

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, 2021

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)	Trading symbol(s)
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.

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

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

Indicate by check mark whether the registrant is a shell company (as defined 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 182,308,999 on April 30, 2021.

**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 (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). 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 regarding potential future financing alternatives, any statements concerning proposed drug candidates, 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, timing of commercial launches 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, any statements concerning estimates and predictions of the COVID-19 pandemic's impact on our business and clinical trials 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 “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 II, 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 terms “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:**
  - we are highly dependent on the success of bempegaldesleukin, our lead immuno-oncology (I-O) candidate, and our business will be significantly harmed if we are not successful in developing this drug candidate;
  - 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 pipeline;
  - significant competition for our polymer conjugate chemistry technology platforms and our partnered and proprietary 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 Collaboration Partners:**
  - we are highly dependent on our collaboration partners to initiate, properly conduct and prioritize clinical trials for bempegaldesleukin and 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; and
  - the operations of our collaboration partners may be more 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 Requirements:**
  - 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;
  - if the market size for a new drug that received approval is significantly smaller than we anticipate, it could negatively impact our revenue, results of operations and financial condition;
  - if third-party payers (including government programs) do not provide payment or reimbursement for our products, those products will not be widely accepted, which would negatively impact our business, results of operations and financial condition; and
  - 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.
- **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.
- **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 negatively 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 Business Operations:** If we are unable to create robust sales, marketing and distribution capabilities or to enter into agreements with third parties to perform these functions, we will be unable to commercialize our drug candidates successfully.
- **Risks Related to Intellectual Property, Litigation and Regulatory Concerns:**
  - we may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to drug candidates granted Breakthrough Therapy designation by the United States Food and Drug Administration (FDA);
  - we or our partners may not obtain regulatory approval for our drug candidates on a timely basis, or at all; and
  - 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 on commercially reasonable terms.

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, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 150,164	\$ 198,955
Short-term investments	887,152	862,941
Accounts receivable	29,156	38,889
Inventory	16,808	15,292
Other current assets	15,771	21,928
Total current assets	1,099,051	1,138,005
Long-term investments	96,093	136,662
Property, plant and equipment, net	58,510	59,662
Operating lease right-of-use assets	124,971	126,476
Goodwill	76,501	76,501
Other assets	1,435	1,461
Total assets	<u>\$ 1,456,561</u>	<u>\$ 1,538,767</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	22,434	22,139
Accrued compensation	23,513	14,532
Accrued clinical trial expenses	41,028	44,207
Accrued contract manufacturing expenses	6,057	11,310
Other accrued expenses	14,833	9,676
Operating lease liabilities, current portion	15,768	13,915
Total current liabilities	123,633	115,779
Operating lease liabilities, less current portion	134,556	136,373
Development derivative liability	4,597	—
Liabilities related to the sales of future royalties, net	195,139	200,340
Other long-term liabilities	4,130	8,980
Total liabilities	462,055	461,472
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares designated or outstanding at March 31, 2021 or December 31, 2020	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized; 182,290 shares and 180,091 shares outstanding at March 31, 2021 and December 31, 2020, respectively	18	18
Capital in excess of par value	3,429,734	3,388,730
Accumulated other comprehensive loss	(3,121)	(2,295)
Accumulated deficit	(2,432,125)	(2,309,158)
Total stockholders' equity	994,506	1,077,295
Total liabilities and stockholders' equity	<u>\$ 1,456,561</u>	<u>\$ 1,538,767</u>

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)

	Three months ended March 31,	
	2021	2020
<b>Revenue:</b>		
Product sales	\$ 4,795	\$ 3,444
Royalty revenue	—	9,719
Non-cash royalty revenue related to sale of future royalties	18,798	9,895
License, collaboration and other revenue	54	27,515
<b>Total revenue</b>	<b>23,647</b>	<b>50,573</b>
<b>Operating costs and expenses:</b>		
Cost of goods sold	5,756	3,811
Research and development	95,604	108,987
General and administrative	31,679	26,217
Impairment of assets and other costs for terminated program	—	45,189
<b>Total operating costs and expenses</b>	<b>133,039</b>	<b>184,204</b>
Loss from operations	(109,392)	(133,631)
<b>Non-operating income (expense):</b>		
Non-cash interest expense on liability related to sale of future royalties	(13,296)	(6,968)
Change in fair value of development derivative liability	(1,599)	—
Interest income and other income (expense), net	1,412	8,352
Interest expense	—	(6,204)
<b>Total non-operating income (expense), net</b>	<b>(13,483)</b>	<b>(4,820)</b>
Loss before provision for income taxes	(122,875)	(138,451)
Provision for income taxes	92	200
<b>Net loss</b>	<b>\$ (122,967)</b>	<b>\$ (138,651)</b>
Basic and diluted net loss per share	\$ (0.68)	\$ (0.78)
Weighted average shares outstanding used in computing basic and diluted net loss per share	181,370	177,185

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)**

	<b>Three months ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Net loss	\$ (122,967)	\$ (138,651)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale investments	(766)	(5,121)
Net foreign currency translation gain (loss)	(60)	(751)
Other comprehensive income (loss)	(826)	(5,872)
Comprehensive loss	<u>\$ (123,793)</u>	<u>\$ (144,523)</u>

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, 2019	176,505	\$ 17	\$ 3,271,097	\$ (1,005)	\$ (1,864,718)	\$ 1,405,391
Shares issued under equity compensation plans	1,358	—	11,347	—	—	11,347
Stock-based compensation	—	—	24,211	—	—	24,211
Comprehensive loss	—	—	—	(5,872)	(138,651)	(144,523)
Balance at March 31, 2020	<u>177,863</u>	<u>\$ 17</u>	<u>\$ 3,306,655</u>	<u>\$ (6,877)</u>	<u>\$ (2,003,369)</u>	<u>\$ 1,296,426</u>

	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 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>

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	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (122,967)	\$ (138,651)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(18,798)	(9,895)
Non-cash interest expense on liability related to sale of future royalties	13,296	6,968
Change in fair value of development derivative liability	1,599	—
Non-cash research and development expense	2,248	—
Stock-based compensation	23,898	25,236
Depreciation and amortization	3,543	4,502
Impairment of advance payments to contract manufacturers and equipment for terminated program	—	20,351
Amortization of premiums (discounts), net and other non-cash transactions	2,345	(1,289)
Changes in operating assets and liabilities:		
Accounts receivable	9,733	(5,229)
Inventory	(1,516)	(1,655)
Operating leases, net	1,541	2,940
Other assets	6,183	1,067
Accounts payable	779	2,687
Accrued compensation	8,981	9,920
Other accrued expenses	(7,345)	7,483
Deferred revenue	(605)	(2,510)
Net cash used in operating activities	<u>(77,085)</u>	<u>(78,075)</u>
<b>Cash flows from investing activities:</b>		
Purchases of investments	(295,314)	(241,068)
Maturities of investments	303,612	439,735
Sales of investments	5,036	—
Purchases of property, plant and equipment	(2,876)	(900)
Net cash provided by investing activities	<u>10,458</u>	<u>197,767</u>
<b>Cash flows from financing activities:</b>		
Proceeds from shares issued under equity compensation plans	17,106	11,077
Cash receipts from development derivative liability	750	—
Net cash provided by financing activities	<u>17,856</u>	<u>11,077</u>
Effect of foreign exchange rates on cash and cash equivalents	(20)	(97)
Net increase (decrease) in cash and cash equivalents	<u>(48,791)</u>	<u>130,672</u>
Cash and cash equivalents at beginning of period	198,955	96,363
Cash and cash equivalents at end of period	<u>\$ 150,164</u>	<u>\$ 227,035</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 4,951</u>
Operating lease right-of-use asset recognized in exchange for lease liabilities	<u>\$ 1,057</u>	<u>\$ 2,133</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, 2021**  
**(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 leverage our proprietary and proven 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 potential therapies for oncology, immunology and virology.

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. At March 31, 2021, we had approximately \$1.1 billion in cash and investments in marketable securities.

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

Our Condensed Consolidated Financial Statements include the financial position, results of operations and cash flows of our wholly-owned subsidiaries: Inheris Biopharma, Inc. (Inheris), Nektar Therapeutics (India) Private Limited (Nektar India), Nektar Therapeutics UK Limited, and Nektar Therapeutics NL B.V. 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 income (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 holding 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, 2021 and 2020.

The accompanying Condensed Consolidated Financial Statements are unaudited. The Condensed Consolidated Balance Sheet data as of December 31, 2020 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, 2020 filed with the SEC on February 26, 2021. 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, 2020.

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 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 our estimates each period, update them to reflect current information and generally recognize any changes in such estimates in the period first identified.

### ***Reclassifications***

Certain items previously reported in specific financial statement captions have been reclassified to conform to the current period presentation. Such reclassifications do not materially impact previously reported revenue, operating loss, net loss, total assets, liabilities or stockholders' equity.

### ***Segment Information***

We operate in one business segment which focuses on applying our technology platform to develop novel drug candidates. Our business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. We are comprehensively managed as one business segment by our Chief Executive Officer.

### ***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, 2021, our accounts receivable includes \$26.2 million for unbilled net expense reimbursements from our collaboration partner Bristol-Myers Squibb Company (BMS) and \$2.9 million under customer contracts from our collaboration partners. As of December 31, 2020, our accounts receivable included \$38.7 million for unbilled net expense reimbursements from BMS and \$0.2 million from customer contracts. 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, 2021 and 2020. We have not recorded a reserve for credit losses at March 31, 2021 or December 31, 2020.

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 industry. While our investment policy requires that we only invest in highly-rated securities and limit our exposure to any single issuer, a deterioration in this industry could have a material effect on our results of operations and financial position. 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 factors, including the effects of the COVID-19 pandemic, 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 proprietary 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 proprietary 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.

### **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, which include commercial milestone payments based on the level of sales. Accordingly, we recognize royalty revenue, including for our non-cash royalties, when the underlying sales occur based on our best estimates of sales of the drugs. Our partners generally pay royalties or commercial milestones 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 after 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 for our proprietary drug candidates and technology development and for certain third parties under collaboration agreements. For our proprietary 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 costs of our clinical trial 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 accrue costs associated with the start-up and reporting phases of the clinical trials ratably over the estimated duration of the start-up and reporting phases. We generally accrue costs associated with the treatment phase of clinical trials based on the estimated activities performed by third parties. 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 based on patient enrollment in the trials. In specific circumstances, such as for certain time-based costs, we recognize clinical trial expenses using a methodology that we consider to 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 is 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.

