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DELTA REPORT

10-K

NKTR - NEKTAR THERAPEUTICS

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	3496
CHANGES	180
DELETIONS	1436
ADDITIONS	1880

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT

☒ OF 1934.

For the fiscal year ended December 31, 2022

December 31, 2023

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	94-3134940
Delaware	94-3134940

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(State or other jurisdiction of incorporation or organization)

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N

455 Mission Bay Boulevard South

San Francisco, California94158

(Address of principal executive offices and zip code)

415-482-5300

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	Name of Each Exchange on Which Registered
Common Stock, $0.0001 par value	NKTR	NASDAQ Global Select Capital Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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). days. Yes ☒ No ☐

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

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

	☒		☐
Large Accelerated Filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The approximate aggregate market value of voting stock held by non-affiliates of the registrant, based upon the last sale price of the registrant's common stock on the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2022 June 30, 2023, as reported on The NASDAQ Global Select Capital Market, was approximately $704 million.

$109 million.

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As of February 21, 2023 February 27, 2024, the number of outstanding shares of the registrant's common stock was 189,235,139. 183,617,817

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DOCUMENTS INCORPORATED BY REFERENCE

Portions of registrant's definitive Proxy Statement to be filed for its 2023 2024 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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NEKTAR THERAPEUTICS

2022

2023 ANNUAL REPORT ON FORM 10-K

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Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are "forward-looking statements" for purposes of this annual report on Form 10-K, including any projections of market size, earnings, revenue, milestone payments, royalties, sales or other financial items, any statements of the plans and objectives of management for future operations (including, but not limited to, preclinical development, clinical trials and manufacturing), any statements related to our financial condition and future working capital needs, any statements related to our prior strategic reorganization and cost restructuring plans, any statements regarding potential future financing alternatives, any statements concerning proposed drug candidates and our future research and development plans, any statements regarding the timing for the start or end of clinical trials or submission of regulatory approval filings, any statements regarding future economic conditions or performance, any statements regarding the initiation, formation, or success of our collaboration arrangements, commercialization activities and product sales levels by our collaboration partners and future payments that may come due to us under these arrangements, any statements regarding our plans and objectives to initiate or continue clinical trials, any statements related to potential, anticipated, or ongoing litigation and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believe," "may," "will," "expects," "plans," "anticipates," "estimates," "potential" or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in

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the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth in Part I, Item 1A "Risk Factors" below and for the reasons described elsewhere in this annual report on Form 10-K. 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 annual report on Form 10-K, the "Company," "Nektar," "we," "us," and "our" refer to Nektar Therapeutics, a Delaware corporation, and, where appropriate, its subsidiaries.

Trademarks

The Nektar brand and product names, including but not limited to Nektar®, 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-K, which risks include, among others:

- **Risks Related to our Research and Development Efforts:**
  - clinical drug development is a lengthy and uncertain process and we may not be able to generate and develop successful drug candidates for commercial use;
  - we are highly dependent on the success of rezpegaldesleukin (previously referred to as NKTR-358) and NKTR-255 and our business will be significantly harmed if either rezpegaldesleukin or NKTR-255 do not continue to advance in clinical studies;
  - the outcomes from competitive immunotherapy clinical trials, and the discovery and development of new potential immunotherapy could have a material and adverse impact on the value of our pipeline;
  - significant competition for our polymer conjugate chemistry technology platforms and our products and drug candidates could make our technologies, drug products or drug candidates obsolete or uncompetitive;
  - preliminary and interim data from our clinical studies are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available; and

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  - clinical trials for any of our drug candidates could be delayed for a variety of reasons. reasons, including delays associated with activating clinical sites and lower than anticipated patient enrollment rates, which are often outside of our control; and
  - we depend on third parties to conduct laboratory experiments, preclinical studies and clinical trials for our biologic candidates and any failure of those p fulfill their obligations according to our instructions and protocol standards could harm our research and development plans and adversely affect our bu

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- **Risks Related to our Financial Condition and Capital Requirements:**
  - we have implemented a 2022there is no guarantee that our prior strategic reorganization plan and cost restructuring plan to focus on prioritizing key research plans will achieve their intended benefits and development efforts and our business will be significantly harmed if either of these plans is unsuccessful;
    - we may need to undertake additional restructuring and cost-saving activities in the future, which could further harm our market valuation, prospects, financial condition and results of operations;measures;
  - 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;
  - a significant source of our revenue is exclusively and capital for research and development has been derived from our collaboration agreements. If agreements, and if we are unable to establish and maintain collaboration partnerships with attractive commercial terms, including significant development milestones and research and development cost-sharing, our business, results of operations and financial condition could suffer; and
  - we expect to continue to incur substantial net losses from operations and may not achieve or sustain profitability in the future.
- **Risks Related to 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, business, financial condition and results of operations could be harmed; and
  - we purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or compl of one of these suppliers could cause delays, loss of revenue and contract liability.
- **Risks Related to Intellectual Property, Litigation and Regulatory Concerns:**
  - we or our partners may not obtain regulatory approval for our drug candidates on a timely basis, or at all;
  - patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual licenses from third parties may be required, which may not be available to us on commercially reasonable terms; and
  - from time to time, we are involved in legal proceedings and may incur substantial litigation costs and liabilities that could adversely affect our business, condition and results of operations.
- **Risks Related to our Collaboration Partners:**
  - we are highly dependent on Eli Lilly and Company, our collaboration partner for advancing rezpegaldesleukin to initiate, properly conduct and prioritize in clinical trials, and while we believe we currently have the materials that are necessary for us to continue clinical development of rezpegaldesleukin, and our ability to perform important additional development and commercialization activities and our business will be significantly harmed if our partner deprioritizes or discontinues clinical trials Eli Lilly and Company fails to continue to cooperate with us in or otherwise harm the prospects transfer of rezpegaldesleukin; all materials associated with the rezpegaldesleukin program; and
  - we may rely on academic and private non-academic institutions to conduct investigator-sponsored clinical studies or trials of our product candidates and any failure by the investigator-sponsor to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to enter into collaboration agreements, obtain regulatory approval or and commercialize for other our product candidates.

- **Risks Related to Supply and Manufacturing:**
  - if we or our contract manufacturers are not able to manufacture drugs or drug substances in sufficient quantities that meet applicable quality standards, our business, financial condition and results of operations could be harmed; and
  - we purchase some of the starting material for drugs and drug candidates from a single source or a limited number of suppliers, and the partial or complete loss of one of these suppliers could cause delays, loss of revenue and contract liability.
- **Risks Related to Intellectual Property, Litigation and Regulatory Concerns:**
  - we or our partners may not obtain regulatory approval for our drug candidates on a timely basis, or at all;
  - patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required, which may not be available to us on commercially reasonable terms; and
  - from time to time, we are involved in legal proceedings and may incur substantial litigation costs and liabilities that could adversely affect our business, financial condition and results of operations.

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

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PART I

Item 1. Business

Nektar Therapeutics is a clinical stage, research-based drug discovery biopharmaceutical company focused on discovering and developing innovative medicines in the field of immunotherapy. Within this growing field, we direct our efforts toward creating new immunomodulatory agents that selectively induce, amplify, attenuate or prevent immune responses in order to achieve desired therapeutic outcomes. We apply our deep understanding of immunology and unparalleled expertise in polymer chemistry to create innovative drug candidates and use our drug development expertise to advance these molecules through preclinical and clinical development. Our pipeline of clinical-stage and preclinical-stage immunomodulatory agents targets the treatment of autoimmune diseases (e.g. rezpegaldesleukin and cancer. NKTR-0165, respectively) and cancer (e.g. NKTR-255). We continue to make significant investments in building and advancing our pipeline of drug candidates as we believe that this is the best strategy to build long-term shareholder value.

Our Drug Candidates and Pipeline

By modulating the immune system, our drug candidates target pathways that play critical roles in a wide range of serious diseases. In autoimmune diseases, our focus is on addressing imbalances in the immune system to restore the body's self-tolerance mechanisms and to achieve immune homeostasis. In oncology, we are focused on activating the immune system's natural tumor-fighting mechanisms.

Autoimmune diseases (rezpegaldesleukin, formerly NKTR-358)

We recognize that many autoimmune diseases are caused by an imbalance in the body's immune system. A failure of the body's self-tolerance mechanisms enables the formation of pathogenic T cells that cause the immune system to mistakenly attack and damage healthy cells in a person's body.Current systemic treatments for autoimmune diseases, including corticosteroids and anti-TNF agents, suppress the immune system broadly and come with severe side effects. Pharmaceutical agents designed to rebalance the immune system by increasing the function of regulatory T cells (Treg cells), powerful inhibitory immune cells, could be used to treat patients suffering from autoimmune disorders and inflammatory diseases.

Rezpegaldesleukin has advanced

Our drug candidate rezpegaldesleukin is a potential first-in-class resolution therapeutic that may address this underlying immune system imbalance in people with autoimmune disorders and inflammatory diseases. It is designed to Phase 2 development, which our collaboration partner, Lilly, has carried out target the interleukin-2 (IL-2) receptor complex in various indications. the body in order to stimulate proliferation of Treg cells. By activating these cells, rezpegaldesleukin may act to bring the immune system back into balance. Rezpegaldesleukin is being developed as a once or twice monthly self-administered injection for a number of autoimmune disorders and inflammatory diseases.

On February 23, 2023 October 13, 2023, we announced the topline final efficacy data from the a Phase 2 1b study of rezpegaldesleukin in adult patients with systemic lupus erythematosus (SLE) atopic dermatitis (Phase 2 Lupus 1b AD Study). at the European Academy of Dermatology and Venereolgy conference. The primary endpoint of final efficacy data from the Phase 2 Lupus Study, a ≥4-points reduction in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score, was not met and Lilly has notified us 1b AD study showed that it does not intend to advance rezpegaldesleukin into Phase 3 development for SLE. Although the Phase 2 Lupus Study did not meet its primary endpoint, patients within the modified intent-to-treat population, defined as all patients who were randomized and received at least one dose of study medication, with moderate-to-sever atopic dermatitis that were treated with rezpegaldesleukin demonstrated improvement in SLEDAI-2K score as compared to placebo. Additionally, clinically meaningful rezpegaldesluekin had dose-dependent improvements were observed in the British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment (BICLA) response eczema area and Lupus Low Disease Activity State (LLDAS) as severity index (EASI), validated investigated global assessment (vIGA), body surface area (BSA), and itch numeric rating scale (NRS) over twelve weeks of treatment compared to placebo, which were sustained post-treatment over an additional thirty-six weeks. Rezpegaldesleukin was well tolerated with no patients in the rezpegaldesleukin groups experiencing severe, serious, or fatal adverse events, and exploratory biomarker data also showed that rezpegaldesleukin led to dose-dependent proliferation of Treg cells, which was consistent with prior studies. no anti-rezpegaldesleukin antibodies were detected.

Lilly has also completed

In late October 2023, we initiated a Phase 1b 2b clinical study of rezpegaldesleukin in patients with moderate-to-severe atopic dermatitis, and we are targeting the initiation of a new Phase 2b clinical study in patients with atopic dermatitis. alopecia areata by the end of March 2024. We and Lilly are working together plan to determine next steps explore other auto-immune indications for the planned Phase 2b study development of rezpegaldesleukin.

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We developed rezpegaldesleukin and own full rights to this drug candidate. Although we previously entered into a license agreement with Eli Lilly and Company in atopic dermatitis as well as 2017 (the Lilly Agreement) to develop and commercialize rezpegaldesleukin, on April 23, 2023, we received from Lilly a potential third Phase 2 study in a yet-to-be-announced autoimmune indication. We previously notice of at-will termination of the Lilly Agreement, and on April 27, 2023, we announced that Lilly we would be discontinuing further development regaining full rights to rezpegaldesleukin.

NKTR-0165

We believe that our preclinical tumor necrosis factor (TNF) receptor type II (TNFR2) agonist asset is a potentially unique bivalent antibody that selectively stimulates TNFR2 receptor activity, without modulation of rezpegaldesleukin in the TNFR1 signaling. TNFR2 signaling drives immunoregulatory function and can provide a direct protective effect for tissue cells. TNFR-2 is

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highly expressed on Tregs, neuronal cells and endothelial cells and has been shown to potentiate the suppressive effects and overall functional properties of Tregs. Our focus is on TNFR2 antibody candidates that show selective Treg cell binding and signaling profiles that may be potentially developed for treatment of autoimmune diseases, such as ulcerative colitis, multiple sclerosis and psoriasis vitiligo. We are carrying out Investigational New Drug (IND) enabling studies for this program in order 2024, after having exercised an option to prioritize gain an exclusive license to specified agonistic antibodies and other indications.

materials that were developed pursuant to a research collaboration and license option agreement we entered into with Biolojic Design, Ltd. in 2021.

Oncology (NKTR-255)

NKTR-255

In oncology, we focus on developing medicines based on targeting biological pathways that stimulate and sustain the body's immune response in order to fight cancer. NKTR-255 is an investigational biologic that is designed to target the interleukin-15 (IL-15) pathway in order to activate the body's innate and adaptive immunity. Activation of the IL-15 pathway enhances the survival and function of natural killer (NK) cells and induces survival of both effector and CD8+ memory T cells. Recombinant human IL-15 is rapidly cleared from the body and must be administered frequently and in high doses limiting its utility due to toxicity. Through optimal engagement of the IL-15 receptor complex, NKTR-255 is designed to enhance functional NK cell populations and the formation of long-term immunological memory, which may lead to sustained and durable anti-tumor immune response. Our development strategy for NKTR-255 is focused on three therapeutic areas: to

enhance response to antibody-dependent cellular cytotoxicity (ADCC) mediated therapies by restoring NK cells, to improve CAR-T cell persistency in cellular therapies and to augment response to checkpoint inhibitors.

We are studying NKTR-255 in ADCC combinations in both liquid and solid tumors. We have initiated a Phase 1 dose escalation and expansion study continuing select developmental studies of NKTR-255 in patients with relapsed or refractory non-Hodgkin lymphoma or multiple myeloma where patients are treated with NKTR-255 as a monotherapy or NKTR-255 in combination with daratumumab. cell therapies and checkpoint inhibitors while we evaluate additional strategic partnership pathways for the program. We have also initiated a Phase 1/2 study of NKTR-255 in patients with relapsed or refractory head and neck squamous cell carcinoma or colorectal cancer where patients are treated with NKTR-255 in combination with cetuximab. We expect to receive data from the expansion stage of both studies in the second half of 2023. We are evaluating NKTR-255 following treatment with CAR-T cell therapy and initiated a Nektar-sponsored Phase 2/3 study (currently in the Phase 2 portion) to evaluate NKTR-255 following Yescarta® Yescarta® or Breyanzi® Breyanzi® CD19 CAR-T cell therapy in patients with large B-cell lymphoma. We expect initial data from lymphoma, and the study to be available in the second half of 2024. Two ongoing investigator sponsored trials are also studying NKTR-255 in combination with CAR-T cell therapy. These studies include a Phase 1 study Fred Hutchinson Cancer Center is evaluating NKTR-255 in combination with following Breyanzi® CD19 CAR-T cell therapy in patients with relapsed or relapsed/refractory large B-cell lymphoma and a Phase 1 study evaluating NKTR-255 in combination with CD19/22 CAR-T cell therapy in patients with relapsed or refractory B-cell acute lymphoblastic leukemia. A third an investigator sponsored study is evaluating NKTR-255 in combination with darvulumab in patients with unresectable Stage 3 non-small cell lung cancer who have received chemoradiation. study. We are continuing our oncology

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clinical collaboration with Merck KGaA and Pfizer Inc. to evaluate the maintenance regimen of NKTR-255 in combination with avelumab, a PD-L1 inhibitor, in patients with locally advanced or metastatic urothelial carcinoma in the Phase II JAVELIN Bladder Medley study. We expect to receive topline data from the study in the second half of 2024. We entered into a new clinical study collaboration with AbelZeta Pharma, Inc. (AbelZeta) (formerly known as CBMG Holdings) to study NKTR-255 in combination with its C-TIL051, a tumor-infiltrating lymphocyte (TIL) therapy, in advanced non-small cell lung cancer (NSCLC) patients that are relapsed or refractory to anti-PD-1 therapy. Under the collaboration, we will contribute NKTR-255 and AbelZeta will add NKTR-255 to its ongoing AbelZeta-sponsored Phase 1 clinical trial. We also have an ongoing investigator sponsored study evaluating NKTR-255 in combination with IMFINZI (darvulumab) in patients with unresectable Stage 3 NSCLC who have received chemoradiation.

