for the reagent, and we expect this situation to continue with this partner in future years. In addition to product sales to this partner, we also receive royalty revenue from this collaboration. In the three months ended March 31, 2022 and 2021, the royalty revenue from this collaboration exceeded the related negative gross profit.

We expect product gross margin to continue to fluctuate in future periods depending on the level and mix of manufacturing orders from our customers. We expect product gross profit to be negative in 2022 as a result of the collaborative arrangement described above.

**Research and Development Expense (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Research and development expense	\$ 107,253	\$ 95,604	\$ 11,649	12 %

Research and development expense consists primarily of clinical study costs, contract manufacturing costs, direct costs of outside research, materials, supplies, licenses and fees as well as personnel costs (including salaries, benefits, and stock-based compensation). Research and development expense also includes certain overhead allocations consisting of support and facilities-related costs. Where we perform research and development activities under a joint development collaboration, such as our collaboration with BMS, we record the expense reimbursement from our partners as a reduction to research and development expense, and we record our share of our partners' expenses as an increase to research and development expense. Under the BMS Collaboration Agreement, BMS generally bears 67.5% of development costs for bempegaldesleukin in combination with Opdivo® and 35% of costs for manufacturing bempegaldesleukin.

Research and development expense increased for the three months ended March 31, 2022 as compared to the three ended March 31, 2021. Research and development expense increased for our clinical trials for bempegaldesleukin in adjuvant melanoma under the BMS Collaboration Agreement and head and neck cancer under our co-development agreement with SFJ, partially offset by a decrease in expense for our clinical trial for bempegaldesleukin in first-line metastatic renal cell carcinoma as we had fully enrolled this trial. During the three months ended March 31, 2022 and March 31, 2021, we recorded \$24.9 million and \$26.7 million, respectively, as reductions of research and development expense for BMS' share of our expenses, net of our share of BMS' expenses.

As discussed in Note 1, BMS and we have decided to discontinue development of bempegaldesleukin in combination with Opdivo® and will wind down the various trials under the BMS Collaboration Agreement, and we have also decided to discontinue all other development of bempegaldesleukin. The cost sharing under the BMS Collaboration Agreement remains unchanged as a result of our decision. We expect to incur significant expenses associated with the wind down of these trials, which we expect to present in the Restructuring, impairment and other costs of terminated program line in our Condensed Consolidated Statement of Operations for the remainder of 2022. Because we will no longer report these expenses in research and development expense, we expect research and development expense to decrease significantly for 2022 as compared to 2021. Additionally, as discussed in Note 1 to our Condensed Consolidated Financial Statements, we have implemented a restructuring plan to reduce our workforce by approximately 70%. Please see our discussion below in Restructuring, impairment and other costs of terminated program for additional information.

Research and development expense also increased for the three months ended March 31, 2022 as compared to the three ended March 31, 2021 due to manufacturing activities for NKTR-255 and development costs for NKTR-358 as Lilly conducts its Phase 1B and Phase 2 studies, for which we are responsible for 25% of costs and Lilly is responsible for 75% of costs. We expect research and development expense for the development of NKTR-255 and NKTR-358 to increase for 2022 as compared to 2021.

The timing and amount of our future clinical trial expenses will vary significantly based upon our evaluation of ongoing clinical results and the structure, timing, and scope of additional clinical development programs and potential clinical collaboration partnerships (if any) for these programs.

In addition to our drug candidates that we plan to evaluate in clinical development during 2022 and beyond, we believe it is vitally important to continue our substantial investment in a pipeline of new drug candidates to continue to build the value of our drug candidate pipeline and our business. Our discovery research organization is identifying new drug candidates across a wide range of molecule classes, including small molecules and large proteins, peptides and antibodies, across multiple therapeutic areas. We also plan from time to time to evaluate opportunities to in-license potential drug candidates from third parties to add to our drug discovery and development pipeline. We plan to continue to advance our most promising early research drug candidates into preclinical development with the objective to advance these early stage research programs to human clinical studies over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In order to advance our drug candidates through clinical development, each drug candidate must be tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical studies for our drug candidates that take several years to complete. The cost and time required to complete clinical trials may vary significantly over the life of a clinical development program as a result of a variety of factors, including but not limited to:

- the number of patients required for a given clinical study design;
- the length of time required to enroll clinical study participants;

- the number and location of sites included in the clinical studies;
- the clinical study designs required by the health authorities (i.e. primary and secondary endpoints as well as the size of the study population needed to demonstrate efficacy and safety outcomes);
- the potential for changing standards of care for the target patient population;
- the competition for patient recruitment from competitive drug candidates being studied in the same clinical setting;
- the costs of producing supplies of the drug candidates needed for clinical trials and regulatory submissions;
- the safety and efficacy profile of the drug candidate;
- the use of clinical research organizations to assist with the management of the trials; and
- the costs and timing of, and the ability to secure, approvals from government health authorities.

Furthermore, our strategy includes the potential of entering into collaborations with third parties to participate in the development and commercialization of some of our drug candidates such as the collaboration that we have already completed for NKTR-358, or clinical collaborations where we would share costs and operational responsibility with a partner. In certain situations, the clinical development program and process for a drug candidate and the estimated completion date will largely be under the control of that third party and not under our control. We cannot forecast with any degree of certainty which of our drug candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

**General and Administrative Expense (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
General and administrative expense	\$ 27,339	\$ 31,679	\$ (4,340)	(14)%

General and administrative expense includes the cost of administrative staffing, commercial, finance and legal activities. General and administrative expense decreased for the three months ended March 31, 2022 compared with the three months ended March 31, 2021. General and administrative expense for the three months ended March 31, 2021 included non-recurring transaction fees for our SFJ co-development agreement and other legal fees. As discussed in Note 1 to our Condensed Consolidated Financial Statements, we have implemented a restructuring plan to reduce our workforce by approximately 70%. Please see discussion below for additional information. As a result, we expect general and administrative expenses in the full year of 2022 to decrease significantly compared to 2021.

**Restructuring, Impairment and Other Costs of Terminated Program (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Restructuring, impairment and other costs of terminated program	\$ 1,475	\$ —	\$ 1,475	>100%

As discussed in Note 1 to our Condensed Consolidated Financial Statements, following the announcements that our registrational trials in bempegaldesleukin failed to meet their primary endpoints, on April 25, 2022, we announced strategic reorganization and cost restructuring plans (together, the Reorganization and Restructuring Plans) to discontinue development of bempegaldesleukin and reduce the workforce from approximately 735 employees to approximately 225 employees, a reduction of approximately 70%. We will recognize all costs of the Reorganization and Restructuring Plans, including severance and benefits for terminated employees and employee compensation and third-party costs for the wind down of the bempegaldesleukin program, net of BMS' reimbursement of our costs, in the restructuring, impairment and other costs of terminated program line in our Condensed Consolidated Statement of Operations.

We expect to recognize approximately \$30.0 to \$35.0 million for severance and related benefits for employees laid off under the Reorganization and Restructuring Plans, primarily in the three months ending June 30, 2022. If we conclude that there is no future economic benefit for the wind down of the bempegaldesleukin program, we may accrue a significant liability for these future costs, provided that we are able to reliably estimate those future costs, and we will record future adjustments as new

information becomes available to us to revise our estimates. The determination to accrue any liability for these future costs does not affect the timing of cash payments to our vendors.

As part of the Reorganization and Restructuring Plans, we currently intend to sublease a substantial portion of our facilities in the San Francisco Bay Area while still maintaining sufficient office and laboratory space to allow our team to continue to develop our proprietary programs. Based on current market conditions in light of the COVID-19 pandemic, we currently expect that any income from a sublease may be less than our lease payments. Accordingly, we may recognize an impairment of our operating lease right-of-use assets and related leasehold improvements and other fixed assets before entering into a sublease, provided that we have committed to the portion of our space which we will sublease and we can develop reliable estimates of the potential sublease income.

For the three months ended March 31, 2022, restructuring, impairment and other costs for terminated program consisted primarily of cancellation fees for certain manufacturing activities for bempegaldesleukin.

#### **Change in fair value of development derivative liability**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Change in fair value of development derivative liability	33,427	(1,599)	\$ 35,026	>100%

As discussed in Note 4 to our Condensed Consolidated Financial Statements, we remeasure the development derivative liability under our co-development agreement with SFJ to fair value at each reporting date. As discussed in Note 4, as of March 31, 2022, due to the results of the metastatic melanoma trial, we concluded that it was remote that SFJ and we would continue the clinical trial in head and neck cancer. Accordingly, we reduced the liability to \$0 as of March 31, 2022 and recognized a corresponding gain in the change in fair value of development derivative liability. As a result of the decision to discontinue the clinical trial in head and neck cancer, we do not expect any to record any future significant adjustments for the change in fair value.

The expense recorded for the change in fair value for the three months ended March 31, 2021 primarily reflected the accretion of our obligation to potentially pay Success Payments to SFJ using our imputed borrowing rate.

#### **Non-Cash Royalty Revenue and Non-Cash Interest Expense**

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Non-cash royalty revenue related to the sales of future royalties	\$ 17,561	\$ 18,798	\$ (1,237)	(7)%
Non-cash interest expense on liability related to the sales of future royalties	\$ (7,529)	\$ (13,296)	\$ 5,767	(43)%

As discussed in Note 5 to our Condensed Consolidated Financial Statements, we recognize non-cash royalty revenue for the 2012 Purchase and Sale Agreement and the 2020 Purchase and Sale Agreement.

#### **2012 Purchase and Sale Agreement**

Non-cash royalty revenue for the 2012 Purchase and Sale Agreement decreased for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021. Non-cash interest expense for the 2012 Purchase and Sales Agreement decreased significantly for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 due to the decrease in the interest rate used to recognize non-cash interest expense from 48% in the three months ended March 31, 2021 to 16% for the three months ended March 31, 2022 as a result of the revaluation of the liability, which we recognized in the three months ended December 31, 2021.

To resolve UCB's challenges to our patents and their resulting obligation to pay us royalties on net sales of CIMZIA® which we had sold to RPI, RPI and UCB negotiated a reduction in the royalty term and decreased royalty rates over the remaining

term, which was implemented through the Settlement Agreement between UCB and us. As a result of accounting for the Settlement Agreement as a debt modification during the three months ended December 31, 2021, we remeasured the liability to fair value using a discount rate of 16%. The Settlement Agreement and revaluation do not affect our cash flows, and the net income statement effect over the term of 2012 Purchase and Sale Agreement remains unchanged.

Over the term of this arrangement, the net proceeds of the transaction of \$114.0 million, consisting of the original proceeds of \$124.0 million, net of \$10.0 million in payments from us to RPI, is amortized as the difference between the non-cash royalty revenue and the sum of the non-cash interest expense and the loss on the revaluation of the liability. To date, we have amortized \$39.6 million of the net proceeds. We periodically assess future non-cash royalty revenues, and we may adjust the prospective effective interest rate based on our best estimates of future non-cash royalty revenue such that future non-cash interest expense will amortize the remaining \$74.4 million of the net proceeds, since RPI receives all of the benefits of the increases in future royalties. There are a number of factors that could materially affect our estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of CIMZIA® and MIRCERA®. As a result, future interest rates could differ significantly, and we will adjust any such change in our estimated interest rate prospectively.

#### 2020 Purchase and Sale Agreement

Non-cash royalty revenue increased for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 and non-cash interest expense decreased for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021. Our estimate of the imputed interest rate reflects that our estimates for sales of MOVANTIK®, ADYNOVATE® and REBINYN® will result in meeting the 2025 Threshold. Because the 2025 Threshold of \$210.0 million and the increase in the threshold to \$240.0 million (if the 2025 Threshold is not timely achieved) limit the amount of royalties payable to HCR, the potential for the implicit interest rate to vary is more limited. Instead, we will receive the benefit of net sales if they exceed the threshold, but do not bear risk of loss or payments to HCR if royalties are less than expected.

#### Interest Income and Other Income (Expense), net (in thousands, except percentages)

	Three Months Ended March 31,		Increase/ (Decrease) 2022 vs. 2021	Percentage Increase/ (Decrease) 2022 vs. 2021
	2022	2021		
Interest income and other income (expense), net	\$ 395	\$ 1,412	\$ (1,017)	(72)%

Interest income and other income (expense) decreased for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 due to lower investment balances which have been utilized to fund our operations. We expect that our interest income and other income (expense), net will decrease for 2022 compared to 2021 for the same reason.

#### Liquidity and Capital Resources

We have financed our operations primarily through revenue from upfront and milestone payments under our strategic collaboration agreements, royalties and product sales, as well as public and private placements of debt and equity securities. As of March 31, 2022, we had approximately \$704.4 million in cash and investments in marketable securities.

We estimate that we have working capital to fund our current business plans for at least the next twelve months from the date of filing. As discussed above, on April 25, 2022, we announced our Reorganization and Restructuring Plans to discontinue development of bempegaldesleukin and to reduce our workforce by approximately 70%. We expect that we will pay severance and benefits for the terminated employees of approximately \$30.0 million to \$35.0 million during 2022. In addition, we currently estimate that we will pay approximately \$70.0 million to \$80.0 million for third-party vendor and employee costs, net of the net BMS reimbursement, for the wind down of the bempegaldesleukin program. The actual costs may differ as vendor and site contracts are modified and ultimately terminated.

We expect the clinical development of our drug candidates, including NKTR-358 and NKTR-255, will continue to require significant investment to continue to advance in clinical development with the objective of obtaining regulatory approval or entering into one or more collaboration partnerships. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions, including \$1.9 billion in total consideration received under our arrangement with BMS, development cost reimbursement from BMS, and a \$150.0 million upfront payment from Lilly for our collaboration agreement for NKTR-358. In the future, we have the opportunity to receive up to \$250.0 million in milestone payments under our collaboration with Lilly.

Our current business is subject to significant uncertainties and risks as a result of, among other factors, clinical and regulatory outcomes for NKTR-358 and NKTR-255, the sales levels for those products for which we are entitled to royalties, if and when they are approved, the sales levels of our products, if and when they are approved, clinical program outcomes, whether,

when and on what terms we are able to enter into new collaboration transactions, expenses being higher than anticipated, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

We have no credit facility or any other sources of committed capital. The availability and terms of various financing alternatives, if required in the future, substantially depend on many factors including the success or failure of drug development programs in our pipeline. The availability and terms of financing alternatives and any future significant payments from existing or new collaborations depend on the positive outcome of ongoing or planned clinical studies, whether we or our partners are successful in obtaining regulatory authority approvals in major markets, and if approved, the commercial success of these drugs, as well as general capital market conditions. We may pursue various financing alternatives to fund the expansion of our business as appropriate.

In the short term, we do not anticipate that the effects of the COVID-19 pandemic will have a material effect on our results of operations or financial position since we do not generate significant cash flows from recurring revenues and our revenues are generally less affected by shelter-in place or similar orders. However, if delays caused by the COVID-19 pandemic in commencing and enrolling patients in our clinical trials or those run by our partners result in a delay in completing these trials, our or our partner's ability to file for regulatory approval and commercialize these products (if approved) and receive associated milestone payments may also be delayed.

Due to the potential for adverse developments in the credit markets, we may experience reduced liquidity with respect to some of our investments in marketable securities. These investments are generally held to maturity, which, in accordance with our investment policy, is less than two years. However, if the need arises to liquidate such securities before maturity, we may experience losses on liquidation. To date we have not experienced any liquidity issues with respect to these securities. We believe that, even allowing for potential liquidity issues with respect to these securities and the effect of the COVID-19 pandemic or other conditions on the financial markets, our remaining cash and investments in marketable securities will be sufficient to meet our anticipated cash needs for at least the next twelve months.

We currently have an effective shelf registration statement on Form S-3 (the 2021 Shelf Registration Statement) on file with the Securities and Exchange Commission, which expires in March 2024. The 2021 Shelf Registration Statement currently permits the offering, issuance and sale by us of up to an aggregate offering price of \$300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, all of which may be offered, issued and sold in "at-the-market" sales pursuant to an equity distribution agreement with Cowen and Company, LLC (the Equity Distribution Agreement). No securities have been sold under the 2021 Shelf Registration Statement or the Equity Distribution Agreement.

#### ***Cash flows from operating activities***

Cash flows used in operating activities for the three months ended March 31, 2022 and 2021 totaled \$88.4 million and \$77.1 million, respectively.

We expect that cash flows used in operating activities, excluding upfront, milestone and other contingent payments received, if any, will decrease for 2022 as compared to 2021 as a result of the various cost restructuring activities described above.

#### ***Cash flows from investing activities***

During the three months ended March 31, 2022 and 2021, the maturities and sales of our investments, net of purchases, totaled \$134.5 million and \$13.3 million, respectively, which we used to fund our operations.

We paid \$4.2 million and \$2.9 million for the purchase or construction of property, plant and equipment in the three months ended March 31, 2022 and 2021, respectively.

#### ***Cash flows from financing activities***

We received proceeds from issuance of common stock related to our employee option and stock purchase plans of \$0.2 million and \$17.1 million in the three months ended March 31, 2022 and 2021, respectively. Additionally, during the three months ended March 31, 2022 and 2021, we received \$0.8 million from SFJ pursuant to our co-development agreement.

#### **Critical Accounting Policies and Estimates**

The preparation and presentation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates on an ongoing basis. Actual results may differ from those estimates under different assumptions or conditions. There have been no material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our market risks at March 31, 2022 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2021 on file with the SEC.

### **Item 4. Controls and Procedures**

#### ***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (Exchange Act) reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

#### ***Changes in Internal Control Over Financial Reporting***

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout the Company. However, there was no change in our internal control over financial reporting that occurred in the three months ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Specifically, despite the fact that most of our employees are working remotely due to the COVID-19 pandemic, we do not believe that our adjustments to how we work have materially impacted our internal controls over financial reporting. We continue to monitor and assess the potential impact of the COVID-19 pandemic, and the related shelter-in-place requirements, on our internal controls and strive to minimize the impact on our internal control design and operating effectiveness.

#### ***Limitations on the Effectiveness of Controls***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART II: OTHER INFORMATION

### Item 1. Legal Proceedings

Reference is hereby made to our disclosures in “Legal Matters” under Note 6 to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q and the information under the heading “Legal Matters” is incorporated by reference herein.

### Item 1A. Risk Factors

We are providing the following cautionary discussion of risk factors, uncertainties and assumptions that we believe are relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Exchange Act and Section 27A of the Securities Act.

Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this section to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. The risks described below may not be the only ones relating to our company. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021.

#### Risks Related to our Business

***We are highly dependent on the success of drug candidates, including NKTR-358 and NKTR-255. If these drug candidates fail in clinical development our business will be significantly harmed.***

Our future success is highly dependent on the clinical success of our drug candidates, including NKTR-358 and NKTR-255. In general, most investigational drugs, including immunology and I-O drug candidates such as NKTR-358 and NKTR-255, respectively, do not become approved drugs. Accordingly, there is a very meaningful risk that our drug candidates will not succeed in one or more clinical trials sufficient to support one or more regulatory approvals. Further, if Lilly, our collaboration partner for NKTR-358, delays the initiation or completion of one or more clinical trials for reasons outside of our control, or is not successful, it would materially harm our market valuation, prospects, financial condition and results of operations. For example, under our collaboration agreement with Lilly, we are eligible for up to \$250.0 million in additional development and regulatory milestones, and a royalty rate up to the low twenties based upon our Phase 3 development cost contribution and the level of annual global product sales. One or more clinical failures of our drug candidates would jeopardize and could result in reduced, delayed or eliminated revenue.

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

***Delays in clinical studies are common and have many causes, and any significant delay in clinical studies being conducted by us or our partners could result in delay in regulatory approvals and jeopardize the ability to proceed to commercialization.***

We or our partners may experience delays in clinical trials of drug candidates. Our partner Lilly is conducting a Phase 2 study of NKTR-358 in patients with SLE as well as two Phase 1b studies in patients with psoriasis and atopic dermatitis. In addition, we have initiated a Phase 1 clinical study of NKTR-255 in adults with relapsed or refractory non-Hodgkin lymphoma or multiple myeloma, as well as a Phase 1/2 clinical study of NKTR-255 in patients with relapsed or refractory head and neck



squamous cell carcinoma or colorectal cancer. These and other clinical studies may not begin on time, enroll a sufficient number of patients or be completed on schedule, if at all. Clinical trials for any of our drug candidates could be delayed for a variety of reasons, including:

- delays in obtaining regulatory authorization to commence a clinical study;
- delays in reaching agreement with applicable regulatory authorities on a clinical study design;
- for drug candidates (such as NKTR-358) partnered with other companies, delays caused by our partner;
- delays caused by the COVID-19 pandemic (see also the risk factor in this Item 1A titled “*Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic*”).
- imposition of a clinical hold by the FDA or other health authorities, which may occur at any time including after any inspection of clinical trial operations or trial sites;
- suspension or termination of a clinical study by us, our partners, the FDA or foreign regulatory authorities due to adverse side effects of a drug on subjects in the trial;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial due to the detriment of enrollment rates;
- delays in manufacturing and delivery of sufficient supply of clinical trial materials;
- changes in regulatory authorities policies or guidance applicable to our drug candidates; and
- delays caused by changing standards of care or new treatment options.

If the initiation or completion of any of the planned clinical studies for our drug candidates is delayed for any of the above or other reasons, results for the studies would be delayed, and consequently the regulatory approval process would be delayed which would also delay our ability to commercialize these drug candidates, which could have a material adverse effect on our business, financial condition and results of operations. Clinical study delays could also shorten any commercial periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

***The outcomes from competitive I-O and combination therapy clinical trials, and the discovery and development of new potential oncology therapies, could have a material and adverse impact on the value of our I-O research and development pipeline.***

The research and development of I-O therapies is a very competitive global segment in the biopharmaceutical industry attracting tens of billions of dollars of investment each year. Our clinical trial plans for NKTR-255 and other I-O therapy drug candidates face substantial competition from other I-O combination regimens already approved, and many more combination therapies that are either ahead of or in parallel development in patient populations where we are studying our drug candidates. As I-O combination therapies are relatively new approaches in cancer treatment and few have successfully completed late stage development, I-O drug development entails substantial risks and uncertainties that include rapidly changing standards of care, identifying contribution of component therapies, patient enrollment competition, evolving regulatory frameworks to evaluate combination regimens, and varying risk-benefit profiles of competing therapies, any or all of which could have a material and adverse impact on the probability of success of I-O drug candidates.

***The risk of clinical failure for any drug candidate remains high prior to regulatory approval and there can be no assurance that our product candidates will obtain regulatory approval.***

A number of companies have suffered significant unforeseen failures in clinical studies due to factors such as inconclusive efficacy or safety, even after achieving preclinical proof-of-concept or positive results from earlier clinical studies that were satisfactory both to them and to reviewing regulatory authorities. Clinical study outcomes remain very unpredictable and it is possible that one or more of our clinical studies could fail at any time due to efficacy, safety or other important clinical findings or regulatory requirements. The results from preclinical testing or early clinical trials of a drug candidate may not predict the results that will be obtained in later phase clinical trials of the drug candidate. We, the FDA, an independent Institutional Review Board (IRB), an independent ethics committee (IEC), or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time for various reasons, including a belief that patients participating in such trials are being exposed to

unacceptable health risks or adverse side effects. Similarly, an IRB or IEC may suspend a clinical trial at a particular trial site. If one or more of our drug candidates fail in clinical studies, it could have a material adverse effect on our business, financial condition and results of operations.

***Significant competition for our polymer conjugate chemistry technology platforms and our partnered and proprietary drugs and drug candidates could make our technologies, drugs or drug candidates obsolete or uncompetitive, which would negatively impact our business, results of operations and financial condition.***

Our advanced polymer conjugate chemistry platforms and our partnered and proprietary products and drug candidates compete with various pharmaceutical and biotechnology companies. Competitors of our polymer conjugate chemistry technologies include Biogen Inc., Horizon Pharma, Dr. Reddy's Laboratories Ltd., SunBio Corporation, Laysan Bio, Inc., Mountain View Pharmaceuticals, Inc., Novo Nordisk A/S (formerly assets held by Neose Technologies, Inc.), and NOF Corporation. Several other chemical, biotechnology and pharmaceutical companies may also be developing polymer conjugation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are many competitors for our drug candidates currently in development. For NKTR-358, there are a number of competitors in various stages of clinical development that are working on programs which are designed to correct the underlying immune system imbalance in the body due to autoimmune disease. In particular, we expect to compete with therapies that could be cytokine-based therapies (Symbiotix, LLC, Janssen, AstraZeneca, and Tizona Therapeutics), regulatory T cell therapies (Targazyme, Inc., Caladrius BioSciences, Inc., and Tract Therapeutics, Inc.), or IL-2-based-therapies (Amgen Inc., Celgene Corporation, GentiBio, Inc., ILTOO Pharma, Kyverna Therapeutics, Merck & Co, through its acquisition of Pandion Therapeutics, and Roche). For NKTR-255, we believe companies that are currently researching and developing engineered IL-15 biologics and cell therapies that could compete with this drug candidate include Artiva Biotherapeutics, Fate Therapeutics, ImmunityBio, Inc., Nkarta therapeutics, NKMax America, and Roche/Genentech (through its partnership with Xencor, Inc.). There can be no assurance that we or our partners will successfully develop, obtain regulatory approvals for and commercialize next-generation or new products that will successfully compete with those of our competitors. Many of our competitors have greater financial, research and development, marketing and sales, manufacturing and managerial capabilities. We face competition from these companies not just in product development but also in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. As a result, our competitors may succeed in developing competing technologies, obtaining regulatory approval or gaining market acceptance for products before we do. These developments could make our products or technologies uncompetitive or obsolete.

***Preliminary and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.***

From time to time, we publish preliminary or interim data from our clinical studies. Preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our business prospects.

#### **Risks Related to our Collaboration Partners**

***We are highly dependent on our collaboration partner to initiate, properly conduct and prioritize clinical trials for NKTR-358 and to perform important additional development and commercialization activities, and our business will be significantly harmed if their actions deprioritize or otherwise harm the prospects of our drug candidates.***

We rely on Lilly (through the Lilly Agreement) to initiate, properly conduct, and prioritize clinical trials and other development-related activities for NKTR-358. Furthermore, we will rely Lilly to perform specified commercialization activities for NKTR-358, pursuant to the our collaboration agreement. In the Lilly fails to initiate, properly conduct and prioritize their obligations under their applicable agreement with us, our business will be significantly harmed. Even if the applicable agreement provides us with enforcement or other curative rights to address the harm caused by Lilly's action (or failure to act), our efforts in pursuing a remedy would be costly and there is no guarantee that efforts would succeed or be sufficient to fully address the harm.

In addition, for reasons outside of our control, the operations of our collaboration partners may be affected by the COVID-19 pandemic than we are, or they may adopt more restrictive procedures for addressing the COVID-19 pandemic, either of which would delay initiating or completing one or more clinical trials involving our drug candidates.

## Risks Related to our Financial Condition and Capital Requirement

### *Our strategic reorganization plan and cost restructuring plan may not be successful.*

On April 25, 2022, we announced strategic reorganization and cost restructuring plans (together, the Reorganization and Restructuring Plans) to prioritize key research and development efforts that will be most impactful to the Company's future, including NKTR-358, NKTR-255 and several core research programs. In connection with the Reorganization and Restructuring Plans, we also announced cost restructuring measures aimed at ensuring we will have significant capital to fund key programs over a multi-year time horizon. There is no guarantee that the Reorganization and Restructuring Plans will achieve their intended benefits or that our post-restructuring focus will be sufficient for us to achieve success. For example, our cost restructuring efforts may not result in the anticipated savings or other economic benefits, or could result in total costs and expenses that are greater than expected, which would require us to seek potentially dilutive financing alternatives, disrupt or restrain the scope of our business activities, and would make it more difficult to attract and retain qualified personnel, each of which could have a material adverse effect on our business, financial condition and prospects.

### *Our results of operations and financial condition depend significantly on the ability of our collaboration partners to successfully develop and market drugs and they may fail to do so.*

Under our collaboration agreements with various pharmaceutical or biotechnology companies, our collaboration partner is generally solely responsible for:

- designing and conducting large scale clinical studies;
- preparing and filing documents necessary to obtain government approvals to sell a given drug candidate; and/or
- marketing and selling the drugs when and if they are approved.

Our reliance on collaboration partners poses a number of significant risks to our business, including risks that:

- we have very little control over the timing and level of resources that our collaboration partners dedicate to commercial marketing efforts such as the amount of investment in sales and marketing personnel, general marketing campaigns, direct-to-consumer advertising, product sampling, pricing agreements and rebate strategies with government and private payers, manufacturing and supply of drug product, and other marketing and selling activities that need to be undertaken and well executed for a drug to have the potential to achieve commercial success;
- collaboration partners with commercial rights may choose to devote fewer resources to the development or marketing of our partnered drugs than they devote to their own drugs or other drugs that they have in-licensed;
- we have very little control over the timing and amount of resources our partners devote to development programs in one or more major markets;
- disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of drug candidates or to litigation or arbitration proceedings;
- disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;
- we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;
- partners may be unable to pay us as expected;
- partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty; and
- partners may respond to natural disasters or health epidemics, such as the COVID-19 pandemic, by ceasing all or some of their development responsibilities (including the responsibility to clinical develop our drug candidates).

Given these risks, the success of our current and future collaboration partnerships is highly unpredictable and can have a substantial negative impact on our business. If the approved drugs fail to achieve commercial success or the drugs in development fail to have positive late stage clinical outcomes sufficient to support regulatory approval in major markets, it could significantly

impair our access to capital necessary to fund our research and development efforts for our drug candidates. If we are unable to obtain sufficient capital resources to advance our drug candidate pipeline, it would negatively impact the value of our business, results of operations and financial condition.

***We have substantial future capital requirements and there is a risk that we may not have access to sufficient capital to meet our current business plan. If we do not receive substantial milestone or royalty payments from our existing collaboration agreements, execute new high value collaborations or other arrangements, or are unable to raise additional capital in one or more financing transactions, we would be unable to continue our current level of investment in research and development.***

As of March 31, 2022, we had cash and investments in marketable securities valued at approximately \$704.4 million. While we believe that our cash position will be sufficient to meet our liquidity requirements through at least the next 12 months, our future capital requirements will depend upon numerous unpredictable factors, including:

- the cost, timing and outcomes of clinical studies and regulatory reviews of our drug candidates, particularly NKTR-358;
- if and when we receive potential milestone payments and royalties from our existing collaborations if the drug candidates subject to those collaborations achieve clinical, regulatory or commercial success;
- the progress, timing, cost and results of our clinical development programs;
- the success, progress, timing and costs of our efforts to implement new collaborations, licenses and other transactions that increase our current net cash, such as the sale of additional royalty interests held by us, term loan or other debt arrangements, and the issuance of securities;
- the number of patients, enrollment criteria, primary and secondary endpoints, and the number of clinical studies required by the regulatory authorities in order to consider for approval our drug candidates and those of our collaboration partners;
- our general and administrative expenses, capital expenditures and other uses of cash; and
- disputes concerning patents, proprietary rights, or license and collaboration agreements that could negatively impact our receipt of milestone payments or royalties or require us to make significant payments arising from licenses, settlements, adverse judgments or ongoing royalties.

A significant multi-year capital commitment is required to advance our drug candidates through the various stages of research and development in order to generate sufficient data to enable high value collaboration partnerships with significant upfront payments or to successfully achieve regulatory approval. In the event we do not enter into any new collaboration partnerships with significant upfront payments and we choose to continue to advance our drug candidates to later stage research and development, we may need to pursue financing alternatives, including dilutive equity-based financings, such as an offering of convertible debt or common stock, which would dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. If sufficient capital is not available to us or is not available on commercially reasonable terms, it could require us to delay or reduce one or more of our research and development programs. If we are unable to sufficiently advance our research and development programs, it could substantially impair the value of such programs and result in a material adverse effect on our business, financial condition and results of operations.

***The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.***

It is very difficult to estimate the commercial potential of drug candidates due to important factors such as safety and efficacy compared to other available treatments, including changing standards of care, third party payer reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic and biosimilar versions of our drug candidates following approval by regulatory authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the commercial potential of the drug candidate, the commercial terms of any collaboration partnership potential for such drug candidate, or if we have already entered into a collaboration for such drug candidate, the revenue potential from royalty and milestone payments could be significantly diminished and this would negatively impact our business, financial condition and results of operations. We also depend on our relationships with other companies for sales and marketing performance and the commercialization of drug candidates. Poor performance by these companies, or disputes with these companies, could negatively impact our revenue and financial condition.

***If government and private insurance programs do not provide payment or reimbursement for our partnered drug or proprietary drugs, those drugs will not be widely accepted, which would have a negative impact on our business, results of operations and financial condition.***

In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. In both domestic and foreign markets, sales of our partnered and proprietary products that receive regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the availability of coverage and payment or reimbursement from third-party payers, such as government programs, including Medicare and Medicaid in the U.S., managed care providers, private health insurers and other organizations. However, eligibility for coverage does not necessarily signify that a biologic candidate will be adequately reimbursed in all cases or at a rate that covers costs related to research, development, manufacture, sale, and distribution. Third-party payers are increasingly challenging the price and cost effectiveness of medical products and services. Therefore, significant uncertainty exists as to the coverage and pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our biologic candidates even if there is adequate coverage and reimbursement from third-party payers. It is unclear what effect, if any, the American Rescue Plan Act will have on the number of covered individuals.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS 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.

Factors payers consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payers are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our proposed products for marketing and could further limit coverage or pricing approvals for, and reimbursement of, our products from government authorities and third-party payers. Federal agencies, Congress and state legislatures have continued to show interest in implementing cost containment programs to limit the growth of health care costs, including price controls, restrictions on reimbursement and other fundamental changes to the healthcare delivery system. In addition, in recent years, Congress has enacted various laws seeking to reduce the federal debt level and contain healthcare expenditures, and the Medicare and other healthcare programs are frequently identified as potential targets for spending cuts. New government legislation or regulations related to pricing or other fundamental changes to the healthcare delivery system as well as a government or third-party payer decision not to approve pricing for, or provide adequate coverage or reimbursement of, our products hold the potential to severely limit market opportunities of such products.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates.

Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

***Recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.***

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act (MMA), contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the U.S. Secretary of Health and Human Services (HHS) certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the U.S. Secretary of HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

***If we are unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer.***

We intend to continue to seek partnerships with pharmaceutical and biotechnology partners to fund a portion of our research and development capital requirements. The timing of new collaboration partnerships is difficult to predict due to availability of clinical data, the outcomes from our clinical studies, the number of potential partners that need to complete due diligence and approval processes, the definitive agreement negotiation process and numerous other unpredictable factors that can delay, impede or prevent significant transactions. If we are unable to find suitable partners or negotiate collaboration arrangements with favorable commercial terms with respect to our existing and future biologic candidates or the licensing of our intellectual property, or if any arrangements we negotiate, or have negotiated, are terminated, it could have a material adverse effect on our business, financial condition and results of operations.

***Our revenue is exclusively derived from our collaboration agreements, which can result in significant fluctuation in our revenue from period to period, and our past revenue is therefore not necessarily indicative of our future revenue.***

Our revenue is exclusively derived from our collaboration agreements, from which we receive upfront fees, research and development reimbursement and funding, milestone and other contingent payments based on clinical progress, regulatory progress or net sales achievements, royalties and product sales. Significant variations in the timing of receipt of cash payments and our recognition of revenue can result from payments based on the execution of new collaboration agreements, the timing of clinical outcomes, regulatory approval, commercial launch or the achievement of certain annual sales thresholds. The amount of our revenue derived from collaboration agreements in any given period will depend on a number of unpredictable factors, including whether and when we or our collaboration partners achieve clinical, regulatory and sales milestones, the timing of regulatory approvals in one or more major markets, reimbursement levels by private and government payers, and the market introduction of new drugs or generic versions of the approved drug, as well as other factors. Our past revenue generated from collaboration agreements is not necessarily indicative of our future revenue. If any of our existing or future collaboration partners fails to develop, obtain regulatory approval for, manufacture or ultimately commercialize any biologic candidate under our collaboration agreement, our business, financial condition, and results of operations could be materially and adversely affected.

***We expect to continue to incur substantial losses and negative cash flow from operations and may not achieve or sustain profitability in the future.***

For the three months ended March 31, 2022, we reported a net loss of \$90.4 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestones and other contingent payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary biologic candidates and the regulatory approval and market success of our biologic candidates. We may not be able to achieve and sustain profitability.