### ***Impairment of Assets and Other Costs for Terminated Program***

On January 14, 2020, the joint FDA Anesthetic Drug Products Advisory Committee and Drug Safety and Risk Management Committee did not recommend approval of our NDA for NKTR-181. As a result, we withdrew our NDA and decided to make no further investments in this program. As a result, in the three months ended March 31, 2020, we wrote off \$19.7 million of advance payments to contract manufacturers for commercial batches of NKTR-181. We also incurred \$25.5 million of additional costs, primarily for non-cancellable commitments to our contract manufacturers and certain severance costs. We present these costs in the Impairment of assets and other costs for terminated program line in our Condensed Consolidated Statement of Operations.

### ***Income Taxes***

For the three months ended March 31, 2021 and 2020, our income tax expense primarily results from taxable income in our Nektar India subsidiary. We have fully reserved our U.S. federal deferred tax assets generated from our net operating losses, as we believe it is not more likely than not that the benefit will be realized.

### ***Shelf Registration***

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.

### **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, 2021	December 31, 2020
Cash and cash equivalents	\$ 150,164	\$ 198,955
Short-term investments	887,152	862,941
Long-term investments	96,093	136,662
Total cash and investments in marketable securities	<u>\$ 1,133,409</u>	<u>\$ 1,198,558</u>

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, 2021 and December 31, 2020, 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):

	March 31, 2021			December 31, 2020	
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Fair Value
Corporate notes and bonds	\$ 510,521	\$ 313	\$ (171)	\$ 510,663	\$ 687,469
Corporate commercial paper	478,448	35	(41)	478,442	313,497
Obligations of U.S. government agencies	4,880	4	—	4,884	2,382
Available-for-sale investments	\$ 993,849	\$ 352	\$ (212)	\$ 993,989	\$ 1,003,348
Money market funds				123,607	179,302
Certificates of deposit				8,254	9,623
Cash				7,559	6,285
Total cash and investments in marketable securities				\$ 1,133,409	\$ 1,198,558

At December 31, 2020, our gross unrealized gains and losses totaled \$1.1 million and \$0.2 million, respectively.

### Note 3 — Inventory

Inventory consists of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	\$ 1,920	\$ 2,422
Work-in-process	13,082	10,703
Finished goods	1,806	2,167
Total inventory	\$ 16,808	\$ 15,292

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. Before the regulatory approval of our drug candidates, we recognize research and development expense for the manufacture of drug products that could potentially be available to support the commercial launch of our drug candidates, if approved.

### 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., an SFJ Pharmaceuticals Group company (SFJ), pursuant to which SFJ will 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 Pharmaceuticals is a global drug development company backed by Blackstone Life Sciences and Abingworth. On February 11, 2021, we entered into a collaboration agreement with MSD International GmbH (MSD), an affiliate of Merck, Sharp & Dohme, pursuant to which MSD will provide Keytruda® at no cost for use in the SCCHN Clinical Trial but will not bear any other costs of the trial.

SFJ will have primary responsibility for the clinical trial management of the SCCHN Clinical Trial, and we will be the sponsor of the SCCHN Clinical Trial and will also have sole responsibility for regulatory interactions and filings for bempegaldesleukin. The SCCHN Clinical Trial provides for an interim futility analysis, and unless the futility criteria are met, SFJ is required to complete the SCCHN Trial, but if the futility criteria is met, SFJ has the responsibility to wind down the SCCHN Clinical Trial at its sole cost. We and BMS, pursuant to the BMS Collaboration Agreement, remain solely responsible for conducting the Phase 3 clinical trials of bempegaldesleukin in combination with Opdivo®, including the treatment of previously untreated unresectable or metastatic melanoma (the “Melanoma Indication” and the “Melanoma Clinical Trial”).



Other than the opportunity to receive Success Payments as outlined below, SFJ has no right to reimbursement of costs incurred by SFJ for the SCCHN Clinical Trial in the event that the Melanoma Clinical Trial and the SCCHN Clinical Trial do not achieve FDA approval. We will pay SFJ a series of success-based annual payments (collectively, the Success Payments) in the event of FDA approval of bempegaldesleukin for the Melanoma Indication, the SCCHN Indication, or both, and in the event of FDA approval of one additional bempegaldesleukin indication. The Success Payments do not begin until the substantial completion of the SCCHN Clinical Trial. The total success-based annual payments for the first indication approved by FDA, whether for the Melanoma Indication or the SCCHN Indication, is an aggregate of \$450.0 million, paid in annual contractual payments over five years, with the first payment being \$30.0 million, with the earliest possible payment expected to occur in late 2024 or early 2025, subject to the substantial completion of the SCCHN Clinical Trial. The total success-based payments for the second indication approved by FDA, whether for the Melanoma Indication or the SCCHN Indication, is an aggregate of \$150.0 million, paid in annual contractual payments over seven years. Finally, in the event of FDA approval for bempegaldesleukin for any indication other than the Melanoma Indication or the SCCHN Indication, we will make a one-time payment of \$37.5 million to SFJ. If the success criterion for the interim futility analysis is not met and SFJ winds down the SCCHN Clinical Trial, then the Success Payments, if any, for the Melanoma Indication and/or the additional bempegaldesleukin indication are reduced pro rata based on the costs incurred by SFJ for the SCCHN Clinical Trial over the aggregate commitment of \$150.0 million.

The SFJ Agreement provides for certain positive and negative covenants, including restrictions on our ability to incur liens on our intellectual property related to bempegaldesleukin (the bempegaldesleukin IP), or assign or convey any right to receive income with respect to the bempegaldesleukin IP (other than royalty and other license fee obligations to licensors), except for the issuance of senior secured debt secured by all or substantially all of our assets, including the bempegaldesleukin IP.

The SFJ Agreement expires upon the payment of all Success Payments to SFJ, unless earlier terminated as provided under the SFJ Agreement. The SFJ Agreement may be terminated by either party for a safety or health concern for the patients, whether by the independent data monitoring company or by mutual agreement of both parties. The SFJ Agreement may also be terminated by either party for material breach or insolvency of the counterparty.

We present the SFJ Agreement as development derivative liability in our Condensed Consolidated Balance Sheets, which we remeasure to fair value at each reporting date. As SFJ conducts the SCCHN Clinical Trial, we record non-cash research and development expense with a corresponding increase to the development derivative liability, and as SFJ remits funding to us to support our internal costs of conducting the trial, we also record a corresponding increase to the development derivative liability. We present the gain (loss) from the remeasurement as Change in fair value of development derivative liability in our Condensed Consolidated Statement of Operations. The following table presents the changes in the development derivative liability from inception on February 12, 2021 to March 31, 2021:

	<b>Three Months Ended March 31, 2021</b>
Fair value at inception on February 12, 2021	\$ —
Non-cash research and development expense	2,248
Cash receipts from SFJ	750
Change in the fair value of development derivative liability	1,599
Fair value at March 31, 2021	<u>\$ 4,597</u>

We valued the derivative using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and we discount such cash flows to present value using a risk-adjusted rate. The key inputs to the valuation include our estimates of the following: (i) the probability and timing of achieving FDA approval in the Melanoma Indication, the SCCHN Indication and any other bempegaldesleukin indication, (ii) the timing of the substantial completion of the SCCHN Clinical Trial that SFJ must achieve before receiving a Success Payment, (iii) the probability of termination of the study due to meeting the interim futility criteria, (iv) the amount of costs incurred by SFJ if the success criterion for the interim futility analysis is not met, (v) SFJ's cost of borrowing (1.0%), and (vi) the Company's imputed cost of borrowing for debt with similar terms (12.2%).

#### **Note 5 — Liability Related to Sale of Future Royalties**

On February 24, 2012, we entered into a purchase and sale agreement (the 2012 Purchase and Sale Agreement) with RPI Finance Trust (RPI), an affiliate of Royalty Pharma, pursuant to which we sold, and RPI purchased, our right to receive royalty payments (the 2012 Transaction Royalties) arising from the worldwide net sales, from and after January 1, 2012, of (a) CIMZIA<sup>®</sup>,

under our license, manufacturing and supply agreement with UCB Pharma (UCB), and (b) MIRCERA<sup>®</sup>, under our license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (together referred to as Roche). We received aggregate cash proceeds of \$124.0 million for the 2012 Transaction Royalties. As part of this sale, we incurred approximately \$4.4 million in transaction costs, which are amortized to interest expense over the estimated life of the 2012 Purchase and Sale Agreement. Although we sold all of our rights to receive royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products, as a result of our ongoing manufacturing and supply obligations related to the generation of these royalties, we continue to account for these royalties as revenue. We recorded the \$124.0 million in proceeds from this transaction as a liability (the 2012 Royalty Obligation) that is amortized using the interest method over the estimated life of the 2012 Purchase and Sale Agreement as royalties from the CIMZIA<sup>®</sup> and MIRCERA<sup>®</sup> products are remitted directly to RPI.

On December 16, 2020, we entered into a purchase and sale agreement (the 2020 Purchase and Sale Agreement) with entities managed by Healthcare Royalty Management, LLC (collectively, HCR). Pursuant to the 2020 Purchase and Sale Agreement, we agreed to sell to HCR certain of our rights to receive royalty payments (the 2020 Transaction Royalties) arising from the worldwide net sales, from and after October 1, 2020 until such time certain return thresholds are met as described below, of (a) MOVANTIK<sup>®</sup> under that certain License Agreement, dated September 20, 2009, by and between Nektar and AstraZeneca AB (AstraZeneca), as amended, (b) ADYNOVATE<sup>®</sup> under that certain Exclusive Research, Development, License and Manufacturing and Supply Agreement, dated September 26, 2005, by and among Nektar, Baxalta US Inc. and Baxalta GmbH (collectively, Baxalta), as amended, (c) REBINYN<sup>®</sup> under that certain Settlement and License Agreement, dated December 21, 2016, by and among Nektar, Novo Nordisk Inc., Novo Nordisk A/S and Novo Nordisk A/G (collectively, Novo Nordisk) and (d) licensed products under that certain Right to Sublicense Agreement, dated October 27, 2017, by and among Nektar, Baxter Incorporated, Baxalta US Inc. and Baxalta GmbH.