Other Research and Development Programs Program and Our Advanced Polymer Conjugate Technology Platform

We believe it is important to maintain a diverse pipeline of new drug candidates to build on the value of our business. Our discovery research organization is continuing to identify new drug candidates by applying our technology platform to a wide range of molecule classes, including small molecules and proteins, peptides and antibodies. We aim to advance our most promising research drug candidates into preclinical development with the objective of advancing these early-stage research programs to human clinical studies over the next several years. One

We continue to progress our preclinical PEG-Colony Stimulating Factor (PEG-CSF1) program. PEG-CSF1 is a polyethylene glycol modified version of our research programs the CSF1 protein that is focused on developing a tumor necrosis factor (TNF) intended to optimize the receptor 2 (TNFR2) agonist antibody. TNFR2 signaling drives immunoregulatory function interaction and can provide a direct protective effect for tissue cells. Our focus is on TNFR2 antibody candidates that show selective Treg cell binding and signaling profiles that may be developed for treatment to selectively modulate resolution processes of autoimmune diseases. In connection with inflammation. We believe this program we are targeting IND readiness for has applications in a lead TNFR2 agonist antibody candidate by the end number of 2023 in order to submit an Investigational New Drug (IND) filing for the first clinical study in 2024. therapeutic indications including acute and chronic inflammation as well as fibrosis. We also plan to continue maintain our preclinical stage oncology asset, NKTR-288, development program. NKTR-288 which is an investigational PEG conjugate of the protein interferon gamma that is designed utilizing a site-specific conjugation approach to modify binding of interferon gamma with one of its substrates and to optimize the pharmacodynamic duration of interferon gamma signaling. We believe this program has therapeutic applications in a number of therapeutic indications including oncology as well as in other infectious diseases.

Our advanced and proven polymer conjugate technology platform is focused on conjugating polyethylene glycol to a pharmaceutically active agent, a process often referred to as “PEGylation.” PEGylation has been a highly effective technology platform for the development of therapeutics with significant commercial success, such as Amgen’s Neulasta (pegfilgrastim) and UCB’s CIMZIA (certolizumab pegol). In addition to inventing new PEGylated drug candidates, our expertise extends to developing robust manufacturing processes for generating the PEGylation reagents that allow us to utilize the full potential of this important technology.

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Our advanced polymer conjugate technology platforms have the potential to offer one or more of the following benefits:

- improve efficacy or safety of a drug as a result of better pharmacokinetics, pharmacodynamics, longer half-life and sustained exposure of the drug;
- improve targeting or binding affinity of a drug to its target receptors with the potential to improve efficacy and reduce toxicity or drug resistance;
- improve solubility of a drug;
- enable oral administration of parenterally-administered drugs, or drugs that must be administered intravenously or subcutaneously, and increase oral bioavailability of small molecules;
- prevent drugs from crossing the blood-brain barrier, or reduce their rate of passage into the brain, thereby limiting undesirable central nervous system effects;

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- reduce first-pass metabolism effects of certain drug classes with the potential to improve efficacy, which could reduce the need for other medicines and reduce toxicity;
- reduce the rates of drug absorption and of elimination or metabolism by improving stability of the drug in the body and providing it with more time to act on its target;
- differentially alter binding affinity of a drug for multiple receptors, improving its selectivity for one receptor over another; and
- reduce immune response to certain macromolecules with the potential to prolong their effectiveness with repeated doses.

We believe that our substantial investment in research and development has the potential to create significant value if one or more of our current drug candidates demonstrates positive clinical results, receives regulatory approval in one or more major markets and achieves commercial success.

Our Collaboration Partner Programs

We decide on a drug-candidate-by-drug-candidate basis, how far to advance clinical development (e.g., Phase 1, 2 or 3) and whether to commercialize products on our own, or seek a partner, or pursue a combination of these approaches. When we determine to seek a partner, our strategy is to selectively access a partner's development, regulatory, or commercial capabilities with the structure of the collaboration depending on factors such as economic risk sharing, the cost and complexity of development, marketing and commercialization needs, therapeutic areas, potential for combination of drug programs, and geographic capabilities.

For example, we announced on February 14, 2018, that we and Bristol-Myers Squibb Company (BMS) executed a global strategic development and commercialization collaboration to develop Nektar's Phase 2 drug candidate, bempegaldesleukin, in combination with Opdivo® (nivolumab). Under the collaboration, BMS made an upfront payment of $1.0 billion and an equity investment of $850 million.Based on results from pre-planned analyses of two late-stage clinical studies of bempegaldesleukin in combination of Opdivo®, we and BMS announced on April 14, 2022, that the companies jointly decided to end the global clinical development program for the combination.We also discontinued all studies of bempegaldesleukin in combination with other drugs or drug candidates.

Our collaboration partners have advanced drug candidates we invented into commercial drug products.In addition, through our collaborations and licensing partnerships with a number of well-known biotechnology and pharmaceutical companies, more than ten products using our PEGylation technology have received regulatory approval in the U.S. or Europe. The following table outlines our collaborations and licensing partnerships. These collaborations generally contain one or more elements including a license to our intellectual property rights and manufacturing and supply agreements under which we may receive manufacturing revenue, milestone payments, and/or royalties on commercial sales of drug products.

Drug	Primary or Target Indications	Drug	Drug Marketer /Partner	Status(1)
Drug	Indications	Marketer/Partner	Status(1)	

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ADYNOVATE® and ADYNOVI® (brand (brand name for ADYNOVATE® in Europe)	Hemophilia A	Takeda Pharmaceutical Company Limited	Approved 2015*
MOVANTIK® (naloxegol tablets) and MOVENTIG® (brand name for MOVANTIK® in Europe)	Opioid-induced constipation in adult patients with chronic non-cancer pain (US); Opioid-induced constipation in adult patients who have and inadequate response to laxatives (EU).	AstraZeneca AB	Approved 2014*

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Drug	Primary or Target Indications	Drug Marketer/Partner	Status(1)
CIMZIA® (certolizumab pegol)	Crohn's disease, Rheumatoid arthritis, and Psoriasis/ Ankylosing Spondylitis	UCB Pharma	Approved 2008**

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MIRCERA® (C.E.R.A.) (Continuous Erythropoietin Receptor Activator)	Anemia associated with chronic kidney disease in patients on dialysis and patients not on dialysis	F. Hoffmann-La Roche Ltd	Approved 2007**
Macugen® (pegaptanib sodium injection)	Age-related macular degeneration	Bausch Health Companies Inc. (formerly, Valeant Pharmaceuticals International, Inc.)	Approved 2004
Somavert® (pegvisomant)	Acromegaly	Pfizer Inc.	Approved 2003
Dapirolizumab Pegol	Systemic Lupus Erythematosus	UCB Pharma (Biogen)	Phase 3

(1) Status definitions are:

Approved — regulatory approval to market and sell product obtained in one or more of the U.S., EU or other countries. Year indicates first regulatory approval.

Phase 3 — drug candidate in large-scale clinical trials conducted to obtain regulatory approval to market and sell the drug (these trials are typically initiated following encouraging Phase 2 trial results).

Approved — regulatory approval to market and sell product obtained in one or more of the U.S., EU or other countries. Yearindicates first regulatory approval.

Phase 3 — drug candidate in large-scale clinical trials conducted to obtain regulatory approval

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* In December 2020, pursuant to a purchase and sale agreement (the “2020 Purchase and Sale Agreement”) we sold our rights to receive royalties on future worldwide new sales of ADYNOVATE®/ADYNOVI® and MOVANTIK®/MOVANTIG® (as well as REBINYN® and specified licensed products under a Right to Sublicense Agreement, dated October 27, 2017) from and after October 1, 2020 until the purchaser of these rights has received payments 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). All rights to receive royalties will return to Nektar once the 2020 Purchase and Sale Agreement expires.

** In February 2012, we sold our rights to receive royalties on future worldwide net sales of CIMZIA® and MIRCERA® effective as of January 1, 2012.

and MOVANTIK

®/MOVANTIG® (as well as REBINYN® and specified licensed products under a Right to Sublicense Agreement, dated October 27, 2017) from and after October 1, 2020 until the purchaser of these rights has received payments 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). All rights to receive royalties will return to Nektar once the 2020 Purchase and Sale Agreement expires.

** In February 2012, we sold our rights to receive royalties on future worldwide net sales of CIMZIA® and MIRCERA® effective as of January 1, 2012.

Government Regulation

Product Development and Approval Process

The research and development, clinical testing, manufacture and marketing of our drug candidates and products using our technologies are subject to regulation by the FDA and by comparable regulatory agencies in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing (in vitro, in animals, and in human clinical trials), manufacture, labeling, storage, recordkeeping, approval, marketing, advertising and promotion of our products.

The approval process required by the FDA before a product using any of our technologies may be marketed in the U.S. depends on whether the chemical composition of the product has previously been approved for use in other dosage forms. If the product is a new chemical entity that has not been previously approved, the process includes the following:

- extensive preclinical laboratory and animal testing;
- submission of an Investigational New Drug (IND) prior to commencing clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for the intended indication;
- extensive pharmaceutical development for the characterization of the chemistry, manufacturing process and controls for the active ingredient and drug product; and

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- submission to the FDA of a New Drug Application (NDA) for approval of a drug or a Biological License Application (BLA) for approval of a biological product.

If the active chemical ingredient has been previously approved by the FDA, the approval process is similar, except that certain preclinical tests, including those relating to systemic toxicity normally required for the IND and NDA or BLA, and clinical trials, may not be necessary if the company has a right of reference to existing preclinical or clinical data under section Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) or is eligible for approval under Section 505(b)(2) of the FDCA or the biosimilars provisions of the Public Health Services Act.

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the safety and efficacy of the product and its chosen formulation. Preclinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices (GLP) regulations. The results of the preclinical tests for drugs, biological products and combination products subject to the primary jurisdiction of the FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) are submitted to the FDA as part of the IND and are reviewed by the FDA before clinical trials can begin. Clinical trials may begin 30 days after receipt of the IND by the FDA, unless the FDA raises objections or requires clarification within that period. Clinical trials involve the administration of the drug to healthy volunteers or patients under the supervision of a qualified, identified medical investigator according to a protocol submitted in the IND for FDA review. Drug products to be used in clinical trials must be manufactured according to current good manufacturing practices (cGMP). Clinical trials are conducted in accordance with protocols that detail the objectives of the study and the parameters to be used to monitor participant safety and product efficacy as well as other criteria to be evaluated in the study. Each protocol is submitted to the FDA in the IND.

Apart from the IND process described above, each clinical study must be reviewed by an independent Institutional Review Board (IRB), and the IRB must be kept current with respect to the status of the clinical study. The IRB considers, among other things, ethical factors, the potential risks to subjects participating in the trial and the possible liability to the institution where the trial is conducted. The IRB also reviews and approves the informed consent form to be signed by the trial participants and any significant changes in the clinical trial.

Clinical trials are typically conducted in three sequential phases. Phase 1 involves the initial introduction of the drug into healthy human subjects (in most cases) and the product generally is tested for tolerability, pharmacokinetics, absorption, metabolism and excretion. Phase 2 involves studies in a limited patient population to:

- determine the preliminary efficacy of the product for specific targeted indications;
- determine dosage and regimen of administration; and
- identify possible adverse effects and safety risks.

If Phase 2 trials demonstrate that a product appears to be effective and to have an acceptable safety profile, Phase 3 trials are typically

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undertaken to evaluate the further clinical efficacy and safety of the drug and formulation within an expanded patient population at geographically dispersed clinical study sites and in large enough trials to provide statistical proof of

efficacy and tolerability. The FDA, the clinical trial sponsor, the investigators or the IRB may suspend clinical trials at any time if, amongst other reasons, any one of them believes that study participants are being subjected to an unacceptable health risk. In some cases, the FDA and the drug sponsor may determine that Phase 2 trials are not needed prior to entering Phase 3 trials.

Following a series of formal meetings and communications between the drug sponsor and the regulatory agencies, the results of product development, preclinical studies and clinical studies are submitted to the FDA as an NDA or BLA for approval of the marketing and commercial shipment of the drug product. The FDA may deny approval if applicable regulatory criteria are not satisfied or may require additional clinical or pharmaceutical testing or requirements. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy all of the criteria for approval. Additionally, the approved labeling may narrowly limit the conditions of use of the product, including the intended uses, or impose warnings, precautions or contraindications which could significantly limit the potential market for the product. Further, as a condition of approval, the FDA may impose post-market surveillance, or Phase 4, studies or risk evaluation and mitigation strategies. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards is not maintained or if safety concerns arise after the product reaches the market. The FDA may require additional post-marketing clinical testing and pharmacovigilance programs to monitor the effect of drug products that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs. After approval, there are ongoing reporting obligations concerning adverse reactions associated with the product, including expedited reports for serious and unexpected adverse events.

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Each manufacturing establishment producing the active pharmaceutical ingredient and finished drug product for the U.S. market must be registered with the FDA and typically is inspected by the FDA prior to NDA or BLA approval of a drug product manufactured by such establishment. Such inspections are also held periodically after commercialization. Manufacturing establishments of U.S. marketed products are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements. They are also subject to U.S. federal, state, and local regulations regarding workplace safety, environmental protection and hazardous controls, among others.

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In situations where our partners are responsible for clinical and regulatory approval procedures, we may still participate in this process by submitting to the FDA a drug master file developed and maintained by us which contains data concerning the manufacturing processes for polymer conjugation materials or drug product. For those products for which we have development responsibility, we prepare and submit an IND and are responsible for additional clinical and regulatory procedures for drug candidates being developed under an IND. The clinical and manufacturing, development and regulatory review and approval process generally takes a number of years and requires the expenditure of substantial resources. Our ability to manufacture and market products, whether developed by us or under collaboration agreements, ultimately depends upon the completion of satisfactory clinical trials and success in obtaining marketing approvals from the FDA and equivalent foreign health authorities.

Sales of our products outside the U.S. are subject to local regulatory requirements governing clinical trials and marketing approval for drugs. Such requirements vary widely from country to country.

In the U.S., the FDA may grant Fast Track or Breakthrough Therapy designation to a drug candidate, which allows the FDA to expedite the review of new drugs that are intended for serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Important features of Fast Track or Breakthrough Therapy designation include a potentially expedited clinical review and close, early communication between the FDA and the sponsor company to improve the efficiency of product development.

In the U.S., under the Orphan Drug Act, the FDA may grant orphan drug designation Orphan Drug Designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. The company that obtains the first FDA approval for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. In addition, the Orphan Drug Act provides for protocol assistance, tax credits, research grants, and exclusions from user fees for sponsors of orphan products. Once a product receives orphan drug exclusivity, a second product that is considered to be the same drug for the same indication generally may be approved during the exclusivity period only if the second product is shown to be “clinically superior” to the original orphan drug in that it is more effective, safer or otherwise makes a “major contribution to patient care” or the holder of exclusive approval cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similar incentives also are available for orphan drugs in the EU.

Coverage, Reimbursement, and Pricing

Sales of any products for which we may obtain regulatory approval depend, in part, on the coverage and reimbursement status of those products. In the U.S., sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payers. Third-party payers include government programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care providers, private health insurers and other organizations. Other countries and jurisdictions will also have their own unique mechanisms for approval and reimbursement.

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The process for determining whether a payer will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list or formulary which might not include all of the FDA-approved products for a particular indication. Third-party payers may also refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Further, private payers often follow the coverage and payment policies established by certain government programs, such as Medicare and Medicaid, which require manufacturers to comply with certain rebate, price reporting, and other obligations. For example, the Medicaid Drug Rebate Program, which is part of the Medicaid program (a program for financially needy patients, among others), requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services under which the manufacturer agrees to report certain prices to the government and pay rebates to state Medicaid programs on outpatient drugs furnished to Medicaid patients, as a condition for receiving federal reimbursement for the manufacturer's outpatient drugs furnished to Medicaid patients. Further, in order for a pharmaceutical product to receive federal reimbursement under Medicare Part B and Medicaid programs or to be sold

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directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the Public Health Service's 340B drug pricing program.

Third-party payers are increasingly challenging the prices charged for medical products and services, and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the price of therapeutics have been a focus in this effort. The U.S. government and state legislatures have shown significant interest in implementing cost-containment programs, including price controls and restrictions on reimbursement, among other controls. Adoption of price controls or other cost-containment measures could limit coverage for or the amounts that federal and state governments or private payers will pay for health care products and services, which could also result in reduced demand for our drug candidates or additional pricing pressures and affect our ultimate profitability, if approved. If third-party payers do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Regulations

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If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- 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 regulatory safe harbors 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. Statute regulatory safe harbors. 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, 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, or 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

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- 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), other licensed health care practitioners 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;
- 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, theremay 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.

If our drug candidates become commercialized, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance

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or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, disgorgement, exclusion from government-funded healthcare programs, such as Medicare and

Medicaid, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act (collectively, the Affordable Care Act), enacted in 2010, expanded the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the Affordable Care Act, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,463 and $23,331 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

In each country or jurisdiction outside of the U.S. in which we seek and receive regulatory approval to commercialize our products, we will be subject to additional laws and regulations specific to those locations. These regulations and laws will also impact, among other things, our proposed sales and marketing programs in those jurisdictions.

Legislative and Regulatory Landscape

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From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, coverage and reimbursement of products regulated by the FDA or other government agencies. In addition to new legislation, FDA and healthcare fraud and abuse and

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coverage and reimbursement regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. For example, in 2010, the United States Congress enacted the Affordable Care Act, which, among other things, included changes to the coverage and payment for drug products under government health care programs.