Other factors that will affect whether we achieve and sustain profitability include our ability, alone or together with our partners, to:

- develop drugs utilizing our technologies, either independently or in collaboration with other pharmaceutical or biotechnology companies;
- effectively estimate and manage clinical development costs, particularly the cost of the clinical studies for NKTR-358 and NKTR-255;
- receive necessary regulatory and marketing approvals;
- maintain or expand manufacturing at necessary levels;
- achieve market acceptance of our partnered products;
- receive revenue or royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities; and
- maintain sufficient funds to finance our activities.

## **Risks Related to the COVID-19 Pandemic**

### ***Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic.***

Our business could be adversely affected, directly or indirectly, by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, including both our own manufacturing operations as well as the manufacturing operations of third parties upon whom we rely. With respect to the ongoing COVID-19 pandemic, national, state and local governments in regions affected by the COVID-19 pandemic have implemented, and may continue to implement or reinstate safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter-in-place orders and shutdowns, business closures and other measures. These measures may disrupt normal business operations both in and outside areas affected by COVID-19 and may have significant negative impacts on our business. Even as these safety precautions are eased or reduced over time, there may be long lasting effects of these precautions on our business that may only be fully realized in the future.

We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic. Throughout the pandemic we have modified our office policies to maintain productivity and safety of our employees. Although we believe these and the other safety measures we have taken in response to the COVID-19 pandemic have not substantially impacted our productivity, it is not certain that this will continue to be the case. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses, employee productivity and availability and employee work culture.

Certain of our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Investigator recruitment, clinical site initiation, patient screening and patient enrollment may be delayed due to, for example, prioritization of hospital resources toward the COVID-19 pandemic. Some patients who are successfully enrolled in clinical trials involving our biologic candidates may not be able to comply with clinical trial protocols due to, for example, shelter-in-place orders impeding movement, disrupted healthcare services, or health issues for suspected or confirmed COVID-19 status. Similarly, our ability to recruit and retain patients and principal investigators and site staff, all of whom may have heightened risk for COVID-19, could adversely impact our clinical trial operations.

Delays and disruptions experienced by our collaborators or other third parties due to the COVID-19 pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect clinical development or regulatory approvals of our biologic candidates. For example, due to recent supply chain disruptions, we have been monitoring our supply chains for any disruptions or constraints caused by the COVID-19 pandemic. To date, we have not experienced any supply impact. However, if we, our collaborators or any third parties which we rely on are adversely effected by any supply disruptions or shortages in raw materials and equipment caused by the COVID-19 pandemic, our ability to manufacture our products and to supply drug candidates for our clinical trials could be negatively impacted, which could harm our business prospects, results of operations and financial condition.

Although we are implementing measures to maintain the integrity of our clinical trials, there is no guarantee that we will prevent all study protocol violations, missed study treatment visits, and other influences that jeopardize reliability and validity of our clinical trial data. If a regulatory authority determines our clinical trial data lacks integrity, there is no guarantee that we will have a remedy to correct or otherwise address the deficiency. Even if such a remedy is identified, the cost for implementing the remedy could be prohibitively expensive, time consuming, or both. As a consequence, a clinical study of our biologic candidate in which the integrity of the clinical study is questioned or doubted may require lengthy and costly remediation measures (such as, for example, over-enrolling patients into the study or repeating the study), thereby causing substantial harm to our business.

Also, the COVID-19 pandemic could postpone necessary interactions with regulators regarding our drug candidates in development and could delay review or approval of our regulatory submissions.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The rapid development and fluidity of the COVID-19 pandemic results in a substantial number of individual variables that could cause a significant negative impact on our operations and our business, thereby precluding useful predictions as to how this pandemic will ultimately affect us. In particular, it is unclear how our business may be affected by the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, and recent resurgences in number and rates of COVID-19 infections. Thus, any current assessment of the effects of the COVID-19 pandemic, including the impact of this disease on our clinical trial timelines, is subject to change. We do not yet know the full extent of potential impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material negative impact on our operations and our business. Furthermore, to the extent the ongoing COVID-19 pandemic adversely affects our operations and business, it may also heighten the other risks described in this “Risk Factors” section.

### **Risks Related to Supply and Manufacturing**

***If we or our contract manufacturers are not able to manufacture biologic substance or substances in sufficient quantities that meet applicable quality standards, it could delay clinical studies, result in reduced sales or constitute a breach of our contractual obligations, any of which could significantly harm our business, financial condition and results of operations.***

If we or our contract manufacturing organizations (CMOs) are not able to manufacture and supply sufficient drug quantities meeting applicable quality standards required to support large clinical studies or commercial manufacturing in a timely manner, it could delay our or our collaboration partners’ clinical studies or result in a breach of our contractual obligations, which could in turn reduce the potential commercial sales of our or our collaboration partners’ products. As a result, we could incur substantial costs and damages and any product sales or royalty revenue that we would otherwise be entitled to receive could be reduced, delayed or eliminated. In most cases, we rely on CMOs to manufacture and supply drug product for our clinical studies and those of our collaboration partners. The manufacturing of biologics involves significant risks and uncertainties related to the demonstration of adequate stability, sufficient purification of the drug substance and drug product, the identification and elimination of impurities, optimal formulations, process and analytical methods validations, and challenges in controlling for all of these variables. These risks and uncertainties are compounded by the COVID-19 pandemic wherein the facilities and employees responsible for manufacturing biologics for use in clinical trials may be negatively impacted such that there is an insufficient supply of study biologic drugs. We have faced and may in the future face significant difficulties, delays and unexpected expenses as we validate third party CMOs required for drug supply to support our clinical studies and the clinical studies and products of our collaboration partners. Failure by us or our CMOs to supply API or drug products in sufficient quantities that meet all applicable quality requirements could result in supply shortages for our clinical studies or the clinical studies and commercial activities of our collaboration partners. Such failures could significantly and materially delay clinical trials and regulatory submissions or result in reduced sales, any of which could significantly harm our business prospects, results of operations and financial condition.

On March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in response to the COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA’s existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.



If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or biologic candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop biologic candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our biologic candidate that such CMO owns independently. This would increase our reliance on such a CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products or biologic candidates. In addition, in the case of the CMOs that supply our biologic candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Building and validating large scale clinical or commercial-scale manufacturing facilities and processes, recruiting and training qualified personnel and obtaining necessary regulatory approvals is complex, expensive and time consuming. In the past, we have encountered challenges in scaling up manufacturing to meet the requirements of large scale clinical trials without making modifications to the drug formulation, which may cause significant delays in clinical development. There continues to be substantial and unpredictable risk and uncertainty related to manufacturing and supply until such time as the commercial supply chain is validated and proven.

***We purchase some of the starting material for biologics and biologic candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause production delays, clinical trial delays, substantial loss of revenue and contract liability to third parties.***

We often face very limited supply of a critical raw material that can only be obtained from a single, or a limited number of, suppliers, which could cause production delays, clinical trial delays, substantial lost revenue opportunities or contract liabilities to third parties. For example, there are only a limited number of qualified suppliers, and in some cases single source suppliers, for the raw materials included in our PEGylation and advanced polymer conjugate drug formulations. Any interruption in supply, diminution in quality of raw materials supplied to us or failure to procure such raw materials on commercially feasible terms could harm our business by delaying our clinical trials, impeding commercialization of approved drugs or increasing our costs.

***Our manufacturing operations and those of our contract manufacturers are subject to laws and other governmental regulatory requirements, which, if not met, would have a material adverse effect on our business, results of operations and financial condition.***

We and our CMOs are required in certain cases to maintain compliance with current good manufacturing practices (cGMP), including cGMP guidelines applicable to active pharmaceutical ingredients, and drug products, and with laws and regulations governing manufacture and distribution of controlled substances, and are subject to inspections by the FDA, or comparable agencies in other jurisdictions administering such requirements. We anticipate periodic regulatory inspections of our drug manufacturing facilities and the manufacturing facilities of our CMOs for compliance with applicable regulatory requirements. Any failure to follow and document our or our CMOs' adherence to such cGMP and other laws and governmental regulations or satisfy other manufacturing and product release regulatory requirements may disrupt our ability to meet our manufacturing obligations to our customers, lead to significant delays in the availability of products for commercial use or clinical study, result in the termination or hold on a clinical study or delay or prevent filing or approval of marketing applications for our products. Failure to comply with applicable laws and regulations may also result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures, administrative detention, or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. Regulatory inspections could result in costly manufacturing changes or facility or capital equipment upgrades to satisfy the FDA that our manufacturing and quality control procedures are in substantial compliance with cGMP. Manufacturing delays, for us or our CMOs, pending resolution of regulatory deficiencies or suspensions could have a material adverse effect on our business, results of operations and financial condition.

## Risks Related to Business Operations

***We depend on third parties to conduct the clinical trials for our biologic candidates and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.***

We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct clinical trials for our biologic candidates. We rely heavily on these parties for the successful execution of our clinical trials. Though we are ultimately responsible for the results of their activities, many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trials, but the independent clinical investigators may prioritize other projects over ours or communicate issues regarding our biologic candidates to us in an untimely manner. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials or the failure of third parties to properly conduct our clinical trials could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

***Our future depends on the proper management of our current and future business operations and their associated expenses.***

Our business strategy requires us to manage our business to provide for the continued development of our proprietary and partnered biologic candidates. Our strategy also calls for us to manage the capital necessary to fund key programs through value-enhancing data and other milestones. If we are unable to manage effectively our current operations, our business, financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our personnel-related costs through reductions in our workforce, which could harm our operations, employee morale and impair our ability to retain and recruit talent. Furthermore, if adequate funds are not available, we may be required to obtain funds through arrangements with partners or other sources that may require us to relinquish rights to certain of our technologies, products or future economic rights that we would not otherwise relinquish or require us to enter into other dilutive financing arrangements on unfavorable terms.

***If we, or our partners through our collaborations, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would adversely affect our business, results of operations and financial condition.***

To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenue we receive will depend upon the efforts of third parties, which may not be successful and over which we have little or no control. In the event that we market our products without a partner, we would be required to build, either internally or through third-party contracts, a sales and marketing organization and infrastructure, which would require a significant investment, and we may not be successful in building this organization and infrastructure in a timely or efficient manner. We would also incur substantial costs in building such capabilities before receiving regulatory approval of our products, which would have an adverse effect on our financial condition if our products are not ultimately approved.

***Because competition for highly qualified technical personnel is intense, we may not be able to attract and retain the personnel we need to support our operations and growth.***

We must attract and retain experts in the areas of research, development (including clinical testing), manufacturing, regulatory and finance, and may need to attract and retain commercial, marketing and distribution experts and develop additional expertise in our existing personnel. We face intense competition from other biopharmaceutical companies, research and academic institutions and other organizations for qualified personnel. Many of the organizations with which we compete for qualified personnel have greater resources than we have. Because competition for skilled personnel in our industry is intense, companies such as ours sometimes experience high attrition rates with regard to their skilled employees. Further, in making employment decisions, job candidates often consider the value of the stock awards they are to receive in connection with their employment. Our equity incentive plan and employee benefit plans may not be effective in motivating or retaining our employees or attracting new employees, and significant volatility in the price of our stock may adversely affect our ability to attract or retain qualified personnel. Furthermore, as a result of our Reorganization and Restructuring plans, our employees may experience distractions or decreases in employee morale and we may experience increased levels of employee attrition and turnover, which would adversely affect our business. If we fail to attract new personnel or to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

***We are dependent on our management team and key technical personnel, and the loss of any key manager or employee may impair our ability to develop our products effectively and may harm our business, operating results and financial condition.***

Our success largely depends on the continued services of our executive officers and other key personnel. The loss of one or more members of our management team or other key employees could seriously harm our business, operating results and financial condition. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are also dependent on the continued services of our technical personnel because of the highly technical nature of our products and the regulatory approval process. Because our executive officers and key employees are not obligated to provide us with continued services, they could terminate their employment with us at any time without penalty. We do not have any post-employment noncompetition agreements with any of our employees and do not maintain key person life insurance policies on any of our executive officers or key employees.

#### **Risks Related to Intellectual Property, Litigation and Regulatory Concerns**

***If we or our partners do not obtain regulatory approval for our biologic candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, our business, results of operations and financial condition will be negatively affected.***

We or our partners may not obtain regulatory approval for biologic candidates on a timely basis, or at all, or the terms of any approval (which in some countries includes pricing approval) may impose significant restrictions or limitations on use. Biologic candidates must undergo rigorous animal and human testing and an extensive review process for safety and efficacy by the FDA and equivalent foreign regulatory authorities. The time required for obtaining regulatory decisions is uncertain and difficult to predict. The FDA and other U.S. and foreign regulatory authorities have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. Further, regulatory authorities have the discretion to analyze data using their own methodologies that may differ from those used by us or our partners, which could lead such authorities to arrive at different conclusions regarding the safety or efficacy of a biologic candidate. In addition, undesirable side effects caused by our biologic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. For example, AstraZeneca is conducting a post-marketing, observational epidemiological study comparing MOVANTIK<sup>®</sup> to other treatments of opioid-induced constipation in patients with chronic, non-cancer pain and the results of this study could at some point in the future negatively impact the labeling, regulatory status, and commercial potential of MOVANTIK<sup>®</sup>, which could reduce our future royalties from sales of MOVANTIK<sup>®</sup>.

Even if we or our partners receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. Our and our partnered drugs that have obtained regulatory approval, and the manufacturing processes for these products, are subject to continued review and periodic inspections by the FDA and other regulatory authorities. Discovery from such review and inspection of previously unknown problems may result in restrictions on marketed products or on us, including withdrawal or recall of such products from the market, suspension of related manufacturing operations or a more restricted label. The failure to obtain timely regulatory approval of drug candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

***We are a party to numerous collaboration agreements and other significant agreements which contain complex commercial terms that could result in disputes, litigation or indemnification liability that could adversely affect our business, results of operations and financial condition.***

We currently derive, and expect to derive in the foreseeable future, substantially all of our revenue from collaboration agreements with biotechnology and pharmaceutical companies. These collaboration agreements contain complex commercial terms, including:

- clinical development and commercialization obligations that are based on certain commercial reasonableness performance standards that can often be difficult to enforce if disputes arise as to adequacy of our partner's performance;
- research and development performance and reimbursement obligations for our personnel and other resources allocated to partnered biologic candidate development programs;
- clinical and commercial manufacturing agreements, some of which are priced on an actual cost basis for products supplied by us to our partners with complicated cost allocation formulas and methodologies;

- intellectual property ownership allocation between us and our partners for improvements and new inventions developed during the course of the collaboration;
- royalties on drug sales based on a number of complex variables, including net sales calculations, geography, scope of patent claim coverage, patent life, generic competitors, bundled pricing and other factors; and
- indemnity obligations for intellectual property infringement, product liability and certain other claims.

We are a party to numerous significant collaboration agreements and other strategic transaction agreements (e.g., financings and asset divestitures) that contain complex representations and warranties, covenants and indemnification obligations. If we are found to have materially breached such agreements, we could be subject to substantial liabilities, which would harm our financial condition.

From time to time, we are involved in litigation matters involving the interpretation and application of complex terms and conditions of our agreements. One or more disputes may arise or escalate in the future regarding our collaboration agreements, transaction documents, or third-party license agreements that may ultimately result in costly litigation and unfavorable interpretation of contract terms, which would have a material adverse effect on our business, financial condition and results of operations.

***We may not be able to obtain intellectual property licenses related to the development of our biologic candidates on a commercially reasonable basis, if at all.***

Numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties relate to pharmaceutical compositions, methods of preparation and manufacturing, and methods of use and administration. We cannot predict with any certainty which, if any, patent rights will be considered relevant to our or our collaboration partners' technology or biologic candidates by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. In certain cases, we have existing licenses or cross-licenses with third parties; however, the sufficiency of the scope and adequacy of these licenses is very uncertain in view of the long development and commercialization cycles for biotechnology and pharmaceutical products. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology to avoid a need to secure a license. If we are required to enter into a license with a third party, our potential economic benefit for the products subject to the license will be diminished. If a license is not available on commercially reasonable terms or at all, we may be prevented from developing and commercializing the biologic, which could significantly harm our business, results of operations, and financial condition.

***If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.***

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own more than 310 U.S. and 1,200 foreign patents and have a number of pending patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition, *inter partes* review, re-examinations or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant and/or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire prior to the commercialization of the biologic. Moreover, even if a patent encompassing a biologic has not expired prior to the biologic's commercialization, the patent may only provide a short period of protection following the commercialization of products. In addition, our patents may be subject to post grant proceedings, such as or *inter partes* review and re-examinations, before the U.S. Patent and Trademark Office (or equivalent proceedings in other jurisdictions), which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications, and plan to file additional patent applications, covering various aspects of our PEGylation and advanced polymer conjugate technologies and our biologic candidates. There can be no assurance that the patent applications for which we apply will actually issue as patents, or do so with commercially relevant and/or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving intellectual property, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an intellectual property license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies or products.

***We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.***

We rely on trade secret protection and other unpatented proprietary rights for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

***If product liability lawsuits are brought against us, we may incur substantial liabilities.***

The manufacture, clinical testing, marketing and sale of medical products involve inherent product liability risks. If product liability costs exceed our product liability insurance coverage (or if we cannot secure product liability insurance), we may incur substantial liabilities that could have a severe negative impact on our financial position. Whether or not we are ultimately successful in any product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources and might result in adverse publicity, all of which would impair our business. Additionally, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

***If we or current or future collaborators or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and civil or criminal penalties.***

Although we do not currently have any products on the market, once we begin commercializing our biologic candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal and state governments of the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of any biologic candidates for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our therapeutic candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration (a term interpreted broadly to include anything of value, including, for example, gifts, discounts, and credits), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the U.S. federal False Claims Act (FCA), which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money owed to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Manufacturers can be held liable under the federal 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 federal False Claims Act also permits a private individual acting as

“whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- provisions of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes, referred to as the “HIPAA All-Payer Fraud Prohibition,” that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the federal Physician Payment Sunshine Act, which require manufacturers of certain drugs and biologics to track and disclose payments and other transfers of value they make to U.S. physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as physician ownership and investment interests in the manufacturer, and that such information is subsequently made publicly available in a searchable format on a CMS website, effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician assistants and nurse practitioners;
- provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, and also includes the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, 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 federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- additionally, state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state transparency reporting and compliance laws; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and which may not have the same effect, thus complicating compliance efforts. These state-equivalent laws may also apply to our business practices, including, but not limited to, research, distribution, and sales or marketing arrangements. 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 also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including administrative, civil or criminal penalties, imprisonment, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***Disruptions to the normal functioning of the FDA and other government agencies could hinder their ability to perform and carry out important roles and activities on which the operation of our business relies, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, suing risk management methods, to meet user fee commitments and goal dates. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be appropriate, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future shutdowns of other government agencies, such as the SEC, may also impact our business through review of our public filings and our ability to access the public markets.

***We are involved in legal proceedings and may incur substantial litigation costs and liabilities that will adversely affect our business, financial condition and results of operations.***

From time to time, we are involved in legal proceedings where we or other third parties are enforcing or seeking intellectual property rights, invalidating or limiting patent rights that have already been allowed or issued, or otherwise asserting proprietary rights through one or more potential legal remedies. Third parties have asserted, and may in the future assert, that we or our partners infringe their proprietary rights, such as patents and trade secrets, or have otherwise breached our obligations to them. A third party often bases its assertions on a claim that its patents cover our technology platform or biologic candidates or that we have misappropriated its confidential or proprietary information. Similar assertions of infringement could be based on future patents that may issue to third parties. For example, we are involved in ongoing litigation with Aether Therapeutics Inc., who in March 2020 filed a complaint against AstraZeneca, Nektar and Daiichi-Sanko, Inc. alleging that MOVANTIK® infringes U.S. Patent Nos. 6,713,488, 8,748,448, 8,883,817 and 9,061,024. In certain of our agreements with our partners, we are obligated to indemnify and hold harmless our collaboration partners from intellectual property infringement, product liability and certain other claims, which could cause us to incur substantial costs and liability if we are called upon to defend ourselves and our partners against any claims. We are also regularly involved in opposition proceedings at the European Patent Office and in inter partes review and re-examination proceedings at the U.S. Patent and Trademark Office where third parties seek to invalidate or limit the scope of our allowed patent applications or issued patents covering (among other things) our biologic candidates and platform technologies. If a third party obtains injunctive or other equitable relief against us or our partners, they could effectively prevent us, or our partners, from developing or commercializing, or deriving revenue from, certain biologics or biologic candidates in the U.S. and abroad. Costs associated with litigation, substantial damage claims, indemnification claims or royalties paid for licenses from third parties could have a material adverse effect on our business, financial condition and results of operations.

From time to time, we are involved in legal proceedings other than those related to intellectual property. In October 2018, we and certain of our executives were named in a putative securities class action complaint filed in the U.S. District Court for the Northern District of California (Case No. 18-cv-06607, which we refer to as the Mulquin action). The Mulquin plaintiffs have challenged public statements Nektar made, between January 2017 and June 2018, about clinical trials of bempedalesleukin. In December 2020, the court dismissed the action with prejudice. The plaintiffs filed a notice of appeal in January 2021 and appellate briefing in the U.S. Court of Appeals for the Ninth Circuit was completed in September 2021. Oral argument was held on December 10, 2021.

In February 2021, a derivative action was filed against certain of the Company's current and former officers and directors in the Court of Chancery of the State of Delaware (C.A. No. 2021-0118-PAF) alleging that the Company's officers and directors breached their fiduciary duties by exposing the Company to securities actions. The parties agreed to stay further proceedings in this action until thirty days after the U.S. Court of Appeal for the Ninth Circuit's final resolution of the appeal in the Mulquin action.

The cost to us in initiating or defending any litigation or other proceeding, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts or result in financial implications either in terms of seeking license arrangements or payment of damages or royalties. There is no guarantee that our insurance coverage for damages resulting from a litigation or the settlement thereof (including the Mulquin action and related shareholder derivative lawsuit) is sufficient, thereby resulting in substantial financial risk to the Company.

Given the nature of lawsuits and complaints, we cannot reasonably estimate a potential future loss or a range of potential future losses for any of the legal proceedings we are currently involved in. However, an unfavorable resolution could potentially have a material adverse effect on our business, financial condition, and results of operations or prospects, and potentially result in paying monetary damages. We have recorded no liability for these matters in our Consolidated Balance Sheets at March 31, 2022.

***If we are found in violation of privacy and data protection laws, we may be required to pay penalties, be subjected to scrutiny by regulators or governmental entities, or be suspended from participation in government healthcare programs, which may adversely affect our business, financial condition and results of operations.***

Our business is subject to many laws and regulations intended to protect the privacy and data of individuals participating in our clinical trials and our employees, among others. For example, with regard to individuals participating in our clinical trials, these laws and regulations govern the safeguarding the privacy, integrity, availability, security and transmission of individually identifiable health information. In addition to federal laws and regulations in the United States, such as the HIPAA requirements relating to the privacy, security and transmission of individually identifiable health information, many state and foreign laws also govern the privacy and security of health information. These laws often differ from each other in significant ways, thus complicating compliance efforts. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

In the United States, California recently enacted the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA has increased our compliance costs and may increase our potential liability. The CCPA has prompted a number of proposals for new federal and state privacy legislation. If passed, these proposals could increase our potential liability, increase our compliance costs and adversely affect our business.

The European Regulation 2016/679, known as the General Data Protection Regulation (GDPR), and the implementing legislation of EU Member States, which became effective on May 25, 2018, apply to the collection and processing of personal data, including health-related information, by companies located in the EU, or in certain circumstances, by companies located outside of the EU and processing personal information of individuals located in the EU. The GDPR is wide-ranging in scope and imposes strict obligations on the ability to process personal data, including health-related information, in particular in relation to their collection, use, disclosure and transfer. These include several requirements relating to, for example, (i) obtaining, in some situations, the consent of the individuals to whom the personal data relates, (ii) the information provided to the individuals about how their personal information is used, and (iii) ensuring the security and confidentiality of the personal data. The GDPR prohibits the transfer of personal data to countries outside of the European Economic Area (EEA), such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Potential pecuniary fines for noncompliant companies may be up to the greater of €20 million or 4% of annual global revenue.

To the extent that we are found liable for the inappropriate collection, storage, use or disclosure of protected information of individuals (such as employees and or clinical patients protected by any privacy or data protection law), we could be subject to reputational harm, monetary fines (such as those imposed by the GDPR and CCPA), civil suits, civil penalties or criminal sanctions and requirements to disclose the breach, and the development of our biologic candidates could be delayed. In addition, we continue to be subject to new and evolving data protection laws and regulations from a variety of jurisdictions, and there is a risk that our systems and processes for managing and protecting data may be found to be inadequate, which could materially adversely affect our business, financial condition and results of operations.

***Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.***



As a research-based biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations (including, but not limited to, the handling and disposal of both our hazardous and non-hazardous waste) is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

#### **Risk related to Investment and Securities**

***The price of our common stock has, and may continue to fluctuate significantly, which could result in substantial losses for investors and securities class action and shareholder derivative litigation.***

Our stock price is volatile. During the three months ended March 31, 2022, based on closing prices on the NASDAQ Global Select Market, the closing price of our common stock ranged from \$4.16 to \$13.72 per share. In response to volatility in the price of our common stock in the past, plaintiffs' securities litigation firms have sought information from us and/or shareholders as part of their investigation into alleged securities violations and breaches of duties (among other corporate misconduct allegations). Following their investigations, plaintiffs' securities litigation firms have often initiated legal action, including the filing of class action lawsuits, derivative lawsuits, and other forms of redress. We expect our stock price to remain volatile and we continue to expect the initiation of legal actions by plaintiffs' securities litigation firms following share price fluctuations. A variety of factors may have a significant effect on the market price of our common stock, including the risks described in this section titled "Risk Factors" and the following:

- announcements of data from, or material developments in, our clinical studies and those of our collaboration partners, including data regarding efficacy and safety, delays in clinical development, regulatory approval or commercial launch – in particular, data from clinical studies of bempegaldesleukin has had a significant impact on our stock price;
- the timing of outcomes from our clinical trials which can be difficult to predict particularly for clinical studies that have event-driven end points such as progression-free survival and overall survival;
- announcements by collaboration partners as to their plans or expectations related to biologic candidates and approved biologics in which we have a substantial economic interest;
- announcements regarding terminations or disputes under our collaboration agreements;
- fluctuations in our results of operations;
- developments in patent or other proprietary rights, including intellectual property litigation or entering into intellectual property license agreements and the costs associated with those arrangements;
- announcements of technological innovations or new therapeutic products that may compete with our approved partnered products or products under development;
- announcements of changes in governmental regulation affecting us or our competitors;
- litigation brought against us or third parties to whom we have indemnification obligations;
- public concern as to the safety of drug formulations developed by us or others;
- our financing needs and activities; and
- general market conditions.

At times, our stock price has been volatile even in the absence of significant news or developments. The stock prices of biotechnology companies and securities markets generally have been subject to dramatic price swings in recent years.

***We have implemented certain anti-takeover measures, which make it more difficult to acquire us, even though such acquisitions may be beneficial to our stockholders.***

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even though such acquisitions may be beneficial to our stockholders. These anti-takeover provisions include:

- establishment of a classified board of directors such that not all members of the board may be elected at one time;
- lack of a provision for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;

- the ability of our board to authorize the issuance of “blank check” preferred stock to increase the number of outstanding shares and thwart a takeover attempt;
- prohibition on stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;
- establishment of advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings; and
- limitations on who may call a special meeting of stockholders.

Further, provisions of Delaware law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from acquiring us. These provisions may also discourage, delay or prevent a third party from acquiring a large portion of our securities or initiating a tender offer or proxy contest, even if our stockholders might receive a premium for their shares in the acquisition over the then-current market prices. We also have a change of control severance benefit plan, which provides for certain cash severance, stock award acceleration and other benefits in the event our employees are terminated (or, in some cases, resign for specified reasons) following an acquisition. This severance plan could discourage a third party from acquiring us.

## General Risk Factors

***We significantly rely on information technology systems, and any failure, inadequacy, interruption, breach, or security lapse of that technology within our internal computer systems, or those of our partners, vendors, CROs, CMOs or other contractors or consultants, may result in a material disruption of our development programs and our operations.***

As part of our business, we collect, store and transmit large amounts of confidential information, proprietary data, intellectual property and personal data. Despite the implementation of security measures, our internal computer systems and those of our partners, vendors, contract research organizations (CROs), contract manufacturing organizations (CMOs) and other contractors and consultants are vulnerable to loss, damage, denial-of-service, unauthorized access, or misappropriation. Such cybersecurity breaches may be the result of unauthorized activity by our employees and contractors, as well as by third parties who use cyberattack techniques involving malware, hacking and phishing, among others. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of an increase in the number of employees adopting a remote working environment during the COVID-19 pandemic, which may be less secure and more susceptible to hacking attacks. Our information technology systems, and those of our partners, vendors, CROs, CMOs or other contractors or consultants are also vulnerable to natural disasters, terrorism, war and telecommunication and electrical failures. Any such compromise or disruption, no matter the origin, may cause an interruption of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our biologic candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. In addition, the loss, corruption or unauthorized disclosure of our trade secrets, personal data or other proprietary or sensitive information could compromise the commercial viability of one or more of our programs, which would negatively affect our business. Also, the costs to us to investigate and mitigate cybersecurity incidents could be significant.

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

Our business is subject to numerous international, federal, state, and other governmental laws, rules, and regulations that may adversely affect our operating results, including, taxation and tax policy changes, tax rate changes, new tax laws, or revised tax law interpretations, which individually or in combination may cause our effective tax rate to increase. In the U.S., the rules dealing with federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, the CARES Act was signed into law and included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

***The United Kingdom’s withdrawal from the EU may have a negative effect on global economic conditions, access to patient markets, and regulatory certainty, which could adversely affect our operations.***

Effective January 31, 2020, the U.K. ceased to be a member state of the EU, a process known as Brexit, and began a transition period, which expired on December 31, 2020.

In December 2020, the U.K. and the EU agreed on a trade and cooperation agreement, under which the EU and the U.K. will now form two separate markets governed by two distinct regulatory and legal regimes. The trade and cooperation agreement

covers the general objectives and framework of the relationship between the U.K. and the EU, including as it relates to trade, transport and visas. Under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire EU single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the EU. Depending on the application of the terms of the trade and cooperation agreement, we, our collaboration partners and others could face new regulatory costs and challenges.

***Global economic and political conditions may negatively affect us and may magnify certain risks that affect our business.***

Our operations and performance have been, and may continue to be, affected by global economic conditions, including, for example, adverse global economic conditions resulting from the COVID-19 pandemic. See also the risk factor in this Item 1A titled “*Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic.*” In addition, our operations and performance may be affected by political or civil unrest or military action, terrorist activity, and unstable governments and legal systems. For example, in late February 2022, Russia commenced a military invasion of Ukraine, and the sustained conflict in Ukraine, including the potential effects of sanctions and retaliatory cyber-attacks on the world economy and markets, has contributed to increased market volatility and uncertainty. In particular, sanctions imposed by the U.S., EU and other countries in response to the conflict between Russia and Ukraine and the potential response to such sanctions may have an adverse impact on our business, including our clinical trials, the financial markets and the global economy. As the conflict in Ukraine continues, there can be no certainty regarding whether the U.S., EU or other governments will impose additional sanctions, or other economic or military measures relating to Russia.

As a result of global economic and political conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients’ ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. Our ability to conduct clinical trials in regions experiencing political or civil unrest could negatively affect clinical trial enrollment or the timely completion of a clinical trial. We believe the aforementioned economic conditions have led and could continue to lead to reduced demand for our and our collaboration partners’ drug products, which could have a material adverse effect on our product sales, business and results of operations.

Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs that result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the U.S. Tariffs, trade restrictions or sanctions imposed by the U.S. or other countries could increase the prices of our and our collaboration partners’ drug products, affect our and our collaboration partners’ ability to commercialize such drug products, or create adverse tax consequences in the U.S. or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the U.S. or other countries could materially adversely affect our results of operations and financial condition.

***Our business could be negatively impacted by corporate citizenship and sustainability matters.***

There is an increased focus from certain investors, employees, and other stakeholders concerning corporate citizenship and sustainability matters, which include environmental concerns and social investments. We could fail to meet, or be perceived to fail to meet, the expectations of these certain investors, employees and other stakeholders concerning corporate citizenship and sustainability matters, thereby resulting in a negative impact to our business.

***If earthquakes or other catastrophic events strike, our business may be harmed.***

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the San Francisco Bay Area, a region known for seismic activity and a potential terrorist target. In addition, we own facilities for the manufacture of products using our advanced polymer conjugate technologies in Huntsville, Alabama and own and lease offices in Hyderabad, India. There are no backup facilities for our manufacturing operations located in Huntsville, Alabama. In the event of an earthquake or other natural disaster, political instability, or terrorist event in any of these locations, our ability to manufacture and supply materials for biologic candidates in development and our ability to meet our manufacturing obligations to our customers would be significantly disrupted and our business, results of operations and financial condition would be harmed. Our collaboration partners and important vendors and suppliers to us or our collaboration partners may also be subject to catastrophic events, such as earthquakes, floods, hurricanes, tornadoes and pandemics any of which could harm our business (including, for example, by disrupting supply chains important to the success of our business), results of operations and financial condition. We have not undertaken a systematic analysis of the potential consequences to our business, results of operations and financial condition from a major earthquake or other catastrophic event, such as a fire, sustained loss of power, terrorist activity or other disaster, and do not have a recovery plan for such disasters. In addition, our insurance coverage may not be sufficient to compensate us for actual losses from any interruption of our business that may occur.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None, including no purchases of any class of our equity securities by us or any affiliate pursuant to any publicly announced repurchase plan in the three months ended March 31, 2022.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

Except as so indicated in Exhibit 32.1, the following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

<u>Exhibit Number</u>	<u>Description of Documents</u>
3.1(1)	<a href="#">Certificate of Incorporation of Inhale Therapeutic Systems (Delaware), Inc.</a>
3.2(2)	<a href="#">Certificate of Amendment of the Amended Certificate of Incorporation of Inhale Therapeutic Systems, Inc.</a>
3.3(3)	<a href="#">Certificate of Ownership and Merger of Nektar Therapeutics.</a>
3.4(4)	<a href="#">Certificate of Ownership and Merger of Nektar Therapeutics AL, Corporation with and into Nektar Therapeutics.</a>
3.5(5)	<a href="#">Amended and Restated Bylaws of Nektar Therapeutics.</a>
31.1(6)	<a href="#">Certification of Nektar Therapeutics' principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>
31.2(6)	<a href="#">Certification of Nektar Therapeutics' principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>
32.1*	<a href="#">Section 1350 Certifications.</a>
101.SCH(6)	Inline XBRL Taxonomy Extension Schema Document.
101.CAL(6)	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB(6)	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE(6)	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF(6)	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104(6)	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

1. Incorporated by reference to Exhibit 3.1 to Nektar Therapeutics' Quarterly Report on Form 10-Q, for the quarter ended June 30, 1998.
2. Incorporated by reference to Exhibit 3.3 to Nektar Therapeutics' Quarterly Report on Form 10-Q, for the quarter ended June 30, 2000.
3. Incorporated by reference to Exhibit 3.1 to Nektar Therapeutics' Current Report on Form 8-K, filed with the SEC on January 23, 2003.
4. Incorporated by reference to Exhibit 3.6 to Nektar Therapeutics' Annual Report on Form 10-K, for the year ended December 31, 2009.
5. Incorporated by reference to Exhibit 3.1 to Nektar Therapeutics' Current Report on Form 8-K, filed with the SEC on December 21, 2020.
6. Filed herewith.

\* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as otherwise stated in such filing.



## CERTIFICATIONS

I, Howard W. Robin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2022 of Nektar Therapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/s/ HOWARD W. ROBIN

**Howard W. Robin**  
**Chief Executive Officer, President and Director**

## CERTIFICATIONS

I, Gil M. Labrucherie, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2022 of Nektar Therapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/s/ GIL M. LABRUCHERIE

**Gil M. Labrucherie**  
**Senior Vice President, Chief Operating Officer, and Chief**  
**Financial Officer**



## SECTION 1350 CERTIFICATIONS\*

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Howard W. Robin, Chief Executive Officer, President and Director of Nektar Therapeutics (the “Company”), and Gil M. Labrucherie, Senior Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the three months ended March 31, 2022, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2022

/s/ HOWARD W. ROBIN

**Howard W. Robin**  
**Chief Executive Officer, President and Director**

/s/ GIL M. LABRUCHERIE

**Gil M. Labrucherie**  
**Senior Vice President, Chief Operating Officer, and Chief Financial Officer**

\* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.