The 2020 Purchase and Sale Agreement will automatically expire, and the payment of the 2020 Transaction Royalties to HCR will cease, when HCR has received payments of the 2020 Transaction Royalties equal to \$210.0 million (the 2025 Threshold), if the 2025 Threshold is achieved on or prior to December 31, 2025, or \$240.0 million, if the 2025 Threshold is not achieved on or prior to December 31, 2025 (or, if earlier, the date on which the last royalty payment under the relevant license agreements is made). If HCR has received payments of the 2020 Transaction Royalties equal to at least \$208.0 million on or prior to December 31, 2025, we have the option to pay the difference between the 2025 Threshold and such 2020 Transaction Royalties, and the 2025 Threshold will be met and the 2020 Purchase and Sale Agreement will expire. After the 2020 Purchase and Sale Agreement expires, all rights to receive the 2020 Transaction Royalties return to Nektar.

On December 30, 2020, we received aggregate cash proceeds of \$150.0 million for the 2020 Transaction Royalties. As part of the sale, we incurred approximately \$3.8 million in transaction costs, which are amortized to interest expense over the estimated life of the 2020 Purchase and Sale Agreement. Although we sold all of our rights to receive royalties from these products, as a result of the limits on the 2020 Transaction Royalties to be received by HCR and our ongoing manufacturing and supply obligations related to the generation of these royalties, we will continue to account for these non-cash royalties as revenue, commencing with royalties for the three months ended December 31, 2020, which HCR received in the three months ended March 31, 2021. We recorded the \$150.0 million in proceeds from this transaction as a liability (the 2020 Royalty Obligation) that will be amortized using the effective interest method over the estimated life of the 2020 Purchase and Sale Agreement.

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. 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 than our original estimates, we will prospectively adjust the imputed interest rate and the related amortization of the applicable Royalty Obligation.

The following table presents our estimates of the annual interest rates over the lives of the agreements and the resulting prospective interest rates used to recognize non-cash interest expense for the three months ended March 31, 2021 and 2020.

	2012 Purchase and Sale Agreement		2020 Purchase and Sale Agreement
	Three months ended March 31,		Three months ended March 31,
	2021	2020	2021
Interest rates - end of period presented			
Implicit interest rate over the life of the agreement	20.2 %	19.5 %	16.0 %
Prospective effective interest rate	48.0 %	38.0 %	16.0 %

In addition, the 2012 and 2020 Purchase and Sale Agreements grant RPI and HCR, respectively, the right to receive certain reports and other information relating to the 2012 and 2020 Transaction Royalties, respectively, and contain other representations and warranties, covenants and indemnification obligations that are customary for transactions of this nature. To our knowledge, we are currently in compliance with these provisions of the 2012 and 2020 Purchase and Sale Agreements; however, if we were to breach our obligations, we could be required to pay damages to RPI and HCR, respectively, that are not limited to the purchase prices we received in the sale 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.

## **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 of 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—66-7-HSG, which we refer to as the Mulquin action). The Mulquin plaintiffs have challenged public statements Nektar made about clinical trials of bempegaldesleukin between January 2017 and June 2018. 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 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 is expected to be completed by September 2021.

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 (Mulquin and Damiba), three 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 officer and directors breached 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 U.S. District Court for the Northern District of California (Case No. 4:20-cv-01088-JSW). The derivative actions in California have been consolidated and the Company has moved to dismiss on the basis that the plaintiffs have neither made a demand on the Company's board of directors nor shown that demand would be futile. The Company's motion to dismiss has been under submission since December 2020.

An additional derivative complaint was filed in February 2021 in the Court of Chancery of the State of Delaware (C.A. No. 2021-0118-PAF). No response to the complaint is due until May 2021.

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 Condensed Consolidated Balance Sheets at either March 31, 2021 or December 31, 2020.

### ***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 any time 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, including our obligation to RPI described in Note 5. In the event it is determined that we breached certain of the representations and warranties or covenants made by us in any such agreements, we could incur substantial indemnification liabilities depending on the timing, nature, and amount of any such claims.

To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations, representations or warranties. 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. We have recorded no liabilities for these obligations in our Condensed Consolidated Balance Sheets at either March 31, 2021 or December 31, 2020.

#### Note 7 — Fair Value Measurement

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis and indicates the level of the fair value hierarchy and the valuation techniques we utilized to determine such fair value:

	As of March 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Corporate notes and bonds	\$ —	\$ 510,663	\$ —	\$ 510,663
Corporate commercial paper	—	478,442	—	478,442
Obligations of U.S. government agencies	—	4,884	—	4,884
Money market funds	123,607	—	—	123,607
Total assets	\$ 123,607	\$ 993,989	\$ —	\$ 1,117,596
<b>Liabilities:</b>				
Development derivative liability	\$ —	\$ —	\$ 4,597	\$ 4,597
	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Corporate notes and bonds	\$ —	\$ 687,469	\$ —	\$ 687,469
Corporate commercial paper	—	313,497	—	313,497
Obligations of U.S. government agencies	—	2,382	—	2,382
Money market funds	179,302	—	—	179,302
Total assets	179,302	\$ 1,003,348	\$ —	\$ 1,182,650
<b>Liabilities:</b>				
Development derivative liability	\$ —	\$ —	\$ —	\$ —

*Level 1* — Quoted prices in active markets for identical assets or liabilities.

*Level 2* — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

We use a market approach to value our Level 2 investments. The disclosed fair value related to our investments is based on market prices from a variety of industry standard data providers and generally represents quoted prices

for similar assets in active markets or has been derived from observable market data. For the three months ended March 31, 2021, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

*Level 3* — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. For the reconciliation of the changes in the development derivative liability and the description of the significant inputs used in estimating its fair value, see Note 4.

#### Note 8 — 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.

In accordance with our collaboration agreements, we recognized license, collaboration and other revenue as follows (in thousands):

Partner	Drug Candidate	Three months ended March 31,	
		2021	2020
Bristol-Myers Squibb Company	Bempegaldesleukin	\$ —	\$ 25,000
Eli Lilly and Company	NKTR-358	—	1,259
Other		54	1,256
	License, collaboration and other revenue	\$ 54	\$ 27,515

During the three months ended March 31, 2021 and 2020, we recognized \$18.8 million and \$44.6 million, respectively, of revenue for performance obligations that we had satisfied in prior periods. This amount includes all of our royalty revenue and non-cash royalty revenue, as well as the \$25.0 million milestone received under our BMS Collaboration Agreement during the three months ended March 31, 2020 described below, because we had previously completed our performance obligations of granting the licenses.

As of March 31, 2021, our collaboration agreements with partners included potential future payments for development and regulatory milestones totaling approximately \$1.7 billion, including amounts from our agreements with BMS and Eli Lilly and Company described below. In addition, under our collaboration agreements we are entitled to receive contingent sales milestone payments, other contingent payments and royalty payments, as described below.

There have been no material changes to our collaboration agreements in the three months ended March 31, 2021.

#### **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 are jointly developing bempegaldesleukin, including, without limitation, in combination with BMS's Opdivo® (nivolumab), and other compounds of BMS, us or any third party. The parties have agreed to jointly commercialize bempegaldesleukin on a worldwide basis. We retained the right to record all worldwide sales for bempegaldesleukin. We will share global commercialization profits and losses with BMS for bempegaldesleukin, with Nektar sharing 65% and BMS sharing 35% of the net profits and losses. 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 of bempegaldesleukin, 35% of costs to BMS and 65% to Nektar.

In April 2018, BMS paid us a non-refundable upfront cash payment of \$1.0 billion. We are eligible to receive additional cash payments up to a total of approximately \$1.455 billion (including the milestones which we have received under Amendment No. 1 described below) upon the achievement of certain development and regulatory milestones, and up to a total of

\$350.0 million upon the achievement of certain sales milestones. In April 2018, BMS also purchased 8,284,600 shares of our common stock pursuant to the Share Purchase Agreement for total additional cash consideration of \$850.0 million.

We determined that the BMS Collaboration Agreement falls within the scope of ASC 808, and we analogized to ASC 606 for the accounting for our performance obligation of the delivery of the licenses to develop and commercialize bempegaldesleukin.

During 2018, we aggregated the total consideration of \$1.85 billion received under the agreements and allocated it between the stock purchase and the revenue-generating elements, because we and BMS negotiated the agreements together and the effective date of the BMS Collaboration Agreement was dependent upon the effective date of the Share Purchase Agreement. We recorded the estimated fair value of the shares of \$790.2 million in stockholders' equity. We allocated the remaining \$1,059.8 million to the transaction price of the collaboration agreement, which we recognized in 2018. We consider the future potential development, regulatory and sales milestones to be variable consideration.

On January 9, 2020, we and BMS entered into Amendment No. 1 (the Amendment) to the BMS Collaboration Agreement. Pursuant to the Amendment, we and BMS agreed to update the Collaboration Development Plan under which we are collaborating and developing bempegaldesleukin. The cost sharing under the Amendment remains unchanged. We received a non-refundable, creditable milestone payment of \$25.0 million for the achievement of the first patient, first visit in the registrational muscle-invasive bladder cancer trial on January 30, 2020, which we recognized in the three months ended March 31, 2020. We have also received a non-refundable, non-creditable milestone payment of \$25.0 million for the achievement of the first patient, first visit in the registrational adjuvant melanoma trial on July 27, 2020. For the creditable milestone, BMS is entitled to deduct the amount paid from future development milestones due to us under the original agreement.

Other than these two milestones which we recognized during 2020, we continue to exclude the other milestones of up to \$1.8 billion from the transaction price as of March 31, 2021 due to the significant uncertainties involved with clinical development and regulatory approval. We re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

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 costs as a reduction of research and development expense and our reimbursement of BMS' costs as research and development expense. During the three months ended March 31, 2021 and 2020, we recorded \$26.7 million and \$30.7 million, respectively, as a reduction of research and development expense for BMS' share of our expenses, net of our share of BMS' expenses. As of March 31, 2021, we have recorded an unbilled receivable of \$26.2 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 with Eli Lilly and Company (Lilly), which became effective on August 23, 2017, to co-develop NKTR-358, a novel immunological drug candidate that we invented. Under the terms of the agreement, we (i) received an initial payment of \$150.0 million in September 2017 and are eligible for up to \$250.0 million in additional development milestones, (ii) will co-develop NKTR-358 with Lilly, for which we were responsible for completing Phase 1 clinical development and certain drug product development and supply activities, (iii) share with Lilly Phase 1B and 2 development costs with 75% of those costs borne by Lilly and 25% of the costs borne by us, (iv) will have the option to contribute funding to Phase 3 development on an indication-by-indication basis ranging from zero to 25% of development costs, and (v) 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 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 agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

We identified our license grant to Lilly, our Phase 1 clinical development obligation and our drug product development obligation as the significant performance obligations in the arrangement. Based on our estimates of the standalone selling prices of the performance obligations, we allocated the \$150.0 million upfront payment as \$125.9 million to the license, \$17.6 million to our portion of the Phase 1 clinical development and \$6.5 million to the drug product development. We recognized the revenue

allocated to the license upon the effective date of the license agreement in August 2017. We recognized revenue for our performance obligations for Phase 1 clinical development and drug product development through March 31, 2020.

Although we are entitled to significant development milestones under this arrangement, through March 31, 2021, 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, in 2012, we sold all of our rights to receive royalties for CIMZIA® under our collaboration with UCB and MIRCERA® under our collaboration agreement with Roche. Additionally, in 2020, we sold our rights to receive royalties for ADYNOVATE® under our collaboration with Baxalta (a subsidiary of Takeda Pharmaceutical Company Ltd.), MOVANTIK® under our collaboration with AstraZeneca and REBINYN® under license agreement with Novo Nordisk. The 2020 transaction provides for a cap, such that, if the cap is achieved, future royalties on these products will return to us. See Note 5 for additional information regarding these agreements.

Additionally, we have collaborations agreements for products under development, under which we are entitled to up to a total of \$40.0 million of development 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 products under these collaboration agreements, we cannot estimate the probability or timing of achieving these milestones, and, therefore, have excluded all development milestones from the respective transaction prices for these agreements.

### Note 9 — 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,	
	2021	2020
Cost of goods sold	\$ 727	\$ 761
Research and development	14,162	15,453
General and administrative	9,009	7,997
Impairment of assets and other costs for terminated program	—	1,025
Total stock-based compensation	\$ 23,898	\$ 25,236

The stock-based compensation expense reported in impairment of assets and other costs for terminated program resulted from executive severance. We accounted for this as a liability award as of March 31, 2020, which we reclassified into equity in three months ended June 30, 2020.

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

	Three months ended March 31,	
	2021	2020
Options granted	121	49
Weighted-average grant-date fair value of options granted	\$ 10.82	\$ 11.88
RSUs granted	367	245
Weighted-average grant-date fair value of RSUs granted	\$ 20.63	\$ 18.91
Shares issued under equity compensation plans	2,199	1,358

### Note 10 — 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, 2021 and 2020, 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, 2021 and March 31, 2020, potentially dilutive securities consisted of the weighted-average common shares underlying outstanding stock options and RSUs.

	<b>Three-months ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Potentially dilutive securities	19,393	18,816



## 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, immunology and virology. 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 building and advancing our pipeline of proprietary 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 the area of 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 are executing a clinical development program evaluating bempedaldesleukin (previously referred to as NKTR-214) in combination with Opdivo<sup>®</sup>, in collaboration with Bristol-Myers Squibb Company (BMS) as well as other independent development work evaluating bempedaldesleukin in combination with other checkpoint inhibitors and agents with potential complementary mechanisms of action. We announced in August of 2019 that the FDA granted a Breakthrough Therapy designation for bempedaldesleukin in combination with Opdivo<sup>®</sup> for the treatment of patients with untreated unresectable or metastatic melanoma. We expect our research and development expense to continue to grow over the next few years as we expand and execute our broad clinical development program for bempedaldesleukin.

On January 9, 2020, we and BMS entered into Amendment No. 1 (the Amendment) to the February 13, 2018, Strategic Collaboration Agreement (the BMS Collaboration Agreement). Pursuant to the Amendment, we and BMS agreed to update the Collaboration Development Plan under which we are collaborating and developing bempedaldesleukin. Specifically, pursuant to the updated Collaboration Development Plan, bempedaldesleukin in combination with Opdivo<sup>®</sup> is currently being evaluated in ongoing registrational trials in first-line metastatic melanoma, first-line cisplatin ineligible, PD-L1 low, locally advanced or metastatic urothelial cancer, first-line metastatic renal cell carcinoma (RCC), muscle-invasive bladder cancer, and adjuvant melanoma, as well as a Phase 1/2 dose escalation and expansion study to evaluate bempedaldesleukin plus Opdivo<sup>®</sup> in combination with either axitinib or cabozantinib in first line RCC in order to support a future Phase 3 registrational trial. Several other registrational-supporting pediatric and safety studies for the combination of bempedaldesleukin and Opdivo<sup>®</sup> are currently underway.

Under the BMS Collaboration Agreement, we and BMS share development costs based on each party's relative ownership interest in the compounds included in the regimen. For example, we share clinical development costs for bempedaldesleukin in combination with Opdivo<sup>®</sup>, BMS 67.5% and Nektar 32.5%. For costs of manufacturing bempedaldesleukin, however, BMS is responsible for 35% and Nektar is responsible for 65% of costs. BMS supplies Opdivo<sup>®</sup> free of charge. We also share commercialization related costs, 35% BMS and 65% Nektar, which we present in general and administrative expense. Our share of development costs is limited to an annual cap of \$125.0 million. To the extent this annual cap is exceeded, BMS reimburses us for the excess, but we recognize our full share of the research and development expense and recognize the reimbursement as a liability. We repay the liability to the extent that our share of development costs is less than the annual cap in a future year, or by reducing a portion of our share of net profits following the first commercial sale of bempedaldesleukin, if approved.

The BMS Collaboration Agreement entitles Nektar to receive up to \$1.455 billion of clinical, regulatory and commercial launch milestones. Of these milestones, we received a non-refundable, creditable milestone payment of \$25.0 million for the first patient, first visit in the registrational muscle-invasive bladder cancer trial, which was achieved on January 30, 2020, and also received a non-refundable, non-creditable milestone payment of \$25.0 million for the first patient, first visit in the registrational adjuvant melanoma trial, which we achieved on July 27, 2020. Of the remaining milestones, \$625.0 million are associated with the approval and launch of bempedaldesleukin in its first indication in the U.S., EU and Japan (which reflects the reduction for the \$25.0 million nonrefundable, creditable milestone for the first patient, first visit in the muscle-invasive bladder cancer trial). As a result, whether and when bempedaldesleukin is approved in any indication will have a significant impact on our future results of operations and financial condition.

Outside of the Collaboration Development Plan with BMS, we are conducting and pursuing additional I-O research and development activities evaluating bempedalsdesleukin in combination with other agents that have potential complementary mechanisms of action. For example, we are independently studying bempedalsdesleukin in combination with Keytruda® in a non-small cell lung cancer (NSCLC) Phase 1/2 trial. In addition, on February 12, 2021, we entered into a financing and co-development collaboration with SFJ Pharmaceuticals to support a Phase 2/3 registrational clinical study of bempedalsdesleukin plus Keytruda® in patients with head and neck cancer whose tumors express PD-L1. Our strategic objective is to establish bempedalsdesleukin as a key component of many I-O combination regimens with the potential to enhance the standard of care in multiple oncology settings. As a result, we expect to continue to make significant and increasing investments exploring the potential of bempedalsdesleukin with mechanisms of action that we believe are synergistic with bempedalsdesleukin based on emerging clinical development outcomes, scientific findings in cancer biology and preclinical development work.

With our non-BMS clinical collaborations for bempedalsdesleukin, generally each party supports the collaboration based on its expertise and resources. For example, our co-development collaboration agreement with SFJ includes both financial support from SFJ in the form of up to \$150.0 million to fund the Phase 2/3 registrational clinical study of bempedalsdesleukin plus Keytruda® in head and neck cancer, as well as operational support from SFJ in managing the clinical trial. In addition, we announced on February 17, 2021, that we had entered into a clinical trial collaboration and supply agreement with Merck wherein we will receive supplies of Keytruda® at no cost to us.

We are also combining bempedalsdesleukin with NKTR-262. NKTR-262 is a small molecule agonist that targets toll-like receptors (TLRs) found on innate immune cells in the body. NKTR-262 is designed to stimulate the innate immune system and promote maturation and activation of antigen-presenting cells (APCs), such as dendritic cells, which are critical to induce the body's adaptive immunity and create antigen-specific cytotoxic T cells. NKTR-262 is being developed as an intra-tumoral injection in combination with systemic bempedalsdesleukin to induce an abscopal response and achieve the goal of tumor regression in cancer patients treated with both therapies. The Phase 1/2 dose-escalation and expansion trial in patients with solid tumors is currently ongoing.

Our next most advanced I-O program is NKTR-255. 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 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 toxicity molecules as well as 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. At the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting, we reported early findings from the Phase 1 dose escalation study that demonstrated expansion of NK and CD8+ T cells in patients with multiple myeloma and non-Hodgkin lymphoma.

In immunology, we are developing NKTR-358, which is designed to correct 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 co-develop NKTR-358. We received an initial payment of \$150.0 million in September 2017 and are eligible for up to an additional \$250.0 million for development and regulatory milestones. We were responsible for completing 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. We will have the option to contribute funding to Phase 3 development on an indication-by-indication basis, ranging from zero to 25% of the Phase 3 development costs and receive a royalty rate on global NKTR-358 sales 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.

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. Results from this study demonstrated a multiple-fold increase in regulatory T cells with no change in CD8 positive or natural killer cell levels and no dose-limiting toxicities were observed. 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, has initiated a Phase 2 study in SLE in October 2020, and has initiated a Phase 2 study in ulcerative colitis. In addition, Lilly is planning to initiate two new Phase 2 studies in undisclosed auto-immune indications.

In virology, we received on October 22, 2020, FDA clearance for an Investigational New Drug application for bempegaldesleukin to be evaluated in a Phase 1b clinical study in adult patients who have been diagnosed with mild COVID-19 infection. The study design allows us to evaluate whether bempegaldesleukin's adaptive immune-stimulating mechanism to promote priming and proliferation of T cells and NK cells could be useful in the emerging treatment options for COVID-19. Enrollment in the Phase 1b randomized, double-blind, placebo-controlled trial began in November 2020. We have also entered into a preclinical research collaboration with Gilead to test the combination of NKTR-255 with therapies in Gilead's antiviral portfolio.

The level of our future research and development investment will depend on a number of trends and uncertainties including clinical study outcomes, future studies required to advance programs to regulatory approval, and the economics related to potential future collaborations that may include up-front payments, development funding, milestones, and royalties. Over the next several years, we plan to continue to make significant investments to advance our early drug candidate pipeline.

We have historically derived all of our revenue and substantial amounts of operating capital from our collaboration agreements including the BMS Collaboration Agreement, pursuant to which we have recognized \$1.11 billion in revenue and recorded \$790.2 million in additional paid in capital for shares of our common stock issued in the transaction. While in the near-term we continue to expect to generate substantially all of our revenue from collaboration arrangements, including the potential remaining \$1.405 billion in development and regulatory milestones under the BMS collaboration, in the medium- to long-term, our plan is to generate significant commercial revenue from proprietary products, the first of which being bempegaldesleukin, if approved. Since we do not have experience commercializing products or an established commercialization organization, there will be substantial risks and uncertainties in future years as we build commercial, organizational, and operational capabilities.

Up until September 30, 2020, we received royalties and milestones from two approved drugs: MOVANTIK<sup>®</sup>, for which we have a collaboration with AstraZeneca; and ADYNOVATE<sup>®</sup>, for which we have a collaboration agreement with Baxalta Inc. (a wholly owned-subsiary of Takeda Pharmaceutical Company Ltd.). MOVANTIK<sup>®</sup> is an oral, peripherally-acting mu-opioid antagonist for the treatment of opioid-induced constipation in adult patients with non-cancer pain which was approved by the FDA and subsequently launched in March 2015 (wherein in the EU, MOVANTIK<sup>®</sup> is sold as MOVENTIG<sup>®</sup> and is indicated for the treatment of opioid-induced constipation in adult patients who have an inadequate response to laxatives, which was approved by health authorities in the European Union and many other countries beginning in 2014). ADYNOVATE<sup>®</sup>, a half-life extension product of Factor VIII was approved by the FDA in late 2015 for use in adults and adolescents, aged 12 years and older, who have Hemophilia A (wherein in the EU, ADYNOVATE<sup>®</sup> is sold as ADYNOVI<sup>®</sup> and was approved by health authorities in Europe in January 2018, and has also been approved in many other countries).

Beginning on October 1, 2020, our rights to receive royalties arising from the worldwide net sales of MOVANTIK<sup>®</sup>/MOVANTIG<sup>®</sup> and ADYNOVATE<sup>®</sup>/ADYNOVI<sup>®</sup>, as well as REBINYN<sup>®</sup> and specified licensed products under a Right to Sublicense Agreement, dated October 27, 2017, were sold for \$150.0 million pursuant to a capped return sale arrangement to entities managed by Healthcare Royalty Management, LLC (collectively, HCR) under a purchase and sale agreement (the 2020 Purchase and Sale Agreement) entered into on December 16, 2020. With regard to the capped return sale arrangement, the 2020 Purchase and Sale Agreement will automatically expire, and HCR's right to receive the sold royalties, will cease when HCR has received payments equaling \$210.0 million (the 2025 Threshold), if the 2025 Threshold is achieved on or prior to December 31, 2025, or \$240.0 million, if the 2025 Threshold is not achieved on or prior to December 31, 2025 (or, if earlier, the date on which the last royalty payment under the relevant license agreements is made). After the 2020 Purchase and Sale Agreement expires, all rights to receive these royalties return to Nektar.

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. For a discussion of these and some of the other key risks and uncertainties affecting our business, see Item 1A. Risk Factors.

While the approved drugs and clinical development programs described above are key elements of our future success, we believe it is critically important that we continue to make substantial investments in our earlier-stage drug candidate pipeline. We have several drug candidates in earlier stage clinical development or being explored in research that we are preparing to advance into the clinic in future years. We are also advancing several other drug candidates in preclinical development in the areas of I-O, immunology, and other therapeutic indications. 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. 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 value.

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

In March 2020, COVID-19, the disease resulting from a novel strain of coronavirus infection, was declared a global pandemic. Many countries, including the United States and India, initially took steps such as restricting travel, closing schools, and issuing shelter-in-place orders to slow or moderate the spread of the virus. More recently, states and countries have adopted individualized approaches to respond to the COVID-19 pandemic. In particular, 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. Although vaccines intended to reduce the incidence and severity of infection are available pursuant to an Emergency Use Authorization granted by the FDA in the U.S. (and under similar authorizations by other health authorities in our countries), it remains unclear how long the negative impacts caused by the coronavirus will continue into the future.

Currently, with respect to the operation of our facilities, we are closely adhering to applicable guidelines and orders. Operations in research, manufacturing and maintenance that occur within our facilities are continuing in accordance with the permissions granted under local government ordinances. Recently, in view of the surge of COVID-19 cases occurring in India, we have further decreased the number of employees working at our facilities in Hyderabad. Across all our locations, we have instituted a temporary work from home policy for all office personnel who do not need to work on site to maintain productivity. At this time, we have not identified a material change to our productivity as a result of these measures, but this could change, particularly if restricted travel, closed schools, and shelter-in-place orders are not removed or significantly eased in the areas in which we operate.

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 and our partners are currently engaged in the clinical testing of our proprietary drug candidates and the COVID-19 pandemic introduces significant 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 proprietary 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. The rapid development and fluidity of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect this disease will have on our clinical trials, our operations and our business. As a result, any current assessment of the effects of the COVID-19 pandemic, including the impact of this disease on our specific clinical programs as discussed below, is difficult to predict and subject to change.

Specifically, for the ongoing registrational clinical trials studying the combination of bempedalsleukin and Opdivo<sup>®</sup> in cancer indications being led by Nektar (such as adjuvant melanoma, RCC and first-line cisplatin ineligible, PD-L1 low, locally advanced or metastatic urothelial cancer), although we have not seen evidence to date that the COVID-19 pandemic has had a significant impact on enrollment for these trials, the future impact of the COVID-19 pandemic on these trials is very difficult to predict and, with regard to individual clinical trial sites within these studies, will likely vary by the geographic region in which they are located.

For Nektar's Phase 1/2 trial studying bempedalsleukin and Keytruda<sup>®</sup> in NSCLC, although the COVID-19 pandemic delayed the initiation of certain investigator sites in Europe earlier in the trial, we currently expect to have initial safety as well as preliminary overall response rate data for the dose-escalation and 0.006 mg/kg NSCLC expansion cohorts of this study in the second half of 2021.

With regard to Nektar's ongoing clinical study of NKTR-262 (the Phase 1/2 REVEAL study), this study has largely remained on track although we have experienced some challenges with new investigator site initiations. Nektar's Phase 1 clinical study of NKTR-255 in patients with relapsed/refractory hematologic malignancies has enrolled slower than anticipated due to challenges caused by the COVID-19 pandemic, and the dose-escalation monotherapy portion of the study is expected to be completed in the first half of 2021. For both of these Nektar-run clinical programs, the ongoing COVID-19 pandemic could still impact investigator site initiations and trial enrollment despite our mitigation efforts.

For clinical studies of our proprietary drug candidates being run by our partners, BMS is enrolling patients in each of the BMS-led registration studies and re-started initiation of new investigator sites in the third quarter of 2020 following a pause in the initiation of new investigator sites it instituted for all of its studies as a result of the COVID-19 pandemic. In the summer of 2020, BMS extended their timeline estimates by approximately six months for the first data read-outs for the first-line melanoma trial. We will continue to monitor the progress of enrollment of the BMS-led studies and projections for topline clinical outcome data.

Our partner Lilly, which is running clinical trials of NKTR-358, has indicated it will likely have delays of at least three to six months following its temporary suspension of recruitment for the ongoing Phase 1b studies in atopic dermatitis and psoriasis as a result of the COVID-19 pandemic. Lilly recently started a Phase 2 study in moderate to severe lupus patients in October and has initiated an additional Phase 2 study in ulcerative colitis. The rapid development and fluidity of the COVID-19 pandemic preclude any firm estimates as to the ultimate effect this disease will have on our collaborators' clinical trials. As a result, there remains substantial uncertainty as to potential impacts on our collaboration partner studies.

With regard to our IND-enabling research, although the COVID-19 pandemic has caused us to reduce the number of employees working at our sites, a subset of our research-based employees continues to conduct laboratory work in our research facilities (which is permitted under the applicable government ordinances). As a result, we continue to make progress in the identification of new drug candidates.

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.

In this respect, we are also incorporating recent direction and flexibility provided by regulatory authorities, including the FDA in its March 18, 2020 Guidance (most recently updated January 27, 2021) entitled "FDA Guidance on Conduct of Clinical Trials of Medicinal Products during COVID-19 Public Health Emergency." This Guidance is continually being updated by FDA and updates can be found on the FDA's website at [www.fda.gov](http://www.fda.gov). In addition, we may refer to guidance documents from other regulatory agencies, such as, for example, the European Medicines Agency's "Implications of coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials" found on [www.ema.europa.eu](http://www.ema.europa.eu), which are also continually being updated.

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 through at least the next twelve months. As of March 31, 2021, we had approximately \$1.1 billion in cash and investments in marketable securities.

**Results of Operations**

Three Months Ended March 31, 2021 and 2020

**Revenue (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Product sales	\$ 4,795	\$ 3,444	\$ 1,351	39 %
Royalty revenue	—	9,719	(9,719)	(100)%
Non-cash royalty revenue related to sale of future royalties	18,798	9,895	8,903	90 %
License, collaboration and other revenue	54	27,515	(27,461)	(100)%
Total revenue	<u>\$ 23,647</u>	<u>\$ 50,573</u>	<u>\$ (26,926)</u>	<u>(53)%</u>

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, 2021 compared to the three months ended March 31, 2020 primarily due to an increase in product demand from our collaboration partners. We expect product sales for the full year of 2021 to increase compared to 2020 due to increased demand from our collaboration partners.

**Royalty Revenue**

As discussed in Note 5 to our Condensed Consolidated Financial Statements, on December 16, 2020, we entered into the 2020 Purchase and Sale Agreement with entities managed by Healthcare Royalty Management, LLC (collectively, HCR), under which we agreed to sell to HCR certain of our rights to receive royalty payments arising on worldwide net sales of MOVANTIK®, ADYNOVATE® and REBINYN® beginning October 1, 2020. As a result, we recognized royalty revenue for these products for the three months ended March 31, 2020, and recognized these royalties as non-cash royalty revenue for the three months ended March 31, 2021. Please see Note 5 to our Consolidated Financial Statements for additional information on the 2020 Purchase and Sale Agreement.

We do not expect to recognize any royalty revenue during 2021, because we will recognize all such royalties as non-cash royalty revenue as a result of the 2020 Purchase and Sale Agreement.

**Non-cash Royalty Revenue Related to Sale 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, 2020, we recognized \$25.0 million in license, collaboration and other revenue for the achievement of the first patient, first visit in the registrational muscle-invasive bladder cancer trial under the BMS Collaboration Agreement. Accordingly, license, collaboration and other revenue decreased during the three months ended March 31, 2021 compared to the three months ended March 31, 2020 due to the recognition of this milestone. We expect that our license, collaboration and other revenue will decrease significantly for the full year of 2021 compared to 2020 as a result of the recognition of this \$25.0 million milestone and the \$25.0 million milestone for the first patient, first visit in the registrational adjuvant melanoma trial, which we recognized in the three months ended June 30, 2020.

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) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Cost of goods sold	\$ 5,756	\$ 3,811	\$ 1,945	51 %
Product gross profit (1)	(961)	(367)	(594)	(162)%
Product gross margin	(20)%	(11)%		

(1) Percentage change represents a worsening, since the negative gross margin has increased.

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.

Product gross margin was negative for the three months ended March 31, 2021 and March 31, 2020. 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 from reagent materials supplied to the partner where our sales are less than our fully burdened manufacturing cost, we also receive royalty revenue from this collaboration. In the three months ended March 31, 2021 and 2020, 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 currently expect product gross margin to be negative in 2021 as a result of the manufacturing arrangement described above.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Research and development expense	\$ 95,604	\$ 108,987	\$ (13,383)	(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 clinical 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.

Research and development expense decreased for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 primarily due to manufacturing activities for bempedalsleukin which were completed during 2020. Additionally, development costs for NKTR-358 decreased for the three months ended March 31, 2021 compared to the three months ended March 31, 2020, reflecting our completion of our Phase 1 clinical development and drug product development deliverables, for which we were responsible for 100% of costs, to the Phase 1B and Phase 2 development, for which we are responsible for 25% of costs and Lilly is responsible for 75% of costs. The costs of our clinical development program, including bempedalsleukin, NKTR-262 and NKTR-255, were consistent between the three months ended March 31, 2021 compared to the three months ended March 31, 2020. During the three months ended March 31, 2021 and 2020, we recorded net reductions to research and development expense for BMS's reimbursements of our costs of \$26.7 million and \$30.7 million, respectively. Under the BMS Collaboration Agreement, BMS generally bears 67.5% of development costs for bempedalsleukin in combination with Opdivo® and 35% of costs for manufacturing bempedalsleukin. Please see Note 8 to our Condensed Consolidated Financial Statements for additional information regarding our BMS Collaboration Agreement.

We expect research and development expense to increase for 2021 compared to 2020 primarily as a result of our continued development of bempedalsleukin, including studies outside of the BMS Collaboration Agreement. In addition, we are collaborating with Lilly to develop NKTR-358, and Lilly will be conducting the recently started Phase 2 studies and other ongoing studies in 2021, for which we are responsible for 25% of costs. We are continuing to enroll patients in the expansion cohorts of the Phase 1/2 study for NKTR-262 in combination with bempedalsleukin. We will continue our Phase 1/2 dose-escalation and expansion studies for NKTR-255 in multiple myeloma, non-Hodgkin lymphoma, relapsed or refractory head and neck squamous cell carcinoma, and colorectal cancer. The timing and amount of our future clinical investments 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 are evaluating in clinical development during 2021, 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 by applying our polymer conjugate technology platform to a wide range of molecule classes, including small molecules and large proteins, peptides and antibodies, across multiple therapeutic areas. 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 those collaborations that we have already completed for bempegaldesleukin and 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.

As noted above, the evolving situation around the COVID-19 pandemic has had varying impacts on the clinical testing of our proprietary 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 pandemic. We have experienced delays of approximately three months for some Nektar-run, earlier-stage clinical studies (such as the Phase 1/2 trial studying bempegaldesleukin and Keytruda® in NSCLC and the Phase 1 dose escalation trial studying NKTR-255 in patients with relapsed/refractory hematologic malignancies) and given the evolving situation around the COVID-19 pandemic it is possible there could be additional delays in the future. In addition, for certain clinical studies involving our proprietary drug candidates that are run by our partners, study timelines have been delayed at least three to six months, and, given the evolving situation around the COVID-19 pandemic, it is possible there could be additional delays in the future. As a result of these delays and potential delays, we may incur additional costs associated with these clinical trials. At this time, we cannot estimate if such increases would have a material effect on our results of operations or financial position.

The risks and uncertainties associated with our research and development projects are discussed more fully in Item 1A. Risk Factors. As a result of the uncertainties discussed above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from a collaboration arrangement or the commercialization of a drug candidate.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
General and administrative expense	\$ 31,679	\$ 26,217	\$ 5,462	21 %

General and administrative expense includes the cost of administrative staffing, business development, commercial, finance and legal activities. General and administrative expense increased during the three months ended March 31, 2021 compared with the three months ended March 31, 2020 primarily due to increased personnel costs as we continue a stage-appropriate build of our commercial capability to co-commercialize bempegaldesleukin with BMS. We expect general and administrative expenses in the full year of 2021 to increase compared to 2020, as we continue to build our commercial capabilities.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Impairment of assets and other costs for terminated program	\$ —	\$ 45,189	\$ (45,189)	(100)%

On January 14, 2020, the joint FDA Anesthetic Drug Products Advisory Committee and Drug Safety and Risk Management Committee did not recommend approval of our NDA for NKTR-181. As a result, we withdrew our NDA and decided to make no further investments in this program. As a result, in the three months ended March 31, 2020, we wrote off

\$19.7 million of advance payments to contract manufacturers for commercial batches of NKTR-181. We also incurred \$25.5 million of additional costs, primarily for non-cancellable commitments to our contract manufacturers and severance costs.

**Interest Expense (in thousands, except percentages)**

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Interest expense	\$ —	\$ 6,204	\$ (6,204)	(100)%

Interest expense during the three months ended March 31, 2020 primarily consisted of interest from our senior secured notes. In October 2015, we issued \$250.0 million in aggregate principal amount of 7.75% senior secured notes due October 2020. On April 13, 2020, we repaid the principal and accrued interest of our senior notes totaling \$254.8 million. As a result, we incurred no interest expense after the repayment date.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
<b>2012 Purchase and Sale Agreement:</b>				
Non-cash royalty revenue related to sale of future royalties	\$ 9,489	\$ 9,719	\$ (230)	(2)%
Non-cash interest expense on liability related to sale of future royalties	\$ 7,797	\$ 6,968	\$ 829	12 %
Interest rates - end of period presented				
Implicit interest rate over the life of the agreement	20.2 %	19.5 %		
Prospective effective interest rate	48.0 %	38.0 %		
<b>2020 Purchase and Sale Agreement:</b>				
Non-cash royalty revenue related to sale of future royalties	\$ 9,309	\$ —	\$ 9,309	>100%
Non-cash interest expense on liability related to sale of future royalties	\$ 5,499	\$ —	\$ 5,499	>100%
Interest rates - end of period presented				
Implicit interest rate over the life of the agreement	16.0 %	N/A		
Prospective effective interest rate	16.0 %	N/A		
<b>Total non-cash royalty revenue related to sale of future royalties</b>	<b>\$ 18,798</b>	<b>\$ 9,719</b>	<b>\$ 9,079</b>	<b>93 %</b>
<b>Total non-cash interest expense on liability related to sale of future royalties</b>	<b>\$ 13,296</b>	<b>\$ 6,968</b>	<b>\$ 6,328</b>	<b>91 %</b>

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

**2012 Purchase and Sale Agreement**

Non-cash royalty revenue for the 2012 Purchase and Sale Agreement decreased marginally for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. Non-cash interest expense for the 2012 Purchase and Sales Agreement increased for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 due to an increase in the estimated implicit interest rate over the life of the transaction, as disclosed above. When forecasted future revenues rise, this results in an increase to the estimated implicit interest rate over the life of the transaction, which, in turn, increases the prospective effective interest rate in the current and future periods. The estimated implicit rate increased from the three months ended March 31, 2020 to the three months ended March 31, 2021 due to an increase in estimated future net sales of CIMZIA®.

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 non-cash interest expense. To date, we have amortized \$49.8 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 \$64.2 million of the net proceeds, since RPI (as defined in Note 5) 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<sup>®</sup> and MIRCERA<sup>®</sup>. 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

As discussed in Note 5 to our Condensed Consolidated Finance Statements and above under Royalty Revenue, we sold our rights to receive royalties for MOVANTIK<sup>®</sup>, ADYNOVATE<sup>®</sup> and REBINYN<sup>®</sup> for sales beginning on October 1, 2020, and therefore we recognized non-cash royalty revenue and non-cash interest expense for the three months ended March 31, 2021, but did not recognize non-cash royalty revenue and non-cash interest expense for the three months ended March 31, 2020. Similarly, non-cash royalty revenue and non-cash interest expense will increase for 2021 compared to 2020. Our estimate of the imputed interest rate reflects our estimates for sales of MOVANTIK<sup>®</sup>, ADYNOVATE<sup>®</sup> and REBINYN<sup>®</sup>, which result in meeting the 2025 Threshold (as defined in Note 5). Because the 2025 Threshold of \$210.0 million and the increase in the threshold to \$240.0 million (if the 2025 Threshold is not 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.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Change in fair value of development derivative liability	\$ 1,599	\$ —	\$ 1,599	>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. The change in fair value recorded for the three months ended March 31, 2021 primarily reflects the accretion of the scenario-based probability-adjusted discounted cash flows of our obligation to potentially pay Success Payments to SFJ using our imputed borrowing rate of 12.2%, net of the accretion of SFJ's obligation to fund the SCCHN Clinical Trial, using SFJ's estimated borrowing rate of 1.0%. We review our estimates at each reporting period, and, in particular, in future periods, as information becomes available, such as the applicable clinical trial results and FDA approval decisions, we will re-evaluate our probability of success estimates related to achieving FDA approval for bempegaldesleukin in the Melanoma Indication, the SCCHN Indication and one additional indication, and will record a corresponding increase or decrease in the fair value of the development derivative liability. Additionally, in future periods, we may adjust our estimate of the probability of a successful interim futility analysis and we will record a corresponding decrease or increase to the fair value of the development derivative liability, reflecting the increase or decrease (as applicable) in the likelihood of SFJ's resulting obligation to complete the full SCCHN Clinical Trial. Such changes in the probabilities of success may result in a material expense or benefit in the period when the information is received. However, based on current clinical timelines, we do not expect material changes to our probability of success assumptions during 2021, and, therefore, we expect to recognize primarily the accretion expense on the discounted cash flows discussed above. See Note 4 for additional information about the development derivative liability.

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

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Interest income and other income (expense), net	\$ 1,412	\$ 8,352	\$ (6,940)	(83)%

Interest income and other income (expense) decreased for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 due to lower investment balances which have been utilized to fund our operations as well as

decreases in market interest rates. The effective interest rate earned on investments which we purchased after the COVID-19 pandemic began has been significantly lower than historical interest rates, and we expect this trend to continue. We expect that our interest income and other income (expense), net will decrease for 2021 compared to 2020 for these same reasons.

### Income Tax Expense

	Three Months Ended March 31,		Increase/ (Decrease) 2021 vs. 2020	Percentage Increase/ (Decrease) 2021 vs. 2020
	2021	2020		
Provision for income taxes	\$ 92	\$ 200	\$ (108)	(54)%

For the three months ended March 31, 2021 and 2020, our income tax expense primarily resulted from taxable income in our Nektar India subsidiary. We have fully reserved our U.S. federal deferred tax assets generated from our net operating losses, as we believe it is not more likely than not that the benefit will be realized.

### Liquidity and Capital Resources

We have financed our operations primarily through revenue from product sales, royalties and strategic collaboration agreements, as well as public offering and private placements of debt and equity securities. At March 31, 2021, we had approximately \$1.1 billion 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 this Form 10-Q. We expect the clinical development of our proprietary drug candidates including bempregaldesleukin, NKTR-358, NKTR-262 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. In April 2018, we received a total of \$1.85 billion from BMS including a \$1.0 billion upfront payment and an \$850.0 million premium investment in our common stock. In July 2017, we entered into a collaboration agreement for NKTR-358 with Lilly, under which we received a \$150.0 million upfront payment. Pursuant to the 2020 Purchase and Sale Agreement, in December 2020 we received \$150.0 million from HCR in exchange for certain of our rights to receive royalty payments arising in respect of worldwide net sales of specified products including ADYNOVATE<sup>®</sup>, MOVANTIK<sup>®</sup>, and REBINYN<sup>®</sup>. In the future, we expect to receive substantial payments from our collaboration agreements with BMS and Lilly. In particular, under the BMS Collaboration Agreement, we are entitled to approximately \$1.455 billion of clinical, regulatory and commercial launch milestones (of which, we have received \$50.0 million). Of the remaining milestones, \$625.0 million are associated with approval and launch of bempregaldesleukin in its first indication in the U.S., EU and Japan (which reflects the reduction for the \$25.0 million nonrefundable, creditable milestone for the first patient, first visit in the muscle-invasive bladder cancer trial that BMS paid to us in March 2020). As a result, whether and when bempregaldesleukin is approved in any indication will have a significant impact on our future liquidity and capital resources. We have no credit facility or any other sources of committed capital.

On February 12, 2021, we entered into a co-development agreement with SFJ Pharmaceuticals (SFJ), pursuant to which SFJ will pay up to \$150.0 million in committed funding to support a Phase 2/3 study of bempregaldesleukin in combination with pembrolizumab (Keytruda<sup>®</sup>) 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). In exchange for funding the SCCHN Clinical Trial, SFJ is entitled to a series of contingent success-based payments with the first payment due after the substantial completion of the SCCHN Clinical Trial which we currently expect to occur in late 2024 or early 2025 as follows: (i) if bempregaldesleukin receives FDA approval for first line metastatic melanoma or the SCCHN Indication, we would pay SFJ \$450.0 million over a series of five annual payments with the first annual payment being \$30.0 million, with the earliest possible payment expected to occur in 2024, subject to the substantial completion of the SCCHN Clinical Trial.; (ii) if bempregaldesleukin receives FDA approval in both first line metastatic melanoma and the SCCHN indication, we would pay SFJ an additional \$150.0 million paid over a series of seven annual payments; and (iii) if bempregaldesleukin receives FDA approval in an indication other than first line metastatic melanoma or the SCCHN indication, a one-time payment of \$37.5 million. See Note 4 to our Condensed Consolidated Financial Statements for additional information.

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 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 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.

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

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.

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, 2021 totaled \$77.1 million.

Cash flows used in operating activities for the three months ended March 31, 2020 totaled \$78.1 million, which includes \$98.1 million of net operating cash uses as well as \$5.0 million for interest payments on our senior secured notes, partially offset by the receipt of the \$25.0 million milestone payment from BMS for the achievement of the first patient, first visit in the registrational muscle invasive bladder cancer trial.

We expect that cash flows used in operating activities, excluding upfront, milestone and other contingent payments received, will increase in the full year of 2021 compared to 2020 primarily as a result of increased research and development expenses.

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

We paid \$2.9 million and \$0.9 million for the purchase or construction of property, plant and equipment in the three months ended March 31, 2021 and 2020, respectively.

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

We received proceeds from issuance of common stock related to our employee option and stock purchase plans of \$17.1 million and \$11.1 million in the three months ended March 31, 2021 and 2020, respectively. Additionally, during the three months ended March 31, 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. Other than the development derivative liability under our co-development agreement with SFJ as described in Note 4 to our Condensed Consolidated Financial Statements, 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, 2020.

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

Our market risks at March 31, 2021 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2020 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, 2021 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 5 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

Investors in Nektar Therapeutics should carefully consider the risks described below before making an investment decision. 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, 2020. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, results of operations, financial condition, cash flows and future prospects and the trading price of our common stock and our ability to repay our senior secured notes could be harmed as a result of any of these risks, and investors may lose all or part of their investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2020, including our consolidated financial statements and related notes, and our other filings made from time to time with the SEC.

#### Risks Related to Our Business

***We are highly dependent on the success of bempegaldesleukin, our lead I-O candidate. We are executing a clinical development program for bempegaldesleukin and clinical and regulatory outcomes for bempegaldesleukin, if not successful, will significantly harm our business.***

Our future success is highly dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize bempegaldesleukin. In general, most investigational drugs, including I-O drug candidates such as bempegaldesleukin, do not become approved drugs. Accordingly, there is a very meaningful risk that bempegaldesleukin will not succeed in one or more clinical trials sufficient to support one or more regulatory approvals. To date, reported clinical outcomes from bempegaldesleukin have had a significant impact on our market valuation, and business prospects and we expect this to continue in future periods. If one or more clinical studies of bempegaldesleukin are delayed (as a result of, for example, our collaboration partner causing a delay of the initiation or completion of one or more clinical trials for reasons outside of our control) or not successful, it would materially harm our market valuation, prospects, financial condition and results of operations. For example, under the BMS Collaboration Agreement, we are entitled to up to approximately \$1.455 billion in development milestone payments (of which we have received \$50.0 million) that are based upon clinical and regulatory successes from the bempegaldesleukin development program. One or more failures in bempegaldesleukin studies could jeopardize such milestone payments, and any product sales or royalty revenue or commercial milestone payments that we would otherwise be entitled to receive could be reduced, delayed or eliminated.

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. We have ongoing trials evaluating bempedalsleukin, including trials evaluating bempedalsleukin as a potential combination treatment with BMS's Opdivo® as well as other ongoing and planned combination trials. Our partner Lilly is conducting two Phase 2 studies of NKTR-358 in patients with SLE and ulcerative colitis as well as two Phase 1b studies in patients with psoriasis and atopic dermatitis. We also continue to enroll patients in a Phase 1/2 study evaluating bempedalsleukin in combination with NKTR-262 in patients with solid tumors. 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 bempedalsleukin and 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 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 bempedalsleukin, NKTR-262, and NKTR-255 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.***

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 proprietary drug candidates currently in development. For bempegaldesleukin, there are numerous companies engaged in developing immunotherapies to be used alone, or in combination, to treat a wide range of oncology indications targeting both solid and liquid tumors. In particular, we expect to compete with therapies with tumor infiltrating lymphocytes, or TILs, chimeric antigen receptor-expressing T cells, or CAR-T, cytokine-based therapies, and checkpoint inhibitors. Potential competitors in the TIL and CAR-T space include Gilead Sciences, Inc. (through its acquisition of Kite Pharma, Inc./NCI, Apeiron Biologics, Philogen S.p.A., Brooklyn ImmunoTherapeutics LLC, Anaveon AG, Adaptimmune LLC, and Novartis AG; potential competitors in the cytokine-based therapies space include Alkermes plc, ImmunityBio, Inc., Neoleukin Therapeutics, Inc., Philogen S.p.A., Roche, Sanofi SA (through its acquisition of Synthorx, Inc.), and Eli Lilly & Co. (through its acquisition of Armo BioSciences); and potential competitors in the checkpoint inhibitor space include GlaxoSmithKline plc (through its acquisition of Tesaro, Inc.), MacroGenics, Inc., Merck, Bristol-Myers Squibb Company, and Roche. 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, ILTOO Pharma, 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.

***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, 2021, based on closing prices on the NASDAQ Global Select Market, the closing price of our common stock ranged from \$16.56 to \$25.46 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 potential 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 bimepegaldesleukin 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 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.

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

***We are highly dependent on our collaboration partners to initiate, properly conduct and prioritize clinical trials for bimepegaldesleukin and 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 BMS (through the BMS Collaboration Agreement) and Lilly (through the Lilly Agreement) to initiate, properly conduct, and prioritize clinical trials and other development-related activities for bimepegaldesleukin and NKTR-358, respectively. Furthermore, we will rely on BMS and Lilly to perform specified commercialization activities for bimepegaldesleukin and NKTR-358, respectively, pursuant to the applicable agreement. In the event BMS or 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 BMS's or 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 more 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 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 (other than Nektar-run trials under the BMS Collaboration Agreement), 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 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, 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 proprietary 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 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, 2021, we had cash and investments in marketable securities valued at approximately \$1.1 billion. On April 13, 2020, we redeemed our senior notes at par and therefore repaid the principal of \$250.0 million and accrued interest of \$4.8 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 — important examples include bempedalsleukin and 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 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 proprietary 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 potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, drug scheduling status, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic 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 payors 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 have received 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, 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 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 payors 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.

- 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, or 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 the 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, 2021, we reported a net loss of \$123.0 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestone 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 bempedalsleukin, NKTR-358, NKTR-262, and NKTR-255;
- receive necessary regulatory and marketing approvals;
- maintain or expand manufacturing at necessary levels;
- achieve market acceptance of our partnered products;
- receive 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 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.

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. For example, we have implemented work from home policies for most employees and limited business travel. 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.

Prolonged remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses, employee productivity and employee work culture. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. If we, our partners, our suppliers, or our contractors experience a cyberattack, experience data accessibility issues, or encounter communication disruptions, our business may suffer as a result of the loss or theft of our important data, and we may be liable for compromising the protection of personal data.

The COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties with whom we seek important goods and services. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties fully due to the COVID-19 pandemic, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. Furthermore, 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.

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.

The COVID-19 pandemic could affect our ability, and the ability third parties on whom we rely, to successfully manufacture sufficient supplies to complete our clinical trials in a timely manner. For example, it may be more difficult to obtain materials or manufacturing slots for the products required to conduct our clinical trials due to the demand for recently authorized vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation.

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 proprietary 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 biologic 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. 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.

## Risks Related to Supply and Manufacturing

***If we or our contract manufacturers are not able to manufacture biologics or biologic 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 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**

***If we are unable to create robust sales, marketing and distribution capabilities or to enter into agreements with third parties to perform these functions, we will be unable to commercialize our biologic candidates successfully.***

We are in the very early stages of building a commercialization and distribution capabilities for bempedalsleukin in the United States and Europe. To commercialize any of our biologic candidates that receive regulatory approval for commercialization, we must develop robust internal sales, marketing and distribution capabilities, and manage inventory, supply, labeling, storage, record keeping, and advertising and promotion capabilities, which is both expensive and time consuming, or enter into arrangements with third parties to perform these services. For example, we have committed to co-commercializing bempedalsleukin with BMS and establish global distribution and infrastructure for us to be able to book global revenue for bempedalsleukin if it achieves regulatory approval. Establishing this commercialization capability requires a significant commitment of financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. Factors that may inhibit our efforts to commercialize our products directly or through partnerships include:

- our inability to recruit and retain management talent to lead key marketing and distribution roles;
- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel and medical science liaisons to obtain access to or successfully educate adequate numbers of physicians about the potential benefits associated with the use of, and to subsequently prescribe, our products;

- the lack of complementary products or multiple product pricing arrangements may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

***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 depend on third parties to conduct the clinical trials for our proprietary 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 proprietary 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.

***We may not be able to manage our growth effectively, which could adversely affect our operations and financial performance.***

The ability to manage and operate our business as we execute our development and growth strategy will require effective planning and execution. Significant rapid growth could strain our management and internal resources, and other problems may arise that could adversely affect our financial performance. We expect that our efforts to grow will place a significant strain on personnel, management systems, infrastructure and other resources. Our ability to effectively manage future growth will also require us to successfully attract, train, motivate, retain and manage new employees and continue to update and improve our operational, financial and management controls and procedures. If we do not manage our growth effectively, our operations and financial performance could be adversely affected.

***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 and potential commercialization of our proprietary and partnered biologic candidates. Our strategy also calls for us to undertake increased research and development activities and establish a commercial organization in collaboration with our partners, while simultaneously managing the capital necessary to support this strategy. If we are unable to manage effectively our current operations and any growth we may experience, 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.

***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. 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**

***We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to biologic candidates granted Breakthrough Therapy designation by the FDA.***

We intend to evaluate and continue ongoing discussions with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our biologic candidates, although we cannot be certain that our biologic candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations.

Breakthrough Therapy designation is intended to expedite the development and review of biologic candidates that are designed to treat serious or life-threatening diseases when preliminary clinical evidence indicates that the biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a biologic candidate as a Breakthrough Therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the biologic candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

Although bempedalsleukin in combination with Opdivo<sup>®</sup> received Breakthrough Therapy designation for the treatment of patients with previously untreated unresectable or metastatic melanoma, we may elect not to pursue Breakthrough Therapy designation for our other biologic candidates, and the FDA has broad discretion whether or not to grant these designations.

Accordingly, even if we believe a particular biologic candidate is eligible for Breakthrough Therapy, we cannot be assured that the FDA would decide to grant it. Breakthrough Therapy designation does not change the standards for biologic approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the Breakthrough Therapy designation. Thus, even though we have received Breakthrough Therapy designation, we may not experience a faster development process or review, and, upon any filing seeking regulatory approval, we may not obtain an approval from the FDA.

***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. For example, although the FDA granted a Breakthrough Therapy designation to bempegaldesleukin in combination with Opdivo® for the treatment of patients with previously untreated unresectable or metastatic melanoma, there is no guarantee regulatory approval will follow, if at all, for this or any indication of bempegaldesleukin on a timely basis. 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® to other treatments of opioid-induced constipation (OIC) 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®.

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 biologic 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, it could subject us to substantial liabilities and 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 300 U.S. and 1,050 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 proprietary 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, 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 a “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, using 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. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. 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, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, 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 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, 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. 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. 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.

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. For example, we are currently involved in German litigation proceedings whereby we and Bayer Healthcare LLC are seeking at least co-ownership rights in certain of each other's patent filings related to PEGylated Factor VIII products. We believe that Bayer's claims to an ownership interest in these is without merit and we are vigorously defending our exclusive ownership rights to this intellectual property. These German litigation proceedings are currently stayed pending the outcome of ongoing mediation efforts. In the U.S., Bayer filed a complaint against Baxalta and Nektar alleging the ADYNOVATE® product infringes a Bayer patent. Although the U.S. court dismissed all of Bayer's claims against Nektar and Nektar was removed as a defendant, a jury found the Bayer patent was valid and infringed, and awarded Bayer damages, the responsibility of which are borne fully by Baxalta. This damages award does not impact our royalties from sales of ADYNOVATE® under our collaboration with Baxalta and Baxalta is currently appealing the decision. In other U.S. proceedings, Nektar and Baxalta filed complaints against Bayer Healthcare alleging Bayer's JIVI® product infringes several Nektar patents. In addition, in response to notices AstraZeneca and we received from the generic companies, Apotex (Apotex Inc. and Apotex Corp.), MSN Laboratories Pvt. Ltd., (MSN) and Aurobindo Pharma USA INC. alerting us that they had filed abbreviated new drug applications (ANDAs) with the FDA to market a generic version of MOVANTIK® (Paragraph IV Certifications), AstraZeneca and we together filed patent infringement suits against each of these generic companies. In these Paragraph IV Certifications, all three generic companies only alleged one patent, U.S. Patent No. 9,012,469, is invalid, unenforceable and/or not infringed by the manufacture, use or sale of their respective generic products. At this time, none of the other five Orange Book listed patents associated with MOVANTIK® are being challenged by these generics companies. On March 25, 2021, RedHill BioPharma (sublicensee of AstraZeneca's global commercialization rights for MOVANTIK®, excluding Europe and Canada) announced that Redhill BioPharma, AstraZeneca and Nektar entered into a settlement and license agreement with MSN pursuant to which the parties agreed to file a stipulation and order to dismiss the lawsuit to conclude the litigation with respect to MSN, and MSN agreed not to sell a generic version of MOVANTIK® in the U.S. until October 1, 2030. In addition, on March 18, 2020, Aether Therapeutics Inc. filed a complaint against AstraZeneca, Nektar and Daiichi-Sanko, Inc. alleging MOVANTIK® infringes U.S. Patent Nos. 6,713,488, 8,748,448, 8,883,817 and 9,061,024. Also, on June 5, 2020, UCB Pharma S.A. and Celltech R&D

Limited (collectively UCB) served notice of a Declaratory Judgment of Patent Invalidation proceeding filed in the United States District Court for the District of Delaware seeking a declaration of invalidity of specified U.S. patents owned by Nektar and licensed to UCB. UCB is also pursuing similar actions in other jurisdictions. 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.

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—66-7-HSG, which we refer to as the Mulquin action). The Mulquin plaintiffs have challenged public statements Nektar made about clinical trials of bempedaldesleukin between January 2017 and June 2018. 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 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 is expected to be completed by September 2021.

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 bempedaldesleukin 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 (Mulquin and Damiba), three 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 officer and directors breached 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 U.S. District Court for the Northern District of California (Case No. 4:20-cv-01088-JSW). The derivative actions in California have been consolidated and the Company has moved to dismiss on the basis that the plaintiffs have neither made a demand on the Company's board of directors nor shown that demand would be futile. The Company's motion to dismiss has been under submission since December 2020.

An additional derivative complaint was filed in February 2021 in the Court of Chancery of the State of Delaware (C.A. No. 2021-0118-PAF). No response to the complaint is due until May 2021.

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 putative securities class action lawsuits and shareholder derivative lawsuits) is sufficient, thereby resulting in substantial financial risk to the Company.

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 March 31, 2021.

***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.

## **General Risks to our Business**

***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.

***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. 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, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or 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 European Union (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 E.U., 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 and others could face new regulatory costs and challenges.

***Global economic 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.*” As a result of global economic 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. We believe such 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, our business may be adversely affected following new or increased tariffs that result in the 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, 2021.

**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.

<b>Exhibit Number</b>	<b>Description of Documents</b>
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>
10.1(6)	<a href="#">Amended and Restated Compensation Plan for Non-Employee Directors ++</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).

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- (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 February 6, 2019.
  - (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.

++ Management contract or compensatory plan or arrangement.

**SIGNATURES**

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

By: /s/ GIL M. LABRUCHERIE

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

Date: May 6, 2021

By: /s/ JILLIAN B. THOMSEN

**Jillian B. Thomsen**  
**Senior Vice President, Finance and Chief Accounting Officer**

Date: May 6, 2021



## CERTIFICATIONS

I, Howard W. Robin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2021 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 6, 2021

/s/ HOWARD W. ROBIN

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**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, 2021 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 6, 2021

/s/ GIL M. LABRUCHERIE

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**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, 2021, 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 6, 2021

/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.