Among the provisions of the Affordable Care Act of importance to potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 70% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. Subsequent legislation extended the 2%

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which remains in effect through 2030. 2031. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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

Furthermore, federal agencies, Congress, state legislatures, and the private sector have shown significant 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. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more

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transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the

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Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. Any proposed or actual changes could limit coverage for or the amounts that federal and state governments will pay for health care products and services, which could also result in reduced demand for our products or additional pricing pressures and affect our ultimate profitability. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Patents and Proprietary Rights

We own more than 300 250 U.S. and 1,500 1,200 foreign patents and a number of pending patent applications that cover various aspects of our technologies. We have filed patent applications, and plan to file additional patent applications, covering various aspects of our advanced polymer conjugate

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technologies and our drug candidates. More specifically, our patents and patent applications cover polymer architecture, drug conjugates, candidates, formulations, methods of making polymers and polymer conjugates, methods of administering polymer conjugates, our drug candidates, and methods of manufacturing polymers and polymer conjugates. Our patent portfolio contains patents and patent applications that encompass our advanced polymer conjugate technology platforms. platforms as well as our drug candidates. Our patent strategy is to file patent applications on innovations and improvements to cover a significant majority of the major pharmaceutical markets in the world. Generally, patents have a term of twenty years from the earliest non-provisional patent application filing priority date (assuming all maintenance fees are paid). In some instances, patent terms can be increased or decreased, depending on the laws and regulations of the country or jurisdiction that issued the patent.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that we can meaningfully protect our trade secrets. Others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to, or disclose, our trade secrets. Please refer to Item 1A. Risk Factors, including but not limited to “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.” In certain situations in which we work with drugs covered by one or more patents, our ability to develop and commercialize our technologies may be affected by limitations in our access to these proprietary drugs. Even if we believe we are free to work with a proprietary drug, we cannot guarantee that we will not be accused of, or determined to be, infringing a third party’s rights and be prohibited from working with the drug or found liable for damages. Any such restriction on access or liability for damages would have a material adverse effect on our business, results of operations and financial condition.

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The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. 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 *inter partes* review, opposition, reexamination or other proceedings that can result in the revocation of the patent or maintenance of the patent but in an amended form (and potentially in a form that renders the patent without commercially relevant 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 early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patent. We may have to participate in post-grant proceedings before the U.S. Patent and Trademark Office, which could result in a loss of the patent and/or substantial cost to us. Please refer to Item 1A. Risk Factors, including without limitation, “If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.”

U.S. and foreign patent rights and other proprietary rights exist that are owned by third parties and relate to pharmaceutical compositions and reagents, and equipment and methods for preparation, packaging and delivery of pharmaceutical compositions. We cannot predict with any certainty which, if any, of these rights will be considered relevant to our technology 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. We could incur substantial costs in defending ourselves and our partners against any such claims. Furthermore, parties making such claims may be able to

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obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and abroad and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from third parties. 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 alternative technology. The failure to obtain licenses if needed may have a material adverse effect on our business, results of operations and financial condition. Please refer to Item 1A. Risk Factors, including without limitation, “We may not be able to obtain intellectual property licenses related to the development of our drug candidates on a commercially reasonable basis, if at all.”

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It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

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Customer Concentrations

Our revenue is derived from our collaboration agreements with partners, under which we may receive a combination of revenue elements including up-front payments for licensing agreements, clinical research reimbursement or co-funding, milestone payments based on clinical progress, regulatory progress or net sales achievements, royalties and/or product sales revenue. Our revenues are concentrated among a limited number of collaboration partners under long-term arrangements. We derive the substantial majority of our PEGylation reagent product sales from UCB and Pfizer. Following the 2020 Purchase and Sale Agreement (wherein under a capped return sale arrangement we sold our rights to receive royalties on future worldwide new sales of MOVANTIK®/MOVANTIG® and ADYNOVATE®/ADYNOVI®, as well as REBINYN®and specified licensed products), other than our product sales, substantially all of our revenues are non-cash royalty revenues. However,

Following the termination of our collaboration agreement with Eli Lilly and Company, we do not have a collaboration agreement for the development of rezpegaldesleukin provides Therefore, we will not receive collaboration-based revenues for the most significant portion of our potential future development lead drug candidates, rezpegaldesleukin and regulatory milestone payments, as well as royalties from net sales of rezpegaldesleukin, if approved. Additionally, NKTR-255 unless we enter into new collaboration agreements for these collaboration partners can provide significant financial support for the development and commercialization drug candidates.

of these programs. For example, Lilly bears 75% of the Phase 2 development costs of rezpegaldesleukin, will bear 100% of the Phase 3 development costs, subject to our right to contribute up to 25% of

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Phase 3 development costs on an indication-by-indication basis, which we have announced our intention to exercise our option to fully fund Nektar's 25% share of the Phase 3 development costs, in exchange for higher royalties, if approved. Lilly will also be responsible for all costs of global commercialization, subject to our option to co-promote in the U.S. under certain conditions.

Competition

Competition in the pharmaceutical and biotechnology industry is intense and characterized by aggressive research and development and rapidly-evolving science, technology, and standards of medical care throughout the world. We frequently compete with pharmaceutical companies and other institutions with 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.

Science and Technology Competition

We face intense science and technology competition from a multitude of technologies seeking to enhance the efficacy, safety and ease of use of approved drugs and new drug molecule candidates. A number of the drug candidates in our pipeline have direct and indirect competition from large pharmaceutical and biopharmaceutical companies. With our advanced polymer conjugate technologies, we believe we have competitive advantages relating to factors such as efficacy, safety, ease of use and cost for certain applications and molecules. We constantly monitor scientific and medical developments in order to improve our current technologies, seek licensing opportunities where appropriate, and determine the best applications for our technology platforms.

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In the fields of advanced polymer conjugate technologies, our competitors include Biogen Idec Inc., Horizon Pharma, JenKem Technology USA, Dr. Reddy's Laboratories Ltd., SunBio Corporation, Laysan Bio, Inc., Mountain View Pharmaceuticals, Inc., SunBio Corporation, NOF Corporation, and Novo Nordisk A/S (assets formerly (formerly assets held by Neose Technologies, Inc.), , NOF Corporation and Aurigene Pharmaceutical Services. Several other chemical, biotechnology and pharmaceutical companies may also be developing advanced polymer conjugate technology or technologies intended to deliver similar scientific and medical benefits. Some of these companies license intellectual property or PEGylation materials to other companies, while others apply the technology to create their own drug candidates.

Product and Program Specific Competition

Rezpegaldesleukin

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, microbiome-based, or toleragenic-based therapies (Symbiotix, (Regeneron, Leo Pharma, Eli Lilly and Company, Galderma, Symbiotix, LLC, Janssen Pharmaceuticals, AstraZeneca and Tizona Therapeutics) AstraZeneca), regulatory T cell therapies (Sangamo Therapeutics, Inc., Quell Therapeutics, Ltd., TxCell, Inc., Sonoma Biotherapeutics, Inc. GentiBio, Inc., Kyvema Therapeutics, Inc. and Tract Therapeutics, Inc.), or IL-2 based therapies (Amgen, Inc., BMS (through its acquisition of Delnia, Inc.), Novartis, Inc., ILTOO Pharma, Xencor, inc., Merck & Co (through its acquisition of Pandion Therapeutics), and Sanofi SA (through its acquisition SA).

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Table of Synthorx, Inc.)). Contents

NKTR-255

There are numerous companies engaged in developing immunotherapies with different approaches to enhancing NK cell populations which are a key component of the innate immune system. The approaches include engineered biologics targeting the IL-15 pathway as well as autologous and allogenic cell therapy approaches. 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 SOTIO Biotech, Inc., Artiva Biotherapeutics, Fate Therapeutics, ImmunityBio, Inc., nkarta therapeutics, Nkarta, Inc., NKMax America, and Roche/Genentech (through its partnership with Xencor, Inc.).

Research and Development

Our total research and development expenditures can be disaggregated into the following significant types of expenses (in millions):

	Year Ended December 31,	
	2022	2021
Third party and direct materials costs	$ 79.2	$176.9
Personnel, overhead and other costs	103.9	158.7
Stock-based compensation and depreciation	35.2	64.7

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Research and development expense	$218.3	$400.3

	Year Ended December 31,	
	2023	2022
Third party and direct materials costs	$ 91.9	$ 72.1
Personnel, overhead and other costs	45.5	30.1
Stock-based compensation and depreciation	8	2

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Research and development expense	$ 114.2	$ 218.3

Manufacturing and Supply

We have a manufacturing facility located in Huntsville, Alabama that manufactures our proprietary PEG reagents for subsequent conjugation to active pharmaceutical ingredients (APIs). The facility is also can be used to produce APIs themselves, as well as form PEG conjugates of those APIs, to support the early phases of clinical development of our drug candidates. development. The facility and associated equipment are designed and operated to be consistent with all applicable laws and regulations. As we do not maintain the capability to manufacture biologics nor finished drug products for our

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development programs, we primarily utilize contract manufacturers to manufacture biologics and finished drug product for us. We also utilize the services of contract manufacturers to manufacture APIs and finished drug products required for later phases of clinical development and eventual commercialization. Our contract manufacturers have contractual obligations to comply with all applicable laws and regulations.

We source drug starting materials for our manufacturing activities from one or more suppliers. For the drug starting materials necessary for our drug candidate development, we have agreements for the supply of such drug components with drug manufacturers or suppliers that we believe have sufficient capacity to meet our demands. However, from time to time, we source critical raw materials and services from one or a limited number of suppliers and there is a risk that if such supply or services were interrupted, it could

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materially harm our business. In addition, we typically order raw materials and services on a purchase order basis for early phase clinical development products and enter into long-term supply arrangements only for late-stage products nearing regulatory approval for marketing authorization.

Environment

As a manufacturer of PEG reagents for the U.S. market, we are subject to inspections by the FDA and the U.S. Environmental Protection Agency for compliance with cGMP and other U.S. regulatory requirements, including U.S. federal, state and local regulations regarding environmental protection and hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure we are in

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compliance with these laws and regulations. To our knowledge, we comply with all material governmental regulations applicable to our business. We would be subject to significant penalties for failure to comply with these laws and regulations.

Human Capital

As of December 31, 2022 December 31, 2023, we had 216 137 employees, of which 140 97 employees were engaged in research and development, manufacturing, and quality activities. Of the 216 Substantially all of our employees 213 were are located in the U.S. We have a number of employees who hold advanced degrees, such as a Ph.D. None of our employees are covered by a collective bargaining agreement, and we have experienced no work stoppages. We are committed to attracting, developing, advancing and retaining a diverse and talented workforce. As part of our measures to attract and retain personnel, we offer

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a total rewards package to our full-time employees consisting of base salary, cash bonuses based on individual and company performance, equity compensation and comprehensive benefits, including health insurance, life insurance, retirement plans, and paid holiday and vacation time. We support our employee's further development by providing professional development opportunities. We believe that we maintain good relations with our employees.

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To complement our own expert professional staff, we utilize specialists in clinical development, regulatory affairs, pharmacovigilance, process engineering, manufacturing and quality assurance. These individuals include scientific advisors as well as independent consultants.

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Available Information

Our website address is *http://www.nektar.com*. The information in, or that can be accessed through, our website is not part of this annual report on Form 10-K. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports are available, free of charge, on or through our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission (SEC). The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding our filings at *www.sec.gov.*

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following table sets forth the names, ages and

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positions of our executive officers as of February 28, 2023 March 5, 2024:

Name	Age	Position
Howard W. Robin	70 71	Director, President and Chief Executive Officer
Jillian B. Thomsen	57 58	Senior Vice President, Interim Chief Financial Officer (Principal Financial and Chief Accounting Officer Officer)
Sandra Gardiner		
Mark A. Wilson, J.D.	51 52	Senior Vice President and Chief Legal Officer

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Jonathan Zalevsky, Ph.D.	48	Chief Research and Development Officer

Howard W. Robin has served as our President and Chief Executive Officer since January 2007 and has served as a member of our boardof directors since February 2007. Mr. Robin served as Chief Executive Officer, President and a director of Sirna Therapeutics, Inc., a biotechnology company, from July 2001 to November 2006 and from January 2001 to June 2001, served as their Chief Operating Officer, President and as a director. From 1991 to 2001, Mr. Robin was Corporate Vice President and General Manager at Berlex Laboratories, Inc. (Berlex), a pharmaceutical products company that is a subsidiary of Schering, AG, and from 1987 to 1991 he served as Vice President of Finance and Business Development and Chief Financial Officer of Berlex. From 1984 to 1987, Mr. Robin was Director of Business Planning and

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Development at Berlex. He was a Senior Associate with Arthur Andersen & Co. prior to joining Berlex. Mr. Robin serves as a director of the Biotechnology Industry Organization, the world's largest biotechnology industry trade organization, and also serves as a director of BayBio, a non-profit trade association serving the Northern California life sciences community. He received his B.S. in Accounting and Finance from Fairleigh Dickinson University in 1974.

Jillian B. Thomsen *Sandra Gardiner* has served as our Senior Vice President, Interim Chief Financial Officer since April 2023. Ms. Gardiner is a partner at FLG Partners, a leading CFO services firm in the Silicon Valley and Chief Accounting Officer since July 2022. From February 2010 a skilled business and finance executive with over 30 years of experience as an EVP and CFO at private and public companies in the Life Sciences sector. Prior to July 2022, Ms. Thomsen

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served as our Senior Vice President, Finance and Chief Accounting Officer. From April 2008 through January 2010 joining Nektar, she served as our the Chief Financial Officer, Executive Vice President of Finance and Chief Accounting Officer Administration, Secretary and from March 2006 through March 2008, Ms. Thomsen served as our Vice President Finance Treasurer of Pulse Biosciences, Inc., a bioelectric medicine company, since November 2019. Prior to joining Pulse Biosciences, she held CFO roles in both domestic and Corporate Controller. Before joining Nektar, Ms. Thomsen was Vice President Finance and Deputy Corporate Controller of Calpine Corporation from September 2002 to February 2006. Ms. Thomsen began her career global companies, operating as a certified public accountant at Arthur Andersen LLP, where she worked from 1990 director to 2002, international subsidiaries throughout Europe, Asia Pacific and specialized in audits

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of multinational consumer products, life sciences, manufacturing and energy companies. Latin America. Ms. Thomsen Gardiner holds a Masters of Accountancy B.A. in Management Economics from the University of Denver and a B.A. in Business Economics from Colorado College. California, Davis.

*Mark A. Wilson*has served as our Senior Vice President and Chief Legal Officer since July 2022. Previously, Mr. Wilson servedas our General Counsel since June 2016. Mr. Wilson joined Nektar in May 2002 and initially served as Patent Counsel and then as Senior Patent Counsel to the company prior to 2008 when he was promoted to Vice President, Intellectual Property. Before joining Nektar in 2002, Mr. Wilson was an associate at Reed & Associates, a patent law firm in Menlo Park, California, where he represented both start-up and Fortune 500 companies. Mr. Wilson received his J.D. from Seton Hall University, School of Law, and his B.S. in

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Pharmacy from Rutgers University, College of Pharmacy. He is registered to practice before the U.S. Patent and Trademark Office and is a member of the California Bar.

*Jonathan Zalevsky*has served as our Chief Research & Development Officer since October 2019. Dr. Zalevsky served as our SeniorVice President, Biology and Preclinical Development from April 2017 through November 2017 and served as our Senior Vice President, Research and Chief Science Officer from November 2017 to October 2019. From July 2015 through April 2017, Dr. Zalevsky served as our Vice President, Biology and Preclinical Development. Prior to joining Nektar, Dr. Zalevsky was Global Vice President and Head of the Inflammation Drug Discovery Unit at Takeda Pharmaceuticals. Prior to working at Takeda, Dr. Zalevsky held a number of research and development positions at Xencor, Inc. Dr. Zalevsky received his Ph.D. in Biochemistry from

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the Tetrad Program at the University of California, San Francisco. He received dual bachelor degrees in Biochemistry and Molecular, Cellular and Developmental Biology from the University of Colorado at Boulder.

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Item 1A. Risk Factors

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

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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 Related to our Business

We are highly dependent on the success of drug candidates, including rezpegaldesleukin (previously referred to as NKTR-358) and NKTR-255. If these drug candidates fail in clinical development our business will be significantly harmed.

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Our future success is highly dependent on the clinical success of our drug candidates, including rezpegaldesleukin and NKTR-255. In general, most investigational drugs, including drug candidates designed to treat patients suffering from autoimmune disorders and cancers, such as rezpegaldesleukin and NKTR-255, respectively, do not become approved drugs. Accordingly, there is a very meaningful risk that our drug candidates will not succeed in one or more clinical trials sufficient to support one or more regulatory approvals. Further, if

We previously relied on Lilly our collaboration partner for rezpegaldesleukin, delays (through the initiation or completion of one or more Lilly Agreement) to initiate, properly conduct, and prioritize clinical trials and other development-related activities for reasons outside of our control, or discontinues development of rezpegaldesleukin for scientific or other reasons, or is not

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successful, it would materially harm our market valuation, prospects, financial condition and results of operations. Under our collaboration agreement with Lilly, we are eligible for up to $250.0 million in additional development and regulatory milestones, and a royalty rate up to the low twenties percent based upon our Phase 3 development cost contribution and the level of annual global product sales. rezpegaldesleukin. In February 2023, we announced that the Phase 2 Lupus Study of rezpegaldesleukin in SLE conducted by Lilly did not meet the study's study's primary endpoint and that Lilly does did not intend to advance rezpegaldesleukin to Phase 3 development in SLE. One or more clinical failures On April 27, 2023, we announced that we had received a notice of termination from Lilly with respect to the Lilly Agreement and we would be regaining the full rights to rezpegaldesleukin from Lilly. Following the return of our drug candidates rights to develop

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rezpegaldesleukin, we will bear all costs of development. We have initiated a Phase 2b study of rezpegaldesleukin in patients with moderate-to-severe atopic dermatitis, and we are targeting by the initiation of a new Phase 2b clinical study of rezpegaldesleukin in patients with alopecia areata by the end of March 2024. We also plan to other auto-immune indications for the development of rezpegaldesleukin. While we believe we currently have the materials that are necessary for us to continue clinical development of rezpegaldesleukin, we may need or benefit from additional materials that Lilly has not yet transferred to us. In the event Lilly fails to promptly and completely transfer to us any additional needed materials or we are not able to independently source these materials, the continued clinical development of rezpegaldesleukin and our business will be significantly harmed. Even if the applicable agreement provides us with enforcement or other curative

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rights to address the potential harm caused by Lilly's action (or failure to act), our efforts in pursuing a remedy would jeopardize be costly and could result in reduced, delayed there is no guarantee that these efforts would succeed or eliminated revenue.

be sufficient to fully address the harm. If continued development of rezpegaldesleukin is not ultimately successful, our market valuation, prospects, financial condition and results of operations would be materially harmed.

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

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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

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control. One or more clinical failures of our drug candidates would jeopardize and could materially harm our business, results of operations and financial condition.

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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 conducting clinical trials of our drug candidates. 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:

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- 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 rezpegaldesleukin) currently or previously partnered with other companies, delays caused by our partner;
- delays caused by the COVID-19 pandemic public health epidemics (see also the risk factor in this Item 1A titled "*Our business could be adversely affected by the effectsof health epidemics including the recent COVID-19 pandemic*").;

[illegible] or trial sites;

[illegible] studies would be delayed, and consequently the regulatory approval process would be delayed which would also delay the ability to commercialize these drug candidates, which could have a material adverse effect on our

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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.

We currently rely on academic and private non-academic institutions to conduct investigator-sponsored clinical studies or trials of our product candidates. Any failure by the investigator-sponsor to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory

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approval or commercialize for other product candidates.

We currently rely on academic and private non-academic institutions to conduct and sponsor clinical studies or trials relating to our product candidates. We do not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored studies or trials as providing adequate support for future clinical trials, whether controlled by us or independent investigators, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information concerning our drug candidates with respect to the investigator-sponsored studies or trials, including access to and the ability to use and reference the data,

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including for our own regulatory filings, resulting from the investigator-sponsored studies or trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the

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investigator-sponsored studies or trials. If we are unable to confirm or replicate the results from the investigator-sponsored studies or trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the

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investigator-sponsored studies or trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored studies or trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored studies or trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate our planned clinical trials and/or may not accept such additional data as adequate to initiate our planned clinical trials.

The outcomes from the clinical trials of drug candidates from

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others, and the discovery and development of new potential therapies in immunology and oncology, could have a material and adverse impact on the value of the drug candidates in our research and development pipeline.

The research and development of immune-modulatory agents 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 rezpegaldesleukin, NKTR-255 and other immunomodulatory agents drug candidates face substantial competition from other regimens already approved, and many more that are either ahead of or in parallel development in patient populations where we are studying our drug candidates. As immunotherapy represent represents a relatively new approach to treatment of autoimmune disorders and cancer and few

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have successfully completed late stage development, drug development in this area entails substantial risks and uncertainties that include rapidly changing standards of care, identifying contribution of components when therapeutic combinations are employed, patient enrollment competition, evolving regulatory frameworks to evaluate 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 our drug candidates.

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

A number of companies have suffered significant unforeseen failures in clinical studies due to factors such as inconclusive

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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

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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 noncompetitive, 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

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technologies include Biogen Inc., Horizon Pharma, JenKem Technology USA, 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.), NOF Corporation and Aurigene Pharmaceutical Services. Several other chemical, biotechnology and pharmaceutical companies may also be developing polymer conjugation technologies or technologies that have similar impact on target drug molecules. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use.

There are many competitors for our drug candidates currently in development. For rezpegaldesleukin, 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

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disease. In particular, we expect to compete with therapies that could be cytokine-based, microbiome-based, or toleragenic-based therapies (Symbiotix, (Regeneron, Leo Pharma, Eli Lilly

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and Company, Galderma, Symbiotix, LLC, Janssen AstraZeneca, and Tizona Therapeutics) Pharmaceuticals, AstraZeneca), regulatory T cell therapies (Sangamo Therapeutics, Inc., Quell Therapeutics, Ltd, TxCell, Inc. Ltd., Sonoma Biotherapeutics, Inc., GentiBio, Inc., Kyvema Therapeutics, Inc. and and Tract Therapeutics, Inc.), or IL-2-based-therapies IL-2 based therapies (Amgen, Inc., BMS (through its acquisition of Delnia, Inc.), Novartis, Inc., ILTOO Pharma, Xencor, Inc. inc., Merck & Co through (through its acquisition of Pandion

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Therapeutics, Therapeutics), and Sanofi SA, through its acquisition of Synthorx, Inc.) SA). 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 SOTIO Biotech, Inc., Artiva Biotherapeutics, Fate Therapeutics, ImmunityBio, Inc., Nkarta, Therapeutics, Inc., 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

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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 noncompetitive 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

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final data and may change as more patient data become available.

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

Risks Related to our Collaboration Partners

We are highly dependent on our collaboration partner to initiate, properly conduct and prioritize

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clinical trials for rezpegaldesleukin and to perform important additional development and commercialization activities, and our business will be significantly harmed if they deprioritize or discontinue clinical trials or otherwise harm the prospects of our drug candidates.

We rely on Lilly (through the Lilly Agreement) to initiate, properly conduct, and prioritize clinical trials and other development-related activities for rezpegaldesleukin. Furthermore, we will rely on Lilly to perform specified commercialization activities for rezpegaldesleukin, pursuant to our collaboration agreement. In the event Lilly fails to initiate, properly conduct and prioritize their obligations under their applicable agreement with us, our business will be significantly harmed.Even if our agreement with Lilly provides us with enforcement or other curative rights to address the harm caused by Lilly's action (or failure to act), our efforts in pursuing a remedy would be costly and

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time-consuming, and there is no guarantee that these efforts would succeed or be sufficient to fully address the harm.

Risks Related to our Financial Condition and Capital Requirement

Our 2022

Additional cost-savings measures may be necessary following implementation of our strategic reorganization plan and cost restructuring plan may not be successful plans.

Our 2022 and we may undertake additional restructuring activities in the future.

On April 25, 2022, we announced our strategic reorganization and cost restructuring plans (together, the 2022 2023 Restructuring Plan) to prioritize Plans prioritized key research and development efforts that will impact the Company's future business activities, including activities involving rezpegaldesleukin, NKTR-255 and several core research programs. In connection with the 2022 Restructuring Plan, we also announced cost restructuring

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measures aimed at ensuring we will have significant capital to fund key programs over a multi-year time horizon. There is no guarantee that the 2022 these Restructuring Plan Plans and their associated cost restructuring measures will achieve its their intended benefits or that our post-restructuring focus will be sufficient for us to achieve success. In addition, in view of the outcome of the Phase 2 Lupus Study and Lilly's decision not to initiate Phase 3 clinical testing of rezpegaldesleukin in SLE, Consequently, we may need to undertake additional restructuring and cost-saving activities in 2023 to further prioritize our key research and development efforts. There is no guarantee efforts and these new efforts will be successful additional restructuring and may further harm our business. For example, our cost restructuring efforts cost-saving activities may not result in the anticipated savings or other economic benefits, may prioritize the wrong drug candidates or wrong indications to study for those drug candidates, or could result in total costs and expenses that are greater than expected, which would require us to seek potentially dilutive financing alternatives, disrupt

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or restrain the scope of our business activities, and would make it more difficult to attract and retain qualified personnel, each of be successful, which could have a material adverse effect on our business, financial condition and prospects prospects.

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

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

- designing and conducting large scale clinical studies;
- preparing and filing documents necessary to obtain government approvals to sell a given drug candidate; and/or

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- 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:

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- 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

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loan or other debt arrangements, and the issuance of securities;

our general and administrative expenses, capital expenditures and other uses of cash;

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;

- disputes concerning patents, proprietary rights, license ar collaboration agreements that cou negatively impact o receipt milestone payments royalties require us make significant payments arising fro licenses, settlements adverse judgments ongoing royalties.

A significar multi-year capital commitmen is required t advance ou drug candidates through the various stages of research ar developmer in order to generate sufficient data to enable high value collaboratio partnerships with significant upfront payments o to

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development or marketing of our partnered drugs than they devote to their own drugs or other drugs that they have in-licensed;

- we have very little control over the timing and amount of resources our partners devote to development programs in one or more major markets;
- disagreements with partners could lead to delays in, or termination of, the research, development or commercialization of drug candidates or to litigation or arbitration proceedings;
- disputes may arise or escalate in the future with respect to the ownership of rights to technology or intellectual property developed with partners;
- we do not have the ability to unilaterally terminate agreements (or partners may have extension or renewal rights) that we believe are not on commercially reasonable terms or consistent with our current business strategy;
- partners may be unable to pay us as expected;
- partners may terminate their agreements with us unilaterally for any or no reason, in some cases with the payment of a termination fee penalty and in other cases with no termination fee penalty; and
- partners may respond to natural disasters or health epidemics, such as the COVID-19 pandemic, by ceasing all or some of their development responsibilities (including the responsibility to clinical develop our drug candidates).

Given these risks, the success of our current and future collaboration partnerships is highly

successfully achieve regulatory approval. In the event w do not ente into any ne collaboratio partnership with significant upfront payments and we choose to continue to advance ou drug candidates later stage research an developmer we may nee to pursue financing alternatives including dilutive equity-base financings, such as an offering of convertible debt or common stock, whic would dilute the percentage ownership o our current common stockholder and could significantly lower the market valu of our common stock. If sufficient capital is no available to us or is not available or commercial

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unpredictable and can have a substantial negative impact on our business. If the approved drugs fail to achieve commercial success or the drugs in development fail to have positive late stage clinical outcomes sufficient to support regulatory approval in major markets, it could significantly impair our access to capital necessary to fund our research and development efforts for our drug candidates. If we are unable to obtain sufficient capital resources to advance our drug candidate pipeline, it would negatively impact the value of our business, results of operations and financial condition.

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

As of December 31, 2022 December 31, 2023, we had cash and investments in marketable securities valued at approximately $505.0 million $329.4 million. While we believe that our cash position will be sufficient to meet our liquidity requirements through at least the next 12 months, our future capital requirements will depend upon numerous unpredictable factors, including:

reasonable terms, it could requir us to delay reduce one or more of our researcl and developmer programs. I we are unable to sufficiently advance ou research an developmer programs, it could substantially impair the value of suc programs and result ir a material adverse effect on ou business, financial condition ar 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

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factors such as safety and efficacy compared to other available treatments, including changing standards of care, third party payer reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic and biosimilar versions of our drug candidates following approval by regulatory authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the commercial potential of the drug candidate, the commercial terms of any collaboration partnership potential for such drug candidate, or if we have already entered into a collaboration for such drug candidate, the revenue potential from royalty and milestone payments could be significantly

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diminished and this would negatively impact our business, financial condition and results of operations. We may also depend on our relationships with other companies for sales and marketing performance and the commercialization of drug candidates. Poor performance by these companies, or disputes with these companies, could negatively impact our revenue and financial condition.

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

In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. In both domestic and foreign markets, sales of our

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partnered and proprietary products that receive regulatory approval will depend in part on market acceptance among physicians and patients, pricing approvals by government authorities and the availability of coverage and payment or reimbursement from third-party payers, such as government programs, including Medicare and Medicaid in the U.S., managed care providers, private health insurers and other organizations. However, eligibility for coverage does not necessarily signify that a biologic candidate will be adequately reimbursed in all cases or at a rate that covers costs related to research, development, manufacture, sale, and distribution. Third-party payers are increasingly challenging the price and cost effectiveness of medical products and services. Therefore, significant uncertainty exists as to the coverage and pricing approvals for, and the payment or reimbursement status of, newly approved healthcare products. For more information, see “Business – Government Regulation –

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Coverage, Reimbursement, and Pricing."

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

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Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree.

Factors payers consider in determining reimbursement are

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

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

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

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting

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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

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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

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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.

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

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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.

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Our revenue is has historically been 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 has historically been exclusively derived from our collaboration agreements (whether based on our drug candidates or polymeric reagents), 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

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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.

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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 year ended December 31, 2022 December 31, 2023, we reported a net loss of $368.2 million $276.1 million. If and when we achieve profitability depends upon a number of factors, including the timing and recognition of milestones and other contingent payments and royalties received, the timing of revenue under our collaboration agreements, the amount of investments we make in our proprietary biologic candidates and the regulatory approval and market success of our biologic candidates. We may not be able to achieve and sustain profitability.

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

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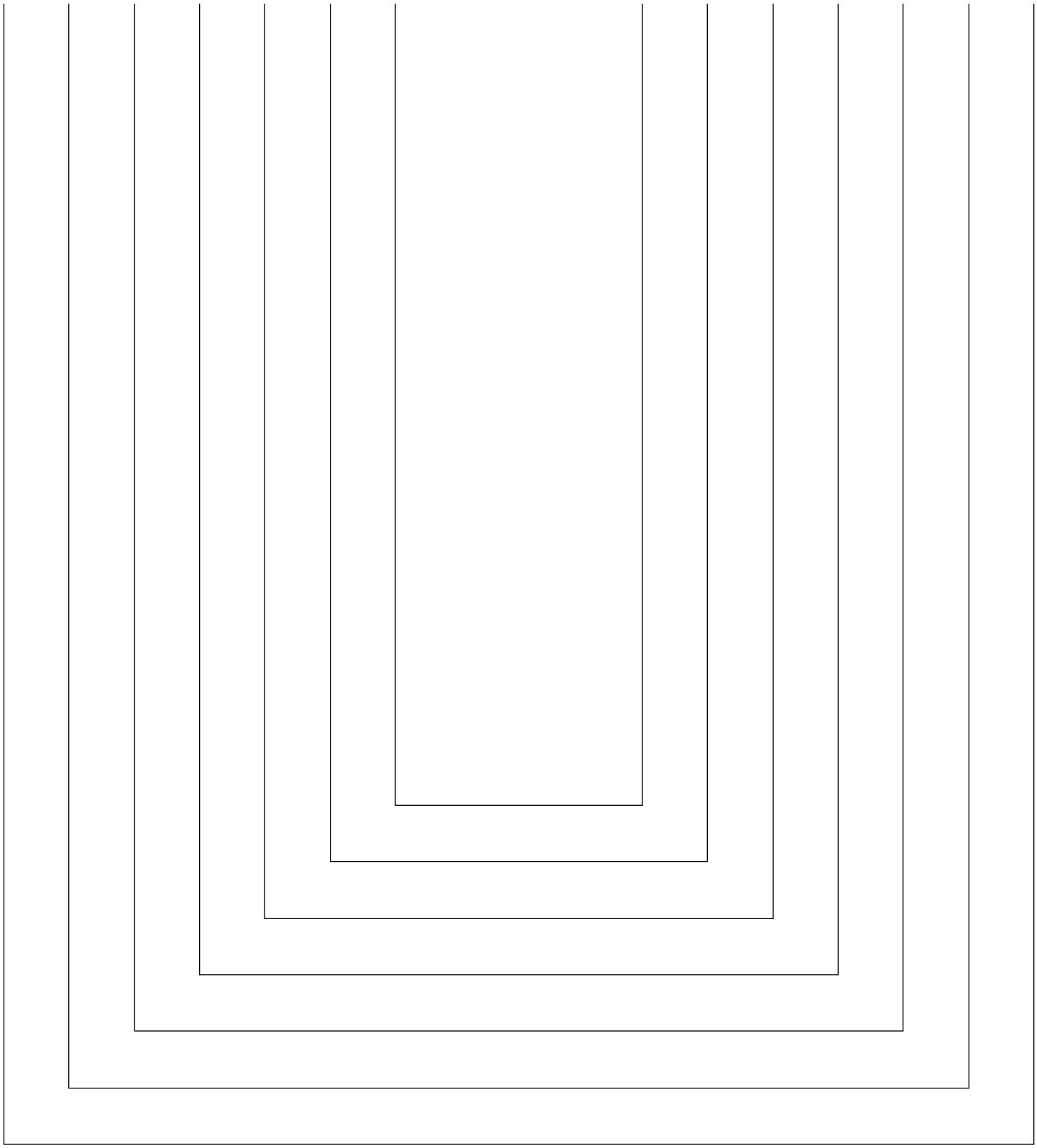

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