Celldex Therapeutics, Inc.
Form 10-K
March 07, 2019

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3191702**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Perryville III Building, 53 Frontage Road, Suite 220, Hampton, New Jersey 08827
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(908) 200-7500**

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

Title of Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $.001	NASDAQ 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 o No ý

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 o No ý

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

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 and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this Chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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. (Check one):

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

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. o

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2018 was $79 million. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the actions of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

The number of shares of common stock outstanding at February 28, 2019 was 12,439,730 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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CELLDEX THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "will," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

our dependence on product candidates, which are still in an early development stage;

our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of our drug candidates and the growth of the markets for those drug candidates;

our ability to raise sufficient capital to fund our animal, preclinical and clinical studies and to meet our liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;

our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;

our ability to negotiate strategic partnerships, where appropriate, for our drug candidates;

our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;

the cost, timing, scope and results of ongoing preclinical and clinical testing;

our expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;

the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;

the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;

the availability, cost, delivery and quality of clinical and commercial-grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners;

our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;

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our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;

our ability to realize the anticipated benefits from the acquisition of Kolltan;

our ability to protect our intellectual property rights, including the ability to successfully defend patent oppositions filed against a European patent related to technology we use in varlilumab, and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention;

our ability to develop and commercialize products without infringing the intellectual property rights of third parties; and

the factors listed under "Risk Factors" in this Annual Report on Form 10-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith, and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

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PART I

Item 1. BUSINESS

Overview

Celldex Therapeutics, Inc., which we refer to as "Celldex," "we," "us," "our" or the "Company," is a biopharmaceutical company focused on the development and commercialization of immunotherapies and other targeted biologics. Our drug candidates are derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. They are aimed at addressing market opportunities for which we believe current therapies are inadequate or non-existent.

We are focusing our efforts and resources on the continued research and development of:

CDX-1140, an agonist human monoclonal antibody targeted to CD40, a key activator of immune response, currently being studied as a single-agent and in combination with CDX-301 in a Phase 1 dose-escalation study in multiple types of solid tumors and B cell lymphomas;

CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3), currently in an early Phase 2 study in advanced head and neck squamous cell cancer in combination with Erbitux®;

CDX-301, a dendritic cell growth factor, currently being evaluated in a combination study with CDX-1140; and

Varlilumab, an immune modulating antibody targeting CD27 designed to enhance a patient's immune response, currently being evaluated for potential combination with CDX-1140, especially in lymphomas which co-express CD40 and CD27 receptors.

We routinely work with external parties to collaboratively advance our drug candidates. In addition to Celldex-led studies, we also have an Investigator Initiated Research (IIR) program with seven studies ongoing with our prioritized drug candidates.

In April 2018, we announced that our Phase 2b METRIC Study of glembatumumab vedotin in metastatic triple-negative breast cancer did not meet its primary endpoint. Based on this result, in the second quarter of 2018, we prioritized our pipeline and evaluated our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. As previously disclosed, in line with this initiative and to conserve resources, we discontinued development of glembatumumab vedotin, CDX-014 and CDX-1401.

Our goal is to build a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. We believe our program assets provide us with the strategic options to either retain full economic rights to our innovative therapies or seek favorable economic terms through advantageous commercial partnerships. This approach allows us to maximize the overall value of our technology and product portfolio while best ensuring the expeditious development of each individual product. Currently, all programs are fully owned by Celldex.

Our future success depends upon many factors, including our ability, and that of any licensees and collaborators that we may have, to successfully develop, obtain regulatory approval for and commercialize our drug candidates. We have had no commercial revenues from sales of our drug candidates, and we have had a history of operating losses. It is possible that we may not be able to successfully develop, obtain regulatory approval for, or commercialize, our drug candidates, and we are subject to a number of risks that you should be aware of before investing in us. These risks are described more fully in "Item 1A. Risk Factors."

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Clinical Development Programs

CDX-1140

CDX-1140 is a fully human agonist monoclonal antibody targeted to CD40, a key activator of immune response, which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. Preclinical studies of CDX-1140 clearly demonstrate strong immune activation effects and low systemic toxicity and support the design of the Phase 1 study to rapidly identify the dose for characterizing single-agent and combination activity.

We initiated a Phase 1 study of CDX-1140 in November 2017. This study is expected to enroll up to approximately 180 patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. The study is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

To this end, in the second quarter of 2018, we amended the Phase 1 study protocol to also explore CDX-1140 in combination with CDX-301. Dendritic cells, which express CD40, are often rare or missing from the tumor microenvironment and are critical for initiating anti-tumor immunity. CDX-301 is being utilized to increase the number of dendritic cells in blood and tissue available for CDX-1140 activation. CDX-1140 should, in turn, activate and mature the dendritic cells, an important step for enhancing anti-tumor immune responses. Several B cell lymphomas, including diffuse large B-cell lymphoma and follicular lymphoma, also express both CD40 and CD27. Celldex's varlilumab is a potent CD27 agonist and has been shown to synergize with CDX-1140 in NHL models and may be evaluated in combination with CDX-1140 in the future.

Interim data from the Phase 1 study were presented in November 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Seventeen patients with solid tumors were enrolled at the time of data analysis (n=13 monotherapy; n=4 combination). Four single-agent dosing cohorts were complete (0.01; 0.03, 0.09 and 0.18 mg/kg) and enrollment to the 0.36 mg/kg monotherapy cohort was ongoing. Enrollment to the first CDX-1140/CDX-301 combination cohort was also ongoing (0.09 mg/kg and 75 ug/kg, respectively). Dose dependent biological effects consistent with CD40-mediated immune activation were reported. CDX-1140 was well tolerated and no MTD had been reached. One patient experienced a grade 3 dose-limiting toxicity (DLT) (pneumonitis and hypoxia) at the single-agent 0.18 mg/kg dose. Per protocol, three additional patients were enrolled in the cohort and no additional DLTs have been observed in this or subsequent cohorts. While the CDX-1140 and CDX-301 combination cohort had just recently opened to enrollment at the time of presentation, preliminary evidence of enhanced immune activation was reported with no observed DLT. Across both arms of the study, there were no significant drug-related changes observed in liver function tests or platelets, which have been observed with other CD40 agonists. Continued enrollment is ongoing to

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define the MTD and select a dose for disease-specific expansion cohorts that will be monitored for clinical activity. We plan to present updated data from the study at a future medical meeting in 2019.

CDX-3379

CDX-3379 is a human monoclonal antibody with half-life extension designed to block the activity of ErbB3 (HER3). We believe ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies and is expressed in many cancers, including head and neck, thyroid, breast, lung and gastric cancers, as well as melanoma. We believe the proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. We believe CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells. Tumor cell death and the ensuing release of new tumor antigens has the potential to serve as a focus for combination therapy with immuno-oncology approaches, even in refractory patients. CDX-3379 has been evaluated in three Phase 1 studies for the treatment of multiple solid tumors that express ErbB3 and is currently being evaluated in a Phase 2 study in combination with Erbitux in Erbitux-resistant, advanced head and neck squamous cell carcinoma.

A Phase 1a/1b study of CDX-3379 was conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. Four combination arms across multiple tumor types were added to evaluate CDX-3379 with several drugs that target EGFR, HER2 or BRAF. They include combinations with Erbitux® (n=16), Tarceva® (n=8), Zelboraf® (n=9) and Herceptin® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one durable complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar® and was considered refractory, as well as an unconfirmed partial response in a patient with thyroid cancer. Initial data were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.

In April 2018, results from a window-of-opportunity study evaluating the effect of CDX-3379 on potential biomarkers in patients with head and neck squamous cell carcinoma (HNSCC) were presented at the American Association for Cancer Research (AACR) Annual Meeting. The study enrolled 12 patients with newly diagnosed HNSCC who received two doses of CDX-3379, at a two-week interval prior to tumor resection. CDX-3379 reduced phosphorylated ErbB3 (pErbB3) levels in 83% (10/12) of patient samples, with greater than or equal to 50% decreases in 58% of patients (7/12), which met the primary study objective. Stable disease was observed in 92% (11/12) of patients prior to surgery, and a patient with HPV-negative disease experienced significant tumor shrinkage (92% in primary tumor; 26% in metastatic lesion). CDX-3379 was well-tolerated, and no treatment-related adverse events were observed.

Preclinical data from the combination of CDX-3379 and Erbitux in xenograft models of head and neck squamous cell carcinoma were also presented at the AACR Annual Meeting in April 2018. Combining CDX-3379 and Erbitux inhibited tumor growth more potently than Erbitux alone. Mechanistic studies demonstrated a reduction of PD-L1 expression from the combination.

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We have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The study employs a Simon two-stage design with an interim futility analysis following enrollment of the first 13 patients. According to the study's two-stage design, if at least one patient achieves an objective response in the first stage, enrollment may progress to the second stage. Enrollment to the first stage of the Phase 2 study (n=13) is complete. While a confirmed complete response has been documented, Celldex will conduct a comprehensive review, including the full data set, before making decisions on future development, as patients are still undergoing treatment and are eligible for evaluation. The primary objective of the study is objective response rate. Secondary objectives include assessments of clinical benefit response (CBR), duration of response (DOR), progression-free survival (PFS) and overall survival (OS), and safety and pharmacokinetics associated with the combination. We plan to present updated data from the study at a future medical meeting in 2019. CDX-3379 is also being studied in an investigator-sponsored study.

Varlilumab

Varlilumab is a fully human agonist monoclonal antibody that binds to and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. We believe varlilumab works primarily by stimulating T cells, an important component of a person's immune system, to attack cancer cells. Restricted expression and regulation of CD27 enables varlilumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, varlilumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *in vitro* and *in vivo* models. Varlilumab was initially studied as a single-agent to establish a safety profile and assess immunologic and clinical activity in patients with cancer, but we believe the greatest opportunity for varlilumab is as an immune activator in combination with other agents.

Single-Agent Phase 1 Study: In an open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers, varlilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients received varlilumab in the study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of an MTD. The majority of adverse events, or AEs, related to treatment were mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade were observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anti-cancer therapy. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

Phase 1/2 Varlilumab/Opdivo Combination Study: In 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb, or BMS, to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, BMS' PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. The Phase 1 portion of the study was initiated in January 2015 and conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo. It was followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts. Enrollment to the Phase 2 portion of the study was completed in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is objective response rate, or ORR, except glioblastoma, where the primary objective is the rate of 12-month OS.

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Data from the ovarian and colorectal cancer cohorts were presented in an oral presentation at the 2018 ASCO Annual Meeting. Sixty-six patients with ovarian cancer were treated in the study (8 patients in Phase 1; 58 patients in Phase 2). Patients had a median of three prior lines of therapy, 91% had Stage IV disease and 66% had PD-L1 negative tumors. The overall response rate was 14% (n=9; 7 confirmed, 2 unconfirmed) across 64 response-evaluable patients. For patients with paired tumor samples (n=24) from before and during treatment, increases in tumor expression of PD-L1 and CD8+ TIL levels were observed. These increases were associated with improved clinical outcome, including improved PFS and response rate.

Forty-two patients with colorectal cancer were treated in the study (21 patients in Phase 1; 21 patients in Phase 2). Patients had a median of four prior lines of therapy, 100% had Stage IV disease and 87% had PD-L1 negative tumors. One patient had disease that was MSI-high and 21 patients had disease that was MSI-low/mismatch repair (MMR) proficient; MSI status for the remaining 20 patients was unknown. One patient with PD-L1 negative, MSI-high disease experienced a confirmed partial response in the Phase 2 study portion. Of note, a patient with PD-L1 negative disease, initially considered MMR proficient as determined by standard screening laboratory analysis, achieved a near complete response in the Phase 1 portion of the study, which continued at last follow-up at 39 months. This patient's tumor had a high mutational burden and mutations in genes regulating DNA repair, which together likely contributed to the response. Disease control rate for the response-evaluable population was 20% (8/41).

In the second quarter of 2018, we reported preliminary data from the head and neck squamous cell carcinoma (HNSCC) and renal cell carcinoma (RCC) cohorts. Twenty-seven patients with HNSCC were treated in the study (3 patients in Phase 1; 24 patients in Phase 2). Patients had a median of two prior lines of therapy, 96% had Stage IV disease, 63% had PD-L1 negative tumors and 52% had HPV positive tumors. The overall response rate was 15% (n=4 confirmed) across 27 response-evaluable patients. In this small sample size, no correlation between PDL-1 status and clinical outcome was observed. Given the changing treatment paradigm in renal cell carcinoma, only fourteen patients with RCC were treated in the study, all in Phase 2. All patients had experienced prior angiogenic therapy, with a range of 1 to 4 prior treatments, 100% had Stage IV disease and 50% had PD-L1 negative tumors. 39% of patients experienced stable disease.

Data from the GBM cohort were presented in November 2018 at the Society for Neuro-oncology (SNO) Annual Meeting. 22 patients with recurrent GBM were treated in the study. The median duration of disease prior to study entry was 13 months. Methylation status was determined in 21 patients (n=5 methylated; n=16 unmethylated). The combination was generally well-tolerated and the safety profile was consistent with that of each agent alone. Without taking into account MGMT status or other prognostic factors, overall results were similar to nivolumab monotherapy in recurrent GBM (OS12 = 42%). In the subset of patients with unmethylated MGMT promoter, a durable therapeutic benefit was achieved (OS at 12 months =50%).

Future development of varlilumab is focused on inclusion in internal combination studies, including potentially in the ongoing Phase 1 trial of CDX-1140, and several external investigator-initiated studies.

CDX-301

CDX-301, a recombinant FMS-like tyrosine kinase 3 ligand, or Flt3L, is a hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells, and in combination with other agents may potentiate anti-tumor responses. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. We believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio, as well as with approved or investigational therapies for the treatment of cancer.

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A Phase 1 study of CDX-301 evaluated seven different dosing regimens of CDX-301 to determine the appropriate dose for further development based on safety, tolerability and biological activity. The data from the study were consistent with previous clinical experience and demonstrated that CDX-301 has an acceptable safety profile to date and can mobilize dendritic cell and hematopoietic stem cell populations in healthy volunteers. The study was published in the journal Bone Marrow Transplantation in 2015.

CDX-301 is being used as a priming agent to potentially increase the number of cells available to respond to CDX-1140 in the ongoing Phase 1 trial of CDX-1140. CDX-301 is also in clinical development for multiple cancers in ongoing investigator-sponsored and collaborative studies, including in combination with treatments that release tumor antigens, such as radiation therapy.

Development Strategy

Immunotherapy Platform

We believe there is untapped potential in immunotherapy that can be captured through the right combination and/or sequence of therapeutic agents. Immunotherapy approaches have encountered difficulties when following standard drug development. The mechanisms of action are complex; activity is generally not dependent on highest tolerated dose; and patient response is highly variable. Our understanding of the immune system, cancer's effect on immune mediated mechanisms and the impact of conventional therapies on the immune system provide a new rationale for combining therapies that may lead to significant clinical benefit for patients with cancer or other diseases.

Our intent is to leverage this knowledge to develop a pipeline of products which we believe may be very effective in combination approaches. Our goal is to design and develop targeted products that maximize the efficacy of immunotherapy regimens through combinations of therapeutic agents in significant and growing markets. We establish governmental and corporate alliances to fund development when appropriate and intend to commercialize our products either through our own direct selling efforts or, for products which we cannot develop ourselves through to commercialization, through corporate partners. This approach allows us to maximize the overall value of our technology and product portfolios while best ensuring the expeditious development of each individual product.

Factors that may significantly harm our commercial success, and ultimately the market price of our common stock, include but are not limited to, announcements of technological innovations or new commercial products by our competitors, disclosure of unsuccessful results of clinical testing or regulatory proceedings and governmental approvals, adverse developments in patent or other proprietary rights, public concern about the safety of products developed by us and general economic and market conditions. See "Item 1A. Risk Factors."

Partnerships

We may enter into co-development and commercialization partnerships for any of our programs where appropriate. In the past, we have entered into collaborative partnership agreements with pharmaceutical and other companies and organizations that provided financial and other resources, including capabilities in research, development, manufacturing, and sales and marketing, to support our research and development programs and may enter into more of them in the future.

Partnership agreements may terminate without benefit to us if the underlying products are not fully developed. If we fail to meet our obligations under these agreements, they could terminate, and we might need to enter into relationships with other collaborators and to spend additional time, money and other valuable resources in the process. We cannot predict whether our collaborators will continue their development efforts or, if they do, whether their efforts will achieve success. Many of our collaborators face the same kinds of risks and uncertainties in their businesses that we face. A delay or

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setback to a partner will, at a minimum, delay the commercialization of any affected drug candidates, and may ultimately prevent it. Moreover, any partner could breach its agreement with us or otherwise not use best efforts to promote our products. A partner may choose to pursue alternative technologies or products that compete with our technologies or drug candidates. In either case, if a partner failed to successfully develop one of our drug candidates, we would need to find another partner. Our ability to do so would depend upon our legal right to do so at the time and whether the product remained commercially viable.

Research Collaboration and License Agreements

We have entered into license agreements whereby we have received licenses or options to license technology, specified patents and/or patent applications. These license and collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain development, regulatory and/or commercial milestones. Summarized below are our significant research collaboration and license agreements for our later-stage drug candidates.

Medarex, Inc. (Medarex), which was acquired by Bristol-Myers Squibb Company (BMS)

Under a license agreement with Medarex, as amended, we acquired access to the UltiMab technology to develop and commercialize human antibodies to CD27, including varlilumab. We may be required to pay Medarex royalty payments in the low-to-mid single digits on any net product sales with respect to the development and commercialization of varlilumab until the later of (i) the expiration of the last to expire applicable patent and (ii) the tenth anniversary of the first commercial sale of such licensed product.

University of Southampton, UK (Southampton)

Under a license agreement with Southampton, we acquired the rights to develop human antibodies towards CD27, a potentially important target for immunotherapy of various cancers. We may be required to pay Southampton milestones of up to approximately $1.0 million upon obtaining first approval for commercial sale in a first indication and royalty payments in the low-single digits on any net product sales with respect to development and commercialization of varlilumab.

Amgen Inc. (Amgen)

Under a license agreement with Amgen, we acquired the exclusive rights to CDX-301 and CD40 ligand, or CD40L. CDX-301 and CD40L are immune modulating molecules that increase the numbers and activity of immune cells that control immune responses. We may be required to pay Amgen milestones of up to $0.9 million upon obtaining first approval for commercial sale in a first indication and royalty payments in the low-single digits on any net product sales with respect to development and commercialization of the technology licensed from Amgen, including CDX-301.

Yale University (Yale)

Under a license agreement with Yale, we may be required to make a one-time payment to Yale of $3.0 million with respect to each therapeutic or prophylactic receptor tyrosine kinase (RTK) royalty-bearing product, including CDX-3379, that achieves a specified commercial milestone. In addition, we may be required to pay a low single-digit royalty on annual worldwide net sales of each RTK royalty-bearing product, including CDX-3379. Unless earlier terminated by us or Yale, the Yale license agreement is due to expire no later than May 2038 but may expire earlier on a country-by-country basis under specified circumstances.

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MedImmune, LLC (MedImmune)

Under a license agreement with MedImmune, we acquired exclusive rights to specified patent rights and know-how that are controlled by MedImmune and relate to the research, development, manufacture and commercialization of CDX-3379. We may be required to pay Medimmune up to $45.0 million upon obtaining specified regulatory and development milestones in the first indication of CDX-3379. In addition, we may be required to pay MedImmune one-time milestone payments of up to $125.0 million if specified annual net sale thresholds are met related to the first indication of CDX-3379. We may also be required to pay MedImmune a tiered royalty on annual net sales of CDX-3379 at rates ranging from high single-digit to low teens percentages. These royalties may be reduced in specified circumstances and are payable on a product-by-product and country-by-country basis until the later to occur of ten years after the first commercial sale of the product in that country and the expiration of MedImmune's patent rights that cover the sale of the product in that country. We may also be required to pay specified royalties on annual net sales of CDX-3379 at a rate in the low single digits to certain other third parties from whom MedImmune licensed certain intellectual property.

Competition

The biotechnology and pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. Other companies are pursuing the development of new therapies that target the same diseases and conditions that we are targeting and may compete directly with our drug candidates. We face competition from companies, major universities and research institutions in the United States and abroad, including a number of large pharmaceutical companies, as well as firms specialized in the development and production of vaccines, adjuvants and immunotherapeutic delivery systems. Some of our competitors possess substantially greater financial, technical and human resources than we possess.

Our competitors may utilize discovery technologies and techniques or partner with collaborators in order to develop products more rapidly or successfully than us or our collaborators are able to. In addition, some competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of drug candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. If we obtain regulatory approval and commence commercial sales of our drug candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both in the U.S. and outside of the U.S.

We also face competition in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies.

Our competitive position will depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient

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capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our drug candidates, obtain the necessary regulatory approvals and successfully manufacture and market our drug candidates. In order to secure capital resources, we anticipate having to sell additional capital stock, which would dilute existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of funding are uncertain because they are at the discretion of the organizations and companies that control the funds. As a result, we may not receive any funds from grants or collaborations. Alternatively, we may borrow funds from commercial lenders, likely at high interest rates, which would increase the risk of any investment in us.

Manufacturing

We are a research and development company and have limited experience in commercial manufacturing. Our ability to conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, depends on the ability of Contract Manufacturing Organizations (CMOs) to manufacture our drug candidates on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices (cGMP) and U.S. and foreign regulatory requirements, as applicable. We also rely on CMOs for manufacturing, packaging, labeling, storing and shipping our drug products. In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and would need to hire and retain significant additional personnel and comply with cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA. We therefore work with CMOs under established manufacturing arrangements that comply with the FDA's requirements and other regulatory standards, although there is no assurance that the manufacturing will be successful.

We operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA regulations, allowing us to distribute drug candidates to clinical sites in the U.S. for early-stage clinical trials. We currently manufacture CDX-1140, CDX-301 and CDX-0159 drug substance in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials. We expect that our existing clinical supplies of CDX-3379 and varlilumab will be sufficient to carry out our current planned clinical development. Additional manufacturing options are under review and may involve utilization of the Fall River facility and/or a CMO. All products are then filled and packaged at CMOs. Any manufacturing failures or compliance issues at contract manufacturers could cause delays in our Phase 1 and Phase 2 clinical studies for these drug candidates.

The manufacturing processes for our drug candidates and immunotherapeutic delivery systems utilize known technologies. We believe that the drug candidates we currently have under development can be scaled up to permit manufacture in commercial quantities. However, there can be no assurance that we will not encounter difficulties in scaling up the manufacturing processes.

While we believe that there is currently sufficient capacity worldwide for the production of our potential products through CMOs, establishing long-term relationships with contract manufacturers and securing multiple sources for the necessary quantities of clinical and commercial materials required can be a challenge due to increasing industry demand for CMO services. Qualifying the initial source of clinical and ultimately commercial material is a time consuming and expensive process due to the highly regulated nature of the pharmaceutical/biotech industry. These costs may be mitigated by the economies of scale realized in commercial manufacture and product sales. The key difficulty in qualifying more than one source for each product is the duplicated time and expense in doing so without the potential to mitigate these costs if the secondary source is never utilized.

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Use of third-party manufacturers limits our control over and ability to monitor the manufacturing process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of our contract manufacturers. If third-party manufacturers fail to meet our manufacturing needs in an acceptable manner, we would face delays and additional costs while we develop internal manufacturing capabilities or find alternate third-party manufacturers. It may not be possible to have multiple third-party manufacturers ready to supply us with needed material at all or without incurring significant costs.

Commercial Organization

We have limited commercial experience in marketing, sales, distribution and product reimbursement. We have the capability to provide current and future market insights to our research and development organization regarding our potential drug candidates. In the future, we may choose to expand our commercial team and build a full-scale commercial organization which we believe could provide us the opportunity to retain marketing rights to our drug candidates and commercialize such products ourselves where we deem appropriate or pursue strategic partnerships to develop, sell, market and distribute our drug candidates where we deem appropriate.

Patents, Licenses and Proprietary Rights

In general, our intellectual property strategy is to protect our technology by filing patent applications and obtaining patent rights covering our own technology, both in the United States and in foreign countries that we consider important to our business. In addition, we have acquired and will seek to acquire as needed or desired, exclusive rights of others through assignment or license to complement our portfolio of patent rights. We also rely on trade secrets, unpatented know-how and technological expertise and innovation to develop and maintain our competitive position.

Patents

The successful development and marketing of products by us will depend in part on our ability to create and maintain intellectual property, including patent rights. We are the owner or exclusive licensee to proprietary patent positions in the areas of immunotherapy technologies, vaccine technologies, antibody technologies and complement inhibitor technology. Although we continue to pursue patent protection for our products, no assurance can be given that any pending application will issue as a patent, that any issued patent will have a scope that will be of commercial benefit or that we will be able to successfully enforce our patent position against infringers. We routinely review our patent portfolio and adjust our strategies for prosecution and maintenance of individual cases according to a number of factors, including program priorities, stage of development and patent term.

We own or license rights under more than 200 granted patents and national and regional patent applications in the U.S. and in major international territories covering inventions relating to our business. The key patents and patent applications owned by us or licensed to us that we consider important to our business include the following (the indicated and estimated patent expiry dates are the estimated expirations if all maintenance fees and annuities are paid when due, and do not include any possible additional terms for Patent Term Extensions (PTEs) or Supplementary Protection Certificates (SPCs), if these may be secured in due course):

We own a portfolio of patent applications directed to CDX-1140 and certain other anti-CD40 antibodies. These patent applications include claims directed to particular anti-CD40 antibody compositions of matter, including CDX-1140 compositions of matter, and methods of using such antibodies. Patent applications in this portfolio are pending in the U.S., Europe, Japan, Australia, Canada, China, India, New Zealand, Republic of Korea, Russian Federation and

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certain other countries. If and when issued the foregoing would have estimated patent expiry dates in 2037.

We have exclusively licensed a portfolio of patents and patent applications relating to particular ErbB3 inhibitors from MedImmune. These patents and patent applications include claims directed to particular anti-ErbB3 antibody compositions of matter, including CDX-3379 compositions of matter, and methods of using such antibodies. Patents have been issued in the U.S., Japan, Australia, China, New Zealand and the Russian Federation which have estimated patent expiry dates in 2032. Patent applications in this portfolio are pending in Europe, Canada, India, Republic of Korea and certain other countries, and any patents that may issue from these applications would also have estimated patent expiry dates in 2032.

The U.S. patent for the composition of matter of CDX-301 has an estimated expiration date in 2020.

We have licensed rights from the University of Southampton under issued U.S., European and Japanese patents and under a pending patent application in Canada relating to the technology used in varlilumab. If and where issued and maintained to full term in due course, these would have estimated patent expiry dates in 2027. In July 2013, the United States Patent and Trademark Office issued a patent to the University of Southampton, that we have an exclusive license to under our license agreement, which broadly supports varlilumab. The patent includes 18 claims covering various methods of treating cancer using agonistic anti-human CD27 antibodies and relates, among other things, directly to our CD27 antibody program and therapeutic uses of varlilumab. In September 2014, two European patent oppositions were filed against the University of Southampton European patent, and at a hearing on November 23, 2016 the European Patent Office (EPO) revoked the European patent on the ground of lack of inventive step. The University of Southampton has filed an appeal against this decision, and we intend to defend the European patent vigorously in cooperation with the University of Southampton. This EPO decision does not affect the later filed Celldex patents and applications for varlilumab. We also have an issued U.S. patent which covers varlilumab as a composition of matter. If maintained to full term this patent would have an estimated patent expiry date in 2034 (including additional term due to Patent Term Adjustment). We also have corresponding patents and patent applications in the major international territories which, if and where issued and maintained to full term in due course, would have estimated patent expiry dates in 2031.

We own a portfolio of patents and patent applications directed to CDX-0159 and other anti-KIT receptor antibodies. These patents and patent applications include claims directed to particular anti-KIT antibody compositions of matter, including CDX-0159 compositions of matter, and methods of using such antibodies. A patent has been issued in the U.S. which would have an estimated patent expiry date in 2034 (including additional term due to Patent Term Adjustment). Patents have also been issued in Europe, Japan, Australia and Singapore, and foreign counterparts are pending in Canada, China, India, Republic of Korea, Russian Federation and certain other countries. If and where issued the foregoing would have estimated patent expiry dates ranging from 2032 to 2033.

We acquired rights to a portfolio of patents and patent applications related to the "TAM family" of RTKs (comprised of Tyro3 AXL and MerTK) receptors which are in-licensed from, or co-owned with, the Salk Institute for Biological Studies. For example, we have an exclusive license to two issued U.S. patents directed to TAM receptor inhibition to treat infections and to a U.S. patent application directed to methods for the modulation of the immune response via targeting TAM receptors. Foreign counterparts to these patents and this patent application are pending in Europe and Canada. If and where issued the foregoing would have estimated patent expiry dates in at least 2028. Further international and provisional patent applications have also recently been filed in respect of particular antibodies targeting MerTK.

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There can be no assurance that patent applications owned by or licensed to us will result in granted patents or that, if granted, the resultant patents will afford protection against competitors with similar technology. It is also possible that third parties may obtain patents or other proprietary rights that may be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, it is possible that those parties will obtain patents that will be sufficiently broad to prevent us from using important technology or from further developing or commercializing important drug candidates and immunotherapeutic systems. If licenses from third parties are necessary but cannot be obtained, commercialization of the covered products might be delayed or prevented. Even if these licenses can be obtained, they would probably require us to pay ongoing royalties and other costs, which could be substantial.

Although a patent has a statutory presumption of validity in the United States, the issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent claims. The validity or enforceability of a patent after its issuance by the Patent and Trademark Office can be challenged in litigation. As a business that uses a substantial amount of intellectual property, we face a heightened risk of intellectual property litigation. If the outcome of the litigation is adverse to the owner of the patent, third parties may then be able to use the invention covered by the patent without authorization or payment. There can be no assurance that our issued patents or any patents subsequently issued to or licensed by us will not be successfully challenged in the future. In addition, there can be no assurance that our patents will not be infringed or that the coverage of our patents will not be successfully avoided by competitors through design innovation.

We are aware that others, including universities and companies, have filed patent applications and have been granted patents in the United States and other countries which claim subject matter potentially useful or necessary to the commercialization of our products. The ultimate scope and validity of existing or future patents which have been or may be granted to third parties, and the availability and cost of acquiring rights in those patents necessary to the manufacture, use or sale of our products presently cannot be determined by us.

Third parties may have or may obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology, including:

- certain patents and pending patent applications in the United States and foreign countries relating to particular receptors, antigens and antigenic fragments targeted by our current drug candidates;

- certain patents and pending patent applications related to particular receptors and other molecules on T-cells, dendritic cells and macrophages that may be useful for generating monoclonal antibodies;

- certain patents held by third parties relating to antibody expression in particular types of host cells; and

- certain patents and pending patent applications in the United States and foreign countries relating to anti-CD27 antibodies and/or anti-PD-L1 antibodies.

We are also aware of a third-party European patent that relates to use of ErbB3 antibodies for treatment of hyperproliferative disorders, including cancer. Counterparts of this patent have also issued in Australia and Japan. As a result of an opposition proceeding, the European patent was revoked in its entirety. The owner of the European patent appealed the decision in the opposition proceeding but the appeal has been rejected so that the decision to revoke the European patent stands. We continue to monitor counterparts in other jurisdictions.

In addition to the patents referred to in the previous paragraphs, there may be other patent applications and issued patents belonging to competitors that may require us to alter our drug

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candidates and immunotherapeutic delivery systems, pay licensing fees or cease some of our activities. If our drug candidates conflict with patents that have been or may be granted to competitors, universities or others, the patent owners could bring legal action against us claiming damages and seeking to enjoin manufacturing and marketing of the patented products. If any of these actions is successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. There can be no assurance that we would prevail in any such action or that any license required under any such third-party patent would be made available on acceptable terms or at all. We believe that there may be significant litigation in the biotechnology industry regarding patent and other intellectual property rights. If we become involved in that litigation, we could consume substantial resources.

Licenses

We have entered into several significant license agreements relating to technologies that are being developed by us. In general, these institutions have granted us an exclusive worldwide license (with right to sublicense) to make, use and sell products embodying the licensed technology, subject to the reservation by the licensor of a non-exclusive right to use the technologies for non-commercial research purposes. Generally, the term of each license is through the expiration of the last of the patents issued with respect to the technologies covered by the license and/or a specified period from first commercial sale on a territory-by-territory basis. We have generally agreed to use reasonable efforts to develop and commercialize licensed products and to achieve specified milestones and pay license fees, milestone payments and royalties based on the net sales of the licensed products or to pay a percentage of sublicense income. If we breach our obligations, the licensor has the right to terminate the license, and, in some cases, convert the license to a non-exclusive license. Generally, we control and are responsible for the cost of defending the patent rights of the technologies that we license.

Proprietary Rights

We also rely on unpatented technology, trade secrets and confidential information, and no assurance can be given that others will not independently develop substantially equivalent information and techniques or otherwise gain access to our know-how and information, or that we can meaningfully protect our rights in such unpatented technology, trade secrets and information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. The agreements generally provide that all inventions conceived by the individual in the course of employment or in providing services to us and all confidential information developed by, or made known to, the individual during the term of the relationship shall be the exclusive property of us and shall be kept confidential and not disclosed to third parties except in limited specified circumstances. There can be no assurance, however, that these agreements will provide meaningful protection for our information in the event of unauthorized use or disclosure of such confidential information.

Government Regulation

Our activities and products are significantly regulated by a number of governmental entities, including the U.S. Food and Drug Administration, or FDA, in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of our products. We must obtain regulatory approval from the FDA and comparable authorities in other countries, as applicable, for our drug candidates before we can commercialize such drugs in the U.S. and foreign jurisdictions. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. Many drug candidates that initially appear promising ultimately do not reach the

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market because they are found to be unsafe or ineffective when tested. Our inability to commercialize a product would impair our ability to earn future revenues.

FDA Approval Process

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil penalties and criminal prosecution.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, application which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of a new drug application, or NDA, or a biologics license application, or BLA, as applicable;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

We expect that all of our clinical drug candidates will be subject to review as biological products under BLA standards.

Data obtained at any stage of testing is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Moreover, during the regulatory process, new or changed drug approval policies may cause unanticipated delays or rejection of our product. We may not obtain necessary regulatory approvals within a reasonable period of time, if at all, or avoid delays or other problems in testing our products. Moreover, even if we received regulatory approval for a product, the approval may require limitations on use, which could restrict the size of the potential market for the product.

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Clinical Trials

The FDA provides that human clinical trials may begin 30 days after receipt and review of an IND application, unless the FDA requests additional information or changes to the study protocol within that period. An IND must be sponsored and filed for each of our proposed drug candidates. Authorization to conduct clinical trials in no way assures that the FDA will ultimately approve the product. Clinical trials are generally conducted in three sequential phases. In a Phase 1 trial, the product is given to a small number of patients to test for safety (adverse effects), determine a recommended Phase 2 dose(s) and evaluate any signals of efficacy. Phase 2 trials are conducted on a limited group of the target patient population; safety, optimal dosage and efficacy are studied. A Phase 3 trial is performed in a large patient population, generally over a wide geographic area to provide evidence for the safety and efficacy of the product. The FDA maintains and exercises oversight authority throughout the clinical trial process.

A product's safety and effectiveness in one clinical trial is not necessarily indicative of its safety and effectiveness in another clinical trial. Moreover, we may not discover all potential problems with a product even after completing clinical trials on it. Some of our products and technologies have undergone only preclinical testing. As a result, we do not know whether they are safe or effective for humans. Also, regulatory authorities may decide, contrary to our findings, that a product is unsafe or not as effective in actual use as its clinical trial results indicated. This could prevent the product's widespread use, require its withdrawal from the market or expose us to liability. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Any such action could materially harm us. Clinical trials are critical to the success of our products but are subject to unforeseen and uncontrollable delay, including delay in enrollment of patients. Any delay in clinical trials could delay our commercialization of a product.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. Under federal law, the submission of most NDAs and BLAs is additionally subject to a substantial application user fee and the sponsor of an approved NDA or BLA is also subject to annual prescription drug program fees.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after receipt before accepting them for filing based on the agency's threshold determination that they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs and BLAs. Most such applications for non-priority products are reviewed within ten to twelve months after filing, and most applications for priority review products, that is, drugs and biologics that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months after filing. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or biological products or products that present

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difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval processes require substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our drug candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA or BLA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will resume review and may subsequently issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as changes in indications, manufacturing changes and labeling, are subject to further testing requirements and FDA review and approval.

Special Regulatory Procedures

Fast track designation The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product, concurrent with or after the filing of the IND for the drug candidate. A drug that receives fast track designation is eligible for some or all of the following: (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for accelerated approval and priority review, if relevant criteria are met; and

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(iv) Rolling Review, which means that a drug company can submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the NDA or BLA is completed before the entire application can be reviewed. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review Under FDA policies, a drug candidate may be eligible for priority review. The priority review program provides for expedited review or an NDA or BLA, typically within a six to eight month time frame from the time a complete application is accepted for filing. Products regulated by the FDA's Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Products regulated by the FDA's Center for Biologics Evaluation and Research, or CBER, are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. A fast track designated drug candidate could be eligible for priority review if supported by clinical data at the time of the BLA or NDA submission.

Accelerated approval Under the law and the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough therapy designation The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate.

Orphan drug designation Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same orphan indication, except in limited circumstances. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

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Pediatric information

Under the Pediatric Research Equity Act of 2003, an NDA, BLA or supplement to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

Post Approval

Any drug or biological products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug or biologic.

In addition, drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biological products are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA was also granted new inspection authorities under FDASIA. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled and warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;

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product seizure or detention, or refusal to permit the import or export of products; or

consent decrees, injunctions or the imposition of civil or criminal prosecution.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA, the Office of the Inspector General of Health and Human Services and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Biosimilars Law

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to provide for an abbreviated approval pathway for biological products that demonstrate biosimilarity to a previously-approved biological product. The BPCIA establishes criteria for determining that a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved. The BPCIA provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCIA, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until 12 years after the reference product's approval. Additionally, the BPCIA establishes procedures by which the biosimilar applicant may provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product. The BPCIA applies to our drug candidates and could be applied to allow approval of biosimilars to our products.

Because the BPCIA is a relatively new law, we anticipate that its contours will be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including FDA issuance of guidance documents, proposed regulations, lawsuits and the FDA's decisions in the course of considering specific applications. Such evolution may significantly affect the impact of the BPCIA on both reference product and biosimilar sponsors.

21st Century Cures Act

On December 13, 2016, Congress passed the 21st Century Cures Act, or the Cures Act. The Cures Act is designed to modernize and personalize health care, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increased funding for the FDA to spend on innovation projects, including for certain oncology-directed research. The new law also amends the Public Health Service Act to reauthorize and expand funding for the National Institutes of Health.

Because the Cures Act has only recently been enacted, its potential effect on our business remains unclear with the exception of a provision requiring that we post our policies on the availability of expanded access programs for individuals. In addition, the Cures Act includes provisions that may be beneficial to us in the future, including a requirement that the FDA assess and publish guidance on the use of novel clinical trial designs, the use of real world evidence in applications, the availability of summary level review for supplemental applications for certain indications and the qualification of drug development tools. Because these provisions allow the FDA several years to develop these policies, their effects on us, if any, could be delayed.

The Cures Act also authorizes funding for the "Cancer Moonshot" initiative. The Cancer Moonshot initiative's strategic goals encourage inter-agency cooperation and fund research and

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innovation to catalyze new scientific breakthroughs, bring new therapies to patients and strengthen prevention and diagnosis. This initiative aims to stimulate drug development through the creation of a public-private partnership with 20 to 30 pharmaceutical and biotechnology companies to expedite cancer researchers' access to investigational agents and approved drugs. This partnership is designed to permit researchers to obtain drugs and other technologies from a preapproved "formulary" list without having to negotiate with each company for individual research projects. We will continue to monitor these developments to assess their potential impacts on our business.

Companion Diagnostic Review and Approval

Our drug candidates may rely on the use of a companion diagnostic. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. Based on recent FDA guidance documents and the FDA's past treatment of companion diagnostics, we believe that the FDA will likely require one or more of our *in vitro* companion diagnostics to obtain Premarket Approval Application, or PMA, in conjunction with approval of the related drug candidate. The receipt and timing of PMA approval may have a significant effect on the receipt and timing of commercial approval for such drug candidates. Currently we rely on third-party collaborators to develop companion diagnostics for our drug candidates.

The PMA process is similar to the NDA and BLA processes and is costly, lengthy and uncertain. PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and then the data submitted in an amendment to the PMA.

Furthermore, even after PMA approval is obtained, numerous regulatory requirements apply to the manufacturer of the companion diagnostic. The FDA enforces these requirements by inspection and market surveillance. These requirements include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off label" uses, the medical device reporting regulation, and the reports of corrections and removals regulation. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for PMA of new products; and withdrawing PMAs already granted.

Federal and State Fraud and Abuse, Data Privacy and Security and Transparency Laws

In addition to FDA restrictions on marketing and promotion of pharmaceutical products, several other types of federal and state laws have been applied to restrict certain marketing business practices in the biopharmaceutical and medical device industries in recent years. These laws include, without limitation, state and federal anti-kickback statutes and false claims statutes and false claims laws, data

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privacy and security laws, as well as transparency laws regarding payments or other items of value provided to health care providers. Applicable state law may be broader in scope than federal law and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, contractual damages, reputational harm, administrative burdens, 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. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to health care professionals.

In addition, the United States Foreign Corrupt Practices Act, or FCPA, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. In many countries, the health care professionals we may interact with may meet the FCPA's definition of a foreign government official.

Foreign Regulation

In order to market any therapeutic or diagnostic product outside of the United States, we need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Under the EU regulatory system, we will submit most of our marketing authorization applications under the centralized procedure. The centralized procedure is compulsory for medicines produced by biotechnology, or are for the treatment of cancer, or officially designated as 'orphan medicines.' The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. As in the United States, we may apply for designation of a drug candidate as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. The EMA grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. Orphan drugs in Europe enjoy economic and marketing benefits, including a 10-year market exclusivity period for the approved indication, but not for the same product, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

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Other Regulatory Processes

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA.

In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will change or what the effect of such changes, if any, may be.

Third-Party Payor Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our drug candidates, if approved, will depend, in part, on the extent to which the costs of the drugs will be covered by third-party payors, including government health programs such as Medicare and Medicaid, as well as commercial health insurers, such as managed care organizations. The process for determining reimbursement rates is separate from the payor coverage decision. Therefore, despite obtaining coverage, reimbursement rates may be lower than expected, which can result in larger out-of-pocket payments for the patient.

In order to secure coverage and reimbursement for any drug that might be approved for sale, we need to conduct analyses and pharmaco-economic studies in order to demonstrate the incremental medical benefit over and above the generally-accepted standard of care and cost-effectiveness of the drug. Our drug candidates may not be considered medically necessary, provide insufficient incremental medical benefit, or may not be deemed cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

The containment of health care costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors 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. If these third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of reimbursement and/or restrictions in formulary placement may be such that they would significantly limit projected sales volumes. In addition to third-party payors, we will also need to negotiate formulary placement with hospitals, health systems and certain independent delivery networks. Such negotiations may be more protracted than anticipated and may be compromised because of similar considerations, relating to insufficient incremental medical benefit and/or cost-effectiveness.

Pricing and reimbursement schemes vary widely from country to country. For example, certain EU member states may approve a specific price and volume for a drug product after which incremental revenues or profits need to be paid back by way of rebates. They may also institutionalize utilization restrictions, curb physicians' drug budgets, provide conditional reimbursement schemes that require additional evidence to be generated post-marketing authorization, etc. The downward pressure on health care costs in general, particularly prescription drugs, has been particularly evident in EU markets, for some time, with evidence pointing to increasing pressures on the horizon. As a result, increasingly high barriers are being erected to the pricing and reimbursement of new drugs, despite regulatory efforts to bring drugs to market sooner. In addition, cross-border trade has existed for some time in the EU, allowing pharmacies in one country to import, at a lower price, drug from another country, further exerting pricing pressures across the EU. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our drugs.

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The marketability of any drugs for which we receive regulatory approval for commercial sale may suffer if third-party payors and/or hospital administrators fail to provide adequate coverage, reimbursement or formulary placement. Coverage policies, third-party reimbursement rates and drug pricing regulations may change in the future. In particular, uncertainty over the long term regarding the Patient Protection and Affordable Care Act, or its replacement in the U.S., may mean that coverage, reimbursement and pricing structures available today may be different in the future. In addition, the States may continue to consider legislation of their own which could further restrict the ability to freely price drugs and/or curb utilization in the U.S. Even if favorable coverage and reimbursement status is attained for one or more drugs for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of December 31, 2018, we employed 137 employees (133 full-time, 2 part-time and 2 interns), 17 of whom have Ph.D. and/or M.D. degrees. Of these employees, 116 were engaged in or directly support research and development activities. We believe that our employee relations are good. We believe that our future success will depend in large part on our ability to attract and retain experienced and skilled employees.

Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our drug candidates. We incurred research and development expenses of $66.4 million, $96.2 million, and $102.7 million during the years ended December 31, 2018, 2017 and 2016, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2019 as we continue to advance our drug candidates through clinical development.

Corporate and Available Information

We are incorporated in Delaware. Our website is located at *http://www.celldex.com.* On our website, investors can obtain, free of charge, a copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material electronically with, or furnish it to, the Securities and Exchange Commission, or SEC. None of the information posted on our website is incorporated by reference into this Annual Report. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding us and other companies that file materials with the SEC electronically.

Item 1A. RISK FACTORS

You should consider carefully these risk factors together with all of the information included or incorporated by reference in this Annual Report in addition to our financial statements and the notes to our financial statements. This section includes forward-looking statements.

The following is a discussion of the risk factors that we believe are material to us at this time. These risks and uncertainties are not the only ones facing us, and there may be additional matters that we are unaware of or that we currently consider immaterial. All of these could adversely affect our business, results of operations, financial condition and cash flows.

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Risks Related to Our Financial Condition and Capital Requirements

We currently have no product revenue and will need to raise capital to operate our business.

To date, we have generated no product revenue and cannot predict when and if we will generate product revenue. We had an accumulated deficit of $962.4 million as of December 31, 2018. Until, and unless, we complete clinical trials and further development, and receive approval from the FDA and other regulatory authorities, for our drug candidates, we cannot sell our drugs and will not have product revenue. We expect to spend substantial funds to continue the research, development and testing of our products that are in the preclinical and clinical testing stages of development and to prepare to commercialize products in anticipation of FDA approval. Therefore, for the foreseeable future, we will have to fund all of our operations and development expenditures from cash on hand, equity or debt financings, licensing fees and grants. Additional financing will be required to meet our liquidity needs. If we do not succeed in raising additional funds on acceptable terms, we might not be able to complete planned preclinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or curtail operations. Any additional sources of financing could involve the issuance of our equity securities, which would have a dilutive effect on our stockholders. No assurance can be given that additional financing will be available to us when needed on acceptable terms, or at all.

We cannot be certain that we will achieve or sustain profitability in the future. Failure to achieve profitability could diminish our ability to sustain operations, pay dividends on our common stock, obtain additional required funds and make required payments on our present or future indebtedness.

We expect to incur future losses and we may never become profitable.

We have incurred operating losses of $156.4 million, $121.5 million and $132.9 million during 2018, 2017 and 2016, respectively, and expect to incur an operating loss in 2019 and beyond. We believe that operating losses will continue in 2019 and beyond because we are planning to incur significant costs associated with the development of our drug candidates. During the years ended December 31, 2018, 2017 and 2016, we incurred $12.4 million, $21.1 million and $24.9 million in clinical trial expense and $4.2 million, $11.4 million and $18.3 million in contract manufacturing expense. Our net losses have had and will continue to have an adverse effect on, among other things, our stockholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot predict when we will become profitable, if at all.

We will need additional capital to fund our operations, including the development, manufacture and potential commercialization of our drug candidates. If we do not have or cannot raise additional capital when needed, we may be unable to develop and ultimately commercialize our drug candidates successfully.

We expect to incur significant costs as we develop our drug candidates. The continuing development and commercialization of our drug candidates requires additional capital beyond our current resources. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $94.0 million. During the next twelve months and beyond, we will take further steps to raise additional capital to fund our liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following:

licensing of drug candidates with existing or new collaborative partners;

possible business combinations;

issuance of debt; or

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issuance of common stock or other securities via private placements or public offerings.

While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that we will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from drug candidates under development. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business.

Our stockholders may be subject to substantial dilution if we elect to pay future milestone consideration to the former Kolltan stockholders in shares of common stock. If we elect to pay future milestone consideration in cash we would likely need to raise additional capital.

The merger agreement between us and Kolltan provides that in the event that certain specified preclinical and clinical development milestones related to Kolltan's development programs and/or Celldex's development programs and certain commercial milestones related to Kolltan's drug candidates are achieved, we will be required to pay Kolltan's former stockholders milestone payments of up to $127.5 million as of December 31, 2018. These milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both, although we are required to maintain a certain percentage of the overall consideration paid in Celldex common stock to satisfy certain tax requirements under the merger agreement. We may require additional capital to fund any milestone payments in cash, depending on the facts and circumstances at the time such payments become due. If we elect to pay the milestones in shares of our common stock, our stockholders would experience substantial dilution.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted, leading to significant changes to U.S. tax law. Among other provisions, the TCJA lowered the U.S. federal corporate income tax rate from 35% to 21%, limited the deduction for net operating losses to 80% of taxable income while providing that net operating loss carryovers for years after 2017 will not expire, imposed a mandatory one-time transition tax on previously deferred foreign earnings and eliminated or reduced certain income tax deductions. The Company has completed its accounting for the tax effects of the TCJA. We have revalued our net deferred tax assets and liabilities at the newly enacted U.S. federal rate, and we recognized a tax benefit of $19.1 million during the year ended December 31, 2017 related to the TCJA. We continue to examine the impact this tax reform legislation, as well as any additional regulatory guidance that may be issued, may have on our business.

Risks Related to Development and Regulatory Approval of Drug Candidates

Our long term success depends heavily on our ability to fund and complete the research and development activities and obtain regulatory approval for our program assets.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical failure can occur at any stage of clinical development. For example, in April 2018, we announced that our randomized, Phase 2b METRIC Study of glembatumumab vedotin in patients with metastatic triple-negative breast cancers that overexpress gpNMB failed to meet its primary endpoint. Based on these results, we also made the decision to discontinue the

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glembatumumab vedotin program across all indications. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate.

We will need substantial additional financing to complete the development of our drug candidates. Further, even if we complete the development of our drug candidates and gain marketing approvals from the FDA and comparable foreign regulatory authorities in a timely manner, we cannot be sure that such drug candidate will be commercially successful in the pharmaceutical market. If the results of clinical trials, the anticipated or actual timing of marketing approvals, or the market acceptance of any of our drug candidates, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

Our drug candidates are subject to extensive regulatory scrutiny.

All of our drug candidates are at various stages of development, and our activities and drug candidates are significantly regulated by a number of governmental entities, including the FDA in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of drugs and drug candidates. We or our partners must obtain regulatory approval for a drug candidate in all of these areas before we can commercialize any of our drug candidates. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. This process typically requires extensive preclinical and clinical testing, which may take longer or cost more than we anticipate, and may prove unsuccessful due to numerous factors. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Companies in the pharmaceutical, biotechnology and immunotherapeutic drug industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Our inability to commercialize a drug candidate would impair our ability to earn future revenues.

If our drug candidates do not pass required tests for safety and effectiveness, we will not be able to obtain regulatory approval and derive commercial revenue from them.

In order to succeed, we will need to obtain regulatory approval for our drug candidates. The FDA has not approved any of our drug candidates for sale to date. Our drug candidates are in various stages of preclinical and clinical testing. Preclinical tests are performed at an early stage of a product's development and provide information about a drug candidate's safety and effectiveness on laboratory animals. Preclinical tests can last years. If a product passes its preclinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. Phase 1 testing generally lasts between 6 and 24 months. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. Phase 2 testing generally lasts between 6 and 36 months. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Phase 3 studies generally last between 12 and 48 months. Once clinical testing is completed and a BLA or NDA is filed with the FDA, it may take more than a year to receive FDA approval.

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In all cases we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the United States and in other countries, since we are developing our drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot assure you that any of the clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval.

The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Preclinical and clinical data are susceptible to various interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and early-stage clinical trials have nonetheless failed to replicate such results in later-stage clinical trials and subsequently failed to obtain marketing approval. Drug candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical and initial clinical trials, even if certain analyses of primary or secondary endpoints in those early trials showed trends towards efficacy. Later-stage clinical trials with larger numbers of patients or longer durations of therapy may also reveal safety concerns that were not identified in earlier smaller or shorter trials. Our failure to demonstrate efficacy and safety data sufficient to support marketing approval for any of our other drug candidates would substantially harm our business, prospectus, financial condition and results of operations.

Product testing is critical to the success of our drug candidates but subject to delay or cancellation if we have difficulty enrolling patients.

As our portfolio of drug candidates moves from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients with the appropriate characteristics. At times we have experienced difficulty enrolling patients, and we may experience more difficulty as the scale of our clinical testing program increases. The factors that affect our ability to enroll patients are largely uncontrollable and include principally the following:

- the nature of the clinical test;
- the size of the patient population;
- patients' willingness to receive a placebo or less effective treatment on the control arm of a clinical study;
- the distance between patients and clinical test sites; and
- the eligibility criteria for the trial.

If we cannot enroll patients as needed, our costs may increase, or we may be forced to delay or terminate testing for a product.

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We may have delays in commencing, enrolling and completing our clinical trials, and we may not complete them at all.

We have not completed the clinical trials necessary to obtain FDA approval to market any of our drug candidates in development. Clinical trials for our products in development may be delayed or terminated as a result of many factors, including the following:

- inability to reach agreements on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in enrolling patients in our clinical trials;
- inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with cGMP requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers, including commercial grade-clinical supply for our Phase 3 clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- drug candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

Any delay or failure to commence, enroll or complete clinical trials and obtain FDA approval for our drug candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular drug candidate.

If serious adverse or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit our development of some of our drug candidates.

If our drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many drugs that initially show promise in early-stage testing are later found to cause side effects that prevent

further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In

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addition, when used in combination with other marketed therapies, our drug candidates may exacerbate adverse events associated with the marketed therapy.

We may expend our resources to pursue a particular drug candidate or indication and forgo the opportunity to capitalize on drug candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing drug candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that may prove to have greater commercial potential.

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

We may be unable to manage multiple late-stage clinical trials for a variety of drug candidates simultaneously.

As our current clinical trials progress, we may need to manage multiple late-stage clinical trials simultaneously in order to continue developing all of our current products. The management of late-stage clinical trials is more complex and time consuming than early-stage trials. Typically, early-stage trials involve several hundred patients in no more than 10 to 30 clinical sites. Late-stage (Phase 3) trials may involve up to several thousand patients in up to several hundred clinical sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program is substantially larger than early-stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, the sponsor is faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently it is possible that conclusions of efficacy or safety may not be acceptable to permit filing of a BLA or NDA for any one of the above reasons or a combination of several.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for certain of our drug candidates could harm our drug development strategy and operational results.

As an element of our clinical development approach, we may seek to screen and identify subsets of patients that express a certain biomarker or that have a certain genetic alteration who may derive meaningful benefit from our development drug candidates. To achieve this, one or more of our drug development programs may be dependent on the development and commercialization of a companion diagnostic by us or by third-party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated drug candidate. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before the related drug candidate may be commercialized. The approval of a companion diagnostic as part of the product label will limit the use of the drug candidate to only those patients who express the specific biomarker it was developed to detect. We or our third-party collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance

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reimbursement for such companion diagnostic, all of which may prevent us from completing our clinical trials or commercializing our drugs on a timely or profitable basis, if at all.

To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related drug candidates or, if regulatory approval is obtained, delay or limit our ability to commercialize our related drug candidates.

Any delay in obtaining regulatory approval would have an adverse impact on our ability to earn future revenues.

It is possible that none of the drug candidates that we develop will obtain the regulatory approvals necessary for us to begin commercializing them. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the nature of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate including, but not limited to, loss of patent term during the approval period. Furthermore, if we, or our partners, do not reach the market with our products before our competitors offer products for the same or similar uses, or if we, or our partners, are not effective in marketing our products, our revenues from product sales, if any, will be reduced.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, adjuvants and vaccine and immunotherapeutic delivery systems and major universities and research institutions. Most of our competitors have substantially greater resources, more extensive experience in conducting preclinical studies and clinical testing and obtaining regulatory approvals for their products, greater operating experience, greater research and development and marketing capabilities and greater production capabilities than those of ours. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products, especially if we experience any delay in obtaining required regulatory approvals.

We may enter into collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates including, where appropriate, for our lead drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.

We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

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If we enter into collaboration agreements for one or more of our lead drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

We have many competitors in our field, and they may develop technologies that make ours obsolete.

Biotechnology, pharmaceuticals and therapeutics are rapidly evolving fields in which scientific and technological developments are expected to continue at a rapid pace. We have many competitors in the U.S. and abroad. Our success depends upon our ability to develop and maintain a competitive position in the product categories and technologies on which we focus. Many of our competitors have greater capabilities, experience and financial resources than we do. Competition is intense and is expected to increase as new products enter the market and new technologies become available. Our competitors may:

develop technologies and products that are more effective than ours, making ours obsolete or otherwise noncompetitive;

obtain regulatory approval for products more rapidly or effectively than us; and

obtain patent protection or other intellectual property rights that would block our ability to develop competitive products.

Risks Related to Commercialization of Our Drug Candidates

We may face delays, difficulties or unanticipated costs in establishing sales, marketing and distribution capabilities or seeking a partnership for the commercialization of our drug candidates, even if regulatory approval is obtained.

We may choose to build a commercial organization which we believe could provide us with the strategic options to either retain full economic rights to our drug candidates or seek favorable economic terms through advantageous commercial partnerships. As a result, we may have full responsibility for commercialization of one or more of our drug candidates if and when they are approved for sale. We currently lack sufficient marketing, sales and distribution capabilities to carry out this strategy. If any of our drug candidates are approved by the FDA, we will need a drug sales force with technical expertise prior to the commercialization of any of our drug candidates. We may not succeed in developing such sales and distribution capabilities, the cost of establishing such sales and distribution capabilities may exceed any product revenue, or our direct marketing and sales efforts may be unsuccessful. We may find it necessary to enter into strategic partnerships, co-promotion or other licensing arrangements. To the extent we enter into such strategic partnerships, co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold such drugs, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful and may not be within our control. If we are unable to enter into such strategic partnerships, co-promotion or other licensing arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future drug candidates. If we are not successful in commercializing any drug candidates, for which we obtain regulatory approval, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may never achieve profitability or become unable to continue the operation of our business.

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If our drug candidates for which we obtain regulatory approval do not achieve broad acceptance from physicians, patients and third-party payors, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our drug candidates, our approved drugs may not gain market acceptance among physicians and patients. We believe that effectively marketing our drug candidates, if any of them are approved, will require substantial efforts, both prior to commercial launch and after approval. Physicians may elect not to prescribe our drugs, and patients may elect not to request or take them, for a variety of reasons, including:

limitations or warnings contained in a drug's FDA-approved labeling;

changes in the standard of care or the availability of alternative drugs for the targeted indications for any of our drug candidates;

limitations in the approved indications for our drug candidates;

the approval, availability, market acceptance and reimbursement for the companion diagnostic, where applicable;

demonstrated clinical safety and efficacy compared to other drugs;

significant adverse side effects;

effectiveness of education, sales, marketing and distribution support;

timing of market introduction and perceived effectiveness of competitive drugs;

cost-effectiveness;

adverse publicity about our drug candidates or favorable publicity about competitive drugs;

convenience and ease of administration of our drug candidates; and

willingness of third-party payors to reimburse for the cost of our drug candidates.

If our future drugs fail to achieve market acceptance, we will not be able to generate significant revenues and may never achieve profitability.

Even if any of our drug candidates receive FDA approval, the terms of the approval may limit such drug's commercial potential. Additionally, even after receipt of FDA approval, such drug would be subject to substantial, ongoing regulatory requirements.

The FDA has complete discretion over the approval of our drug candidates. If the FDA grants approval, the scope of the approval may limit our ability to commercialize such drug, and in turn, limit our ability to generate substantial product revenue. For example, the FDA may grant approval contingent on the performance of costly post-approval clinical trials or subject to warnings or contraindications. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for such drug will be subject to extensive and ongoing regulatory requirements. In addition, manufacturers of our drug

candidates are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug candidates, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the drug from the market or suspension of manufacturing. If we, our

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drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- consent decrees;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of drugs or import bans.

The regulatory requirements and policies may change, and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of any of our drug candidates. If there is not sufficient reimbursement for our future drugs, it is less likely that such drugs will be widely used.

Market acceptance and sales of any of our drug candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future health care reform measures in both the United States and foreign jurisdictions. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In addition, government authorities and these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for these drugs. In addition, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future drugs to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of drugs from other countries, could reduce the net price we receive for any future marketed drugs. As a result, our future drugs might not ultimately be considered cost-effective.

We cannot be certain that reimbursement will be available for any drug candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future drugs. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any drug candidates that we develop.

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Other factors could affect the demand for and sales and profitability of any drug candidates that we may commercialize in the future.

In general, other factors that could affect the demand for and sales and profitability of our future drugs include, but are not limited to:

- the timing of regulatory approval, if any, of competitive drugs;
- our or any other of our partners' pricing decisions, as applicable, including a decision to increase or decrease the price of a drug, and the pricing decisions of our competitors;
- government and third-party payor reimbursement and coverage decisions that affect the utilization of our future drugs and competing drugs;
- negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party, which could cause the sales of our future drugs to decrease or a future drug to be recalled;
- the degree of patent protection afforded our future drugs by patents granted to or licensed by us and by the outcome of litigation involving our or any of our licensor's patents;
- the outcome of litigation involving patents of other companies concerning our future drugs or processes related to production and formulation of those drugs or uses of those drugs;
- the increasing use and development of alternate therapies;
- the rate of market penetration by competing drugs; and
- the termination of, or change in, existing arrangements with our partners.

Any of these factors could have a material adverse effect on the sales of any drug candidates that we may commercialize in the future.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We may seek approval for our drug candidates outside the United States and may market future products in international markets. In order to market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting the MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals, and even if we file we may not receive necessary approvals to commercialize our products in any market.

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If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our drug candidates are approved for commercialization outside of the United States, we expect that we will be subject to additional risks related to international operations and entering into international business relationships, including:

different regulatory requirements for drug approvals;

reduced protection for intellectual property rights, including trade secret and patent rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

workforce uncertainty in countries where employment regulations are different than, and labor unrest is more common than, in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, floods and fires; and

difficulty in importing and exporting clinical trial materials and study samples.

Risks Related to Reliance on Third Parties

We rely on third parties to plan, conduct and monitor our clinical tests, and their failure to perform as required would interfere with our product development.

We rely on third parties to conduct a significant portion of our clinical development activities. These activities include clinical patient recruitment and observation, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. We conduct project management and medical and safety monitoring in-house for some of our programs and rely on third parties for the remainder of our clinical development activities. If any of these third parties is unable to perform in a quality and timely manner, and at a feasible cost, our clinical studies will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory standards, our testing could be delayed, cancelled or rendered ineffective.

We rely on contract manufacturers over whom we have limited control. Should the cost, delivery and quality of clinical materials manufactured by us in our Fall River facility or supplied by contract manufacturers vary to our disadvantage, our business operations could

suffer significant harm.

We have limited experience in commercial manufacturing. We rely on CMOs to manufacture drug substance and drug product for any late-stage clinical studies of our drug candidates as well as for future commercial supplies. Our ability to conduct late-stage clinical trials, manufacture and commercialize our drug candidates, if regulatory approval is obtained, depends on the ability of such third parties to manufacture our drug candidates on a large scale at a competitive cost and in

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accordance with cGMP and foreign regulatory requirements, if applicable. We also rely on CMOs for filling, packaging, storage and shipping of drug product. In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and would need to hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA.

Prior to approval of any drug candidate, the FDA must review and approve validation studies for drug product. The manufacturing processes for our drug candidates and immunotherapeutic delivery systems utilize known technologies. We believe that the products we currently have under development can be scaled up to permit manufacture in commercial quantities. However, there can be no assurance that we will not encounter difficulties in scaling up the manufacturing processes. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. CMOs may encounter difficulties in scaling up production, including problems involving raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, changing priorities within the CMOs, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such drug candidate. These risks become more acute as we scale up for commercial quantities, where a reliable source of drug product becomes critical to commercial success. The commercial viability of any of our drug candidates, if approved, will depend on the ability of our contract manufacturers to produce drug product on a large scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the drug.

We operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA regulations, allowing us to distribute potential products to clinical sites in the U.S. for early-stage clinical trials. We currently manufacture CDX-1140, CDX-301 and CDX-0159 drug substance in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials. We expect that our existing clinical supplies of CDX-3379 and varlilumab will be sufficient to carry out our current planned clinical development. Additional manufacturing options are under review and may involve utilization of the Fall River facility and/or a CMO. All products are then filled and packaged at contract manufacturers. Any manufacturing failures or compliance issues at contract manufacturers could cause delays in our Phase 1 and Phase 2 clinical studies for these drug candidates.

Our leading drug candidates require specialized manufacturing capabilities and processes. We may face difficulty in securing commitments from U.S. and foreign contract manufacturers as these manufacturers could be unwilling or unable to accommodate our needs. Relying on foreign manufacturers involves peculiar and increased risks, including the risk relating to the difficulty foreign manufacturers may face in complying with cGMP requirements as a result of language barriers, lack of familiarity with cGMP or the FDA regulatory process or other causes, economic or political instability in or affecting the home countries of our foreign manufacturers, shipping delays, potential changes in foreign regulatory laws governing the sales of our product supplies, fluctuations in foreign currency exchange rates and the imposition or application of trade restrictions.

There can be no assurances that contract manufacturers will be able to meet our timetable and requirements. Further, contract manufacturers must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. As noted above, non-U.S. contract manufacturers may face special challenges in complying with cGMP requirements, and although we are not currently dependent on non-U.S. collaborators or contract manufacturers, we may

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choose or be required to rely on non-U.S. sources in the future as we seek to develop stable supplies of increasing quantities of materials for ongoing clinical trials of larger scale. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop, manufacture, sell and deliver products on a timely and competitive basis.

We currently rely on third-party collaborators to develop and commercialize companion diagnostic tests for certain of our drug candidates.

We do not have experience or capabilities in developing, administering, obtaining regulatory approval for, or commercializing companion diagnostic tests and will need to rely in large part on third-party collaborators to perform these functions. Companion diagnostic tests are subject to regulation by the FDA and similar regulatory authorities outside of the United States as medical devices and require separate regulatory approval prior to commercialization. We are dependent on such third-party collaborators to obtain regulatory approval and commercialize such companion diagnostic tests. Such third-party collaborators:

- may not perform its obligations as expected or as required under our collaboration agreement;
- may encounter production difficulties that could constrain the supply of the companion diagnostic test;
- may have difficulties gaining acceptance of the use of the companion diagnostic test in the clinical community;
- may not pursue commercialization of the companion diagnostic test even if they receive any required regulatory approvals;
- may elect not to continue the development or commercialization of the companion diagnostic test based on changes in the third parties' strategic focus or available funding, or external factors such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of the companion diagnostic test; and
- may terminate their relationship with us.

If such third-party collaborators fail to develop, obtain regulatory approval or commercialize the companion diagnostic test, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our drug candidates.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.

Because we rely on third parties to develop our drug candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs which may require us to share trade secrets

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under the terms of research and development partnership or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position.

Risks Related to Business Operations

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

From time to time we may consider strategic transactions, including acquisitions of companies, such as our acquisition of Kolltan in the fourth quarter of 2016, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, acquisitions of assets and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend greatly on the intellectual capabilities and experience of our key executives and scientists, and the loss of any of them could affect our ability to develop our products.

The loss of any of our executive officers could harm us. We entered into employment agreements with each of our executive officers, although an employment agreement as a practical matter does not guarantee retention of an employee. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our

future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key opinion leaders and heads of

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academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for this type of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

We may expand our clinical development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect that if our drug candidates continue to progress in development, we may require significant additional investment in personnel, management systems and resources, particularly in the build out of our commercial capabilities. To date we have hired a core commercial team to plan for potential commercial launches if any of our drug candidates are approved. Over the next several years, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage this potential future growth, we may continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may not realize the anticipated benefits of our acquisition of Kolltan.

The success of the Kolltan merger will depend on, among other things, the successful development of the preclinical and clinical programs acquired from Kolltan. Following the acquisition, we decided to modify the Fc portion of CDX-0158 because approximately two-thirds of the patients in the Phase 1 dose-escalation study of CDX-0158 in patients with advanced refractory gastrointestinal stromal tumors, or GIST, and other KIT positive tumors had infusion reactions. This second-generation version, called CDX-0159, also includes modifications to increase the half-life of the antibody, giving it an additional advantage over CDX-0158. We are developing CDX-0159 in-house with the intention of replacing CDX-0158 in clinical development. As a result in the third quarter of 2017, we recorded a non-cash partial impairment charge of $13.0 million related to this clinical program due to changes in projected development and regulatory timelines. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty and therefore we will continue to evaluate the development progress for the anti-KIT program and monitor the remaining $27.0 million intangible asset for further impairment. If we experience further delays or do not successfully develop the preclinical and clinical programs acquired from Kolltan, we may incur further impairment charges and may not realize the anticipated benefits of the Kolltan acquisition, which would have an adverse effect on our business prospects and results of operations.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable privacy laws, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing

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and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and launched a Health Care Compliance program, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

We may not be able to successfully integrate our existing technology or to modify our technologies to create new immunotherapeutic drugs.

If we are able to integrate our acquired assets and licensed assets with our immunotherapy technologies, we believe these assets will give our immunotherapeutic drugs a competitive advantage. However, if we are unable to successfully integrate licensed assets, or other technologies which we have acquired or may acquire in the future, with our existing technologies and potential products currently under development, we may be unable to realize any benefit from our acquisition of these assets, or other technologies which we have acquired or may acquire in the future, and we may face the loss of our investment of financial resources and time in the integration process.

We believe that our immunotherapy technology portfolio may offer opportunities to develop immunotherapeutic drugs that treat a variety of cancers and inflammatory and infectious diseases by stimulating a patient's immune system against those diseases. If our immunotherapy technology portfolio cannot be used to create effective immunotherapeutic drugs against a variety of diseases, we may lose all or portions of our investment in development efforts for new drug candidates.

Our internal computer systems, or those of our CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from cyberattacks, malicious intrusion, computer viruses, unauthorized access, loss of data privacy, natural disasters, terrorism, war and telecommunication, electrical failures or other significant disruption. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development or commercialization of our drug candidates could be delayed.

Our business requires us to use hazardous materials, which increases our exposure to dangerous and costly accidents.

Our research and development activities involve the use of hazardous chemicals, biological materials and radioactive compounds. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by applicable laws and

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regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, an injured party will likely sue us for any resulting damages with potentially significant liability. The ongoing cost of complying with environmental laws and regulations is significant and may increase in the future.

We face the risk of product liability claims, which could exceed our insurance coverage, and product recalls, each of which could deplete our cash resources.

As a participant in the pharmaceutical, biotechnology and immunotherapeutic drug industries, we are exposed to the risk of product liability claims alleging that use of our drug candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of our drug candidates and may be made directly by patients involved in clinical trials of our products, by consumers or health care providers or by individuals, organizations or companies selling our products. Product liability claims can be expensive to defend, even if the drug or drug candidate did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a drug candidate moves through the development pipeline to commercialization. Under our license agreements, we are required to maintain clinical trial liability insurance coverage up to $15 million. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaborative agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and have a material adverse effect on our business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business and inhibit or prevent development of our drug candidates and, if approval is obtained, commercialization of our future drugs.

Risks Related to Intellectual Property

We license technology from other companies to develop products, and those companies could influence research and development or restrict our use of it. In addition, if we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

Companies that license technologies to us that we use in our research and development programs may require us to achieve milestones or devote minimum amounts of resources to develop products using those technologies. They may also require us to make significant royalty and milestone payments, including a percentage of any sublicensing income, as well as payments to reimburse them for patent costs. The number and variety of our research and development programs require us to establish priorities and to allocate available resources among competing programs. From time to time we may choose to slow down or cease our efforts on particular products. If in doing so we fail to fully perform our obligations under a license, the licensor can terminate the license or permit our competitors to use the technology. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. Moreover, we may lose our right to market and sell any products based on the licensed technology. The occurrence of such events could materially harm our business.

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Our ability to successfully develop and, if regulatory approval is obtained, commercialize our drug candidates may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our drug candidates and technologies.

Our success depends in part on our ability to obtain and maintain patent protection and other intellectual property protection for our drug candidates and proprietary technology. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates and technology that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing drugs and technologies.

Biotechnology patents involve complex legal, scientific and factual questions and are highly uncertain. To date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents, particularly in regard to patents for technologies for human uses like those we use in our business. We cannot predict whether the patents we or our licensors seek will issue. If such patents are issued, a competitor may challenge them and limit their scope. Moreover, our patents may not afford effective protection against competitors with similar technology. A successful challenge to any one of our patents could result in a third party's ability to use the technology covered by the patent. We also face the risk that others will infringe, avoid or circumvent our patents. Technology that we license from others is subject to similar risks and this could harm our ability to use that technology. If we, or a company that licenses technology to us, were not the first creator of an invention that we use, our use of the underlying product or technology will face restrictions, including elimination. For example, in September 2014, two European patent oppositions were filed against the University of Southampton European patent, and at a hearing on November 23, 2016 the European Patent Office (EPO) revoked the European patent on the ground of lack of inventive step. The University of Southampton has filed an appeal against this decision, and we intend to defend the European patent vigorously in cooperation with the University of Southampton. This EPO decision does not affect the later filed Celldex patents and applications for varlilumab. We also have an issued U.S. patent which covers varlilumab as a composition of matter.

If we must defend against suits brought against us or prosecute suits against others involving intellectual property rights, we will incur substantial costs. In addition to any potential liability for significant monetary damages, a decision against us may require us to obtain licenses to patents or other intellectual property rights of others on potentially unfavorable terms. If those licenses from third parties are necessary but we cannot acquire them, we would attempt to design around the relevant technology, which would cause higher development costs and delays and may ultimately prove impracticable.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our drug candidates. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or drug candidates, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

We are aware of a third-party European patent that relates to use of ErbB3 antibodies for treatment of hyperproliferative disorders, including cancer. A counterpart of this patent has also issued

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in Japan and Australia. As a result of an opposition proceeding, the European patent was revoked in its entirety. The owner of the European patent has appealed the decision in the opposition proceeding but the appeal has been rejected so that the decision to revoke the European patent stands. We continue to monitor counterparts in other jurisdictions. While we cannot predict whether claims will issue in these other jurisdictions or whether the scope of such claims would be relevant to our activities, these applications entail comparable risks to us in these other jurisdictions.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

We rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees that obligate them to assign their inventions to us. However, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease

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developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Regulatory Risks

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation for some of our product candidates in the United States. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate, will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We may seek fast track designation for some of our product candidates or priority review of applications for approval of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If our processes and systems are not compliant with regulatory requirements, we could be subject to delays in submitting BLAs, NDAs or restrictions on marketing of drugs after they have been approved.

We currently are developing drug candidates for regulatory approval and are in the process of implementing regulated processes and systems required to obtain and maintain regulatory approval for our drug candidates. Certain of these processes and systems for conducting clinical trials and manufacturing material must be compliant with regulatory requirements before we can apply for regulatory approval for our drug candidates. These processes and systems will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. If we are unable to achieve compliance in a timely fashion or if compliance issues are identified at any point in the development and approval process, we may experience delays in filing for regulatory approval for our drug

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candidates or delays in obtaining regulatory approval after filing. In addition, any later discovery of previously unknown problems or safety issues with approved drugs or manufacturing processes, or failure to comply with regulatory requirements may result in restrictions on such drugs or manufacturing processes, withdrawal of drugs from the market, the imposition of civil or criminal penalties or a refusal by the FDA and/or other regulatory bodies to approve pending applications for marketing approval of new drugs or supplements to approved applications, any of which could have a material adverse effect on our business. In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as filing and maintenance of marketing authorizations and safety reporting or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs for which we or they obtain approval may be subject to later restrictions on manufacturing or sale or may even risk withdrawal, which could have a material adverse effect on our business.

Even if we receive regulatory approval for a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our drug candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our drug candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

warning letters;

civil or criminal penalties and fines;

injunctions;

consent decrees;

suspension or withdrawal of regulatory approval;

suspension of any ongoing clinical studies;

voluntary or mandatory product recalls and publicity requirements;

refusal to accept or approve applications for marketing approval of new drugs;

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restrictions on operations, including costly new manufacturing requirements; or

seizure or detention of drugs or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products, and our business may suffer.

We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education 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, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;

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 from Medicare, Medicaid or other third-party payors that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

state law and foreign 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 payor, including commercial insurers, 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 may not have the same effect, thus complicating compliance efforts.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and the EU.

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States we are subject to various state and federal privacy and data security regulations, including but not limited to HIPAA and as amended in 2014 by the HITECH Act. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the EU, and this regulation will become more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) comes into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

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Risks Related to Our Capital Stock

Our history of losses and uncertainty of future profitability make our common stock a highly speculative investment.

We have had no commercial revenue to date from sales of our drug candidates. We had an accumulated deficit of $962.4 million as of December 31, 2018. We expect to spend substantial funds to continue the research and development testing of our drug candidates.

In anticipation of FDA approval of these products, we will need to make substantial investments to establish sales, marketing, quality control, regulatory compliance capabilities and commercial manufacturing alliances. These investments will increase if and when any of these drug candidates receive FDA approval. We cannot predict how quickly our lead drug candidates will progress through the regulatory approval process. As a result, we may continue to lose money for several years.

We cannot be certain that we will achieve or sustain profitability in the future. Failure to achieve profitability could diminish our ability to sustain operations, pay dividends on our common stock, obtain additional required funds and make required payments on our present or future indebtedness.

We completed the reverse stock split in order to regain compliance with the listing requirements of NASDAQ. However, the reverse stock split may not result in our stock price remaining compliant with the minimum price requirements of NASDAQ.

Our common stock is listed on the NASDAQ Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $1.00 per share. On May 29, 2018, we received a written notice from NASDAQ indicating that we are not in compliance with the minimum bid price requirement for continued listing on the NASDAQ Global Market and, effective November 28, 2018, our common stock commenced trading on the NASDAQ Capital Market. In connection with the transfer to the NASDAQ Capital Market, we were granted an additional 180 days in which to regain compliance with the minimum bid price requirement, or, until May 28, 2019.

At our annual meeting of stockholders in June 2018, our stockholders approved a proposal to grant discretionary authority to our Board of Directors to amend our certificate of incorporation to effect a reverse stock split of our outstanding shares of common stock within a range of one share of common stock for every ten shares of common stock to one share of common stock for every fifteen shares of common stock, with the exact reverse stock split ratio to be decided by the Board of Directors. On February 8, 2019 we announced that our Board of Directors had approved a one for fifteen reverse stock split of our issued and outstanding shares of common stock. On February 11, 2019, our common stock began trading on a split-adjusted basis on the NASDAQ Capital Market. On February 26, 2019, we received formal notice from NASDAQ that we had regained compliance with the minimum $1.00 bid price requirement and the matter is now closed.

There can be no assurance that in the future we will be able to maintain compliance with the minimum bid price requirement or we will otherwise be in compliance with other NASDAQ listing criteria. If we fail to maintain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the NASDAQ Capital Market in the future and NASDAQ determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from NASDAQ and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a

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national securities exchange or quoted on NASDAQ that has a market price of less than $5.00 per share, subject to certain exceptions).

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2018 through December 2018, the market price of our common stock has fluctuated from a high of $46.20 per share in the first quarter of 2018, to a low of $2.75 per share in the fourth quarter of 2018 (giving retroactive effect to our recently completed one for fifteen reverse stock split). Our progress in developing and commercializing our products, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. Adverse changes to the price of our common stock could result in an impairment to the amount recorded to goodwill on our balance sheet. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

We completed the reverse stock split of our shares of common stock, which may reduce and may limit the market trading liquidity of the shares due to the reduced number of shares outstanding, and may potentially have an anti-takeover effect.

We completed the reverse stock split of our common stock by a ratio of one for fifteen effective February 8, 2019. The liquidity of our common stock may be adversely affected by the reverse stock split as a result of the reduced number of shares outstanding following the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales. Reducing the number of outstanding shares of our common stock through the reverse stock split is intended, absent other factors, to increase the per share market price of our common stock. However, other factors, such as our financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock. As a result, there can be no assurance that the reverse stock split will result in the intended benefits, that the market price of our common stock will remain higher following the reverse stock split or that the market price of our common stock will not decrease in the future. Further, since the reverse stock split was not accompanied by a corresponding decrease in the number of shares authorized for issuance under our Third Restated Certificate of Incorporation, the relative increase in the number of shares authorized for issuance could, under certain circumstances, have an anti-takeover effect by enabling our Board of Directors to issue additional shares of common stock in a transaction making it more difficult for a party to obtain control of us by tender offer or other means.

If certain preclinical and clinical milestones are achieved, our stockholders may experience significant dilution as a result of milestone payments to former Kolltan stockholders.

The merger agreement pursuant to which we acquired Kolltan provides that, in the event that certain specified preclinical and clinical development milestones related to Kolltan's development

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programs and/or Celldex's development programs and certain commercial milestones related to Kolltan's drug candidates are achieved, we will be required to pay Kolltan's stockholders milestone payments of up to $127.5 million as of December 31, 2018. These milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both, subject to the provisions of the merger agreement. The number of shares of our common stock issuable in connection with a milestone payment, if any, will be determined based on the average closing price per share of our common stock for the five trading day period ending three calendar days prior to the achievement of such milestone. If we elect to issue additional shares of our common stock, in lieu of paying cash, for such milestone payments, our stockholders may experience significant dilution.

Our ability to use our net operating loss carryforwards will be subject to limitation and, under certain circumstances, may be eliminated.

Utilization of our net operating loss and research and development credit carryforwards may be subject to substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

In October 2007, June 2009, December 2009 and December 2013, we experienced a change in ownership as defined by Section 382 of the Internal Revenue Code. Historically, we have raised capital through the issuance of capital stock on several occasions which, combined with shareholders' subsequent disposition of those shares, has resulted in three changes of control, as defined by Section 382. As a result of these ownership changes, utilization of our Federal net operating loss carryforwards is subject to an annual limitation. Any unused annual limitation may be carried over to later years, and the amount of the limitation may, under certain circumstances, be subject to adjustment if the fair value of our net assets is determined to be below or in excess of the tax basis of such assets at the time of the ownership change, and such unrealized loss or gain is recognized during the five-year period after the ownership change. Subsequent ownership changes, as defined in Section 382, could further limit the amount of net operating loss carryforwards and research and development credits that can be utilized annually to offset future taxable income.

We have not undertaken a study to assess whether an ownership change or multiple ownership changes has occurred for (i) acquired businesses prior to the acquisition, (ii) the Company on the state level, (iii) the Company since March 2015 or (iv) research and development credits. If, based on such a study, we were to determine that there has been an ownership change at any time since its formation, utilization of net operating loss or tax credit carryforwards would be subject to an annual limitation under Section 382.

Refer to Note 14, "Income Taxes," in the accompanying notes to the financial statements for additional discussion on income taxes.

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Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2018 our significant leased properties are described below.

Property Location	Approximate Square Feet	Use	Lease Expiration Date
Hampton, New Jersey	49,600	Headquarters, Office and Laboratory	July 2020(1)
Needham, Massachusetts	46,700	Office and Laboratory	July 2020(2)
Fall River, Massachusetts	28,900	Manufacturing Facility	July 2020(3)
New Haven, Connecticut	17,700	Office and Laboratory	October 2020(4)

(1) Lease includes two renewal options of five years each.

(2) Lease includes two renewal options of five years each.

(3) Lease includes two renewal options of five years each.

(4) Lease includes one renewal option of 18 months.

Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock currently trades on the Nasdaq Capital Market (NASDAQ) under the symbol "CLDX." On February 8, 2019, we effected a one for fifteen reverse stock split of our common stock. As of February 28, 2019, there were approximately 209 shareholders of record of our common stock. On February 28, 2019 the closing price of our common stock, as reported by NASDAQ, was $5.32 per share. We have not paid any dividends on our common stock since our inception and do not intend to pay any dividends in the foreseeable future.

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CELLDEX THERAPEUTICS, INC., NASDAQ MARKET INDEX U.S. AND PEER GROUP INDICES

The graph below compares the cumulative total stockholder return on the common stock for the period from December 31, 2013 through December 31, 2018, with the cumulative return on (i) NASDAQ U.S. Benchmark TR Index and (ii) NASDAQ Pharmaceutical (Subsector) Index. The comparison assumes investment of $100 on December 31, 2013 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends. The points on the graph are as of December 31 of the year indicated.

	2013	2014	2015	2016	2017	2018
Celldex Therapeutics, Inc.	$ 100	$ 75	$ 65	$ 15	$ 12	$ 1
NASDAQ U.S. Benchmark TR Index	$ 100	$ 112	$ 113	$ 128	$ 155	$ 147
NASDAQ Pharmaceutical (Subsector) Index	$ 100	$ 122	$ 128	$ 127	$ 151	$ 163

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Item 6. SELECTED FINANCIAL DATA

The following selected financial data are derived from our audited financial statements. The statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 have been derived from our audited financial statements included in Item 8 of this Annual Report on Form 10-K. This data should be read in conjunction with our audited financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

STATEMENTS OF OPERATIONS DATA
(In thousands, except per share amounts)

	Year Ended December 31,				
	2018	**2017**	**2016**	**2015**	**2014**
REVENUE:					
Product Development and Licensing Agreements	$ 3,341	$ 3,153	$ 2,174	$ 1,442	$ 838
Contracts and Grants	6,197	9,590	4,612	4,038	2,748
Total Revenue	9,538	12,743	6,786	5,480	3,586
OPERATING EXPENSE:					
Research and Development	66,449	96,171	102,726	100,171	104,381
Other Operating Expense	99,525	38,099	36,976	34,850	21,635
Total Operating Expense	165,974	134,270	139,702	135,021	126,016
Operating Loss	(156,436)	(121,527)	(132,916)	(129,541)	(122,430)
Investment and Other Income, Net	4,487	4,214	4,386	2,344	4,350
Net Loss Before Income Tax Benefit	$ (151,949)	$ (117,313)	$ (128,530)	$ (127,197)	$ (118,080)
Income Tax Benefit	765	24,282			
Net Loss	$ (151,184)	$ (93,031)	$ (128,530)	$ (127,197)	$ (118,080)
Basic and Diluted Net Loss Per Common Share	$ (14.48)	$ (10.86)	$ (18.99)	$ (19.66)	$ (19.81)
Shares Used in Calculating Basic and Diluted Net Loss Per Common Share	10,442	8,570	6,769	6,470	5,960

(Reflects one for fifteen reverse stock split effective February 8, 2019)

BALANCE SHEET DATA
(In thousands)

	December 31,				
	2018	**2017**	**2016**	**2015**	**2014**
Working Capital*	$ 86,477	$ 117,020	$ 160,346	$ 264,696	$ 180,494
Total Assets	155,809	315,624	383,358	337,584	248,014
Long-Term Liabilities	19,147	51,519	82,704	17,239	11,863

Accumulated Deficit	(962,438)	(812,517)	(719,486)	(590,956)	(463,759)
Total Stockholders' Equity	124,060	236,369	265,431	290,105	211,660

*

Total current assets less total current liabilities

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Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

On February 8, 2019 we announced that our Board of Directors had approved a one for fifteen reverse stock split of our issued and outstanding shares of common stock, effective February 8, 2019. On February 11, 2019, our common stock began trading on a split-adjusted basis on the NASDAQ Capital Market. The number of authorized shares of the Company remain unchanged. Stockholders who would have otherwise been entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. All share and per share amounts in this Annual Report are shown on a post-split basis.

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of immunotherapies and other targeted biologics. Our drug candidates are derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. They are aimed at addressing market opportunities for which we believe current therapies are inadequate or non-existent.

We are focusing our efforts and resources on the continued research and development of:

CDX-1140, an agonist human monoclonal antibody targeted to CD40, a key activator of immune response, currently being studied as a single-agent and in combination with CDX-301 in a Phase 1 dose-escalation study in multiple types of solid tumors and B cell lymphomas;

CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3), currently in an early Phase 2 study in advanced head and neck squamous cell cancer in combination with Erbitux®;

CDX-301, a dendritic cell growth factor, currently being evaluated in a combination study with CDX-1140; and

Varlilumab, an immune modulating antibody targeting CD27 designed to enhance a patient's immune response, currently being evaluated for potential combination with CDX-1140, especially in lymphomas which co-express CD40 and CD27 receptors.

We routinely work with external parties to collaboratively advance our drug candidates. In addition to Celldex-led studies, we also have an Investigator Initiated Research (IIR) program with seven studies ongoing with our prioritized drug candidates.

In April 2018, we announced that our Phase 2b METRIC Study of glembatumumab vedotin in metastatic triple-negative breast cancer did not meet its primary endpoint. Based on this result, in the second quarter of 2018, we prioritized our pipeline and evaluated our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. As previously disclosed, in line with this initiative and to conserve resources, we discontinued development of glembatumumab vedotin, CDX-014 and CDX-1401.

Our goal is to build a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. We believe our program assets provide us with the strategic options to either retain full economic rights to our innovative therapies or seek favorable economic terms through advantageous commercial partnerships. This approach allows us to maximize the overall value of our technology and product portfolio while best ensuring the expeditious development of each individual product. Currently, all programs are fully owned by Celldex.

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the length of time

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generally varies substantially according to the type, complexity, novelty and intended use of a drug candidate. It is not unusual for the clinical development of these types of drug candidates to each take five years or more, and for total development costs to exceed $100 million for each drug candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1 - 2 Years
Phase 2	1 - 5 Years
Phase 3	1 - 5 Years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the drug candidate.

We test potential drug candidates in numerous preclinical studies for safety, toxicology and immunogenicity. We may then conduct multiple clinical trials for each drug candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain drug candidates in order to focus our resources on more promising drug candidates.

An element of our business strategy is to pursue the discovery, research and development of a broad portfolio of drug candidates. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of drug candidates, our dependence on the success of one or a few drug candidates increases.

Regulatory approval is required before we can market our drug candidates as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the regulatory agency must conclude that our clinical data demonstrate that our product candidates are safe and effective. Historically, the results from preclinical testing and early clinical trials (through Phase 2) have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, our business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our drug candidates. In the event that third parties take over the clinical trial process for one of our drug candidates, the estimated completion date would largely be under control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants, contracts or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into

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collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

During the past five years through December 31, 2018, we incurred an aggregate of $469.9 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the years ended December 31, 2018, 2017 and 2016. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
		(In thousands)	
CDX-1140	$ 5,666	$ 6,909	$ 3,802
CDX-3379	3,778	4,167	416
CDX-301	1,927	1,294	4,053
Varlilumab	9,026	14,940	28,554
Anti-KIT Program	7,330	4,156	279
TAM	5,452	5,512	438
Glembatumumab vedotin	16,397	36,873	30,156
CDX-014	1,600	2,534	3,623
CDX-1401	455	836	4,323
Other Programs	14,818	18,950	27,082
Total R&D Expense	$ 66,449	$ 96,171	$ 102,726

Clinical Development Programs

CDX-1140

CDX-1140 is a fully human agonist monoclonal antibody targeted to CD40, a key activator of immune response, which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. Preclinical studies of CDX-1140 clearly demonstrate strong immune activation effects and low systemic toxicity and support the design of the Phase 1 study to rapidly identify the dose for characterizing single-agent and combination activity.

We initiated a Phase 1 study of CDX-1140 in November 2017. This study is expected to enroll up to approximately 180 patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. The study is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability,

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pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

To this end, in the second quarter of 2018, we amended the Phase 1 study protocol to also explore CDX-1140 in combination with CDX-301. Dendritic cells, which express CD40, are often rare or missing from the tumor microenvironment and are critical for initiating anti-tumor immunity. CDX-301 is being utilized to increase the number of dendritic cells in blood and tissue available for CDX-1140 activation. CDX-1140 should, in turn, activate and mature the dendritic cells, an important step for enhancing anti-tumor immune responses. Several B cell lymphomas, including diffuse large B-cell lymphoma and follicular lymphoma, also express both CD40 and CD27. Celldex's varlilumab is a potent CD27 agonist and has been shown to synergize with CDX-1140 in NHL models and may be evaluated in combination with CDX-1140 in the future.

Interim data from the Phase 1 study were presented in November 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Seventeen patients with solid tumors were enrolled at the time of data analysis (n=13 monotherapy; n=4 combination). Four single-agent dosing cohorts were complete (0.01; 0.03, 0.09 and 0.18 mg/kg) and enrollment to the 0.36 mg/kg monotherapy cohort was ongoing. Enrollment to the first CDX-1140/CDX-301 combination cohort was also ongoing (0.09 mg/kg and 75 ug/kg, respectively). Dose dependent biological effects consistent with CD40-mediated immune activation were reported. CDX-1140 was well tolerated and no MTD had been reached. One patient experienced a grade 3 dose-limiting toxicity (DLT) (pneumonitis and hypoxia) at the single-agent 0.18 mg/kg dose. Per protocol, three additional patients were enrolled in the cohort and no additional DLTs have been observed in this or subsequent cohorts. While the CDX-1140 and CDX-301 combination cohort had just recently opened to enrollment at the time of presentation, preliminary evidence of enhanced immune activation was reported with no observed DLT. Across both arms of the study, there were no significant drug-related changes observed in liver function tests or platelets, which have been observed with other CD40 agonists. Continued enrollment is ongoing to define the MTD and select a dose for disease-specific expansion cohorts that will be monitored for clinical activity. We plan to present updated data from the study at a future medical meeting in 2019.

CDX-3379

CDX-3379 is a human monoclonal antibody with half-life extension designed to block the activity of ErbB3 (HER3). We believe ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies and is expressed in many cancers, including head and neck, thyroid, breast, lung and gastric cancers, as well as melanoma. We believe the proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. We believe CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells. Tumor cell death and the ensuing release of new tumor antigens has the potential to serve as a focus for combination therapy with immuno-oncology approaches, even in refractory patients. CDX-3379 has been evaluated in three Phase 1 studies for the treatment of multiple solid tumors that express ErbB3 and is currently being evaluated in a Phase 2 study in combination with Erbitux in Erbitux-resistant, advanced head and neck squamous cell carcinoma.

A Phase 1a/1b study of CDX-3379 was conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. Four combination arms across multiple tumor types were added to evaluate CDX-3379 with several drugs

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that target EGFR, HER2 or BRAF. They include combinations with Erbitux® (n=16), Tarceva® (n=8), Zelboraf® (n=9) and Herceptin® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one durable complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar® and was considered refractory, as well as an unconfirmed partial response in a patient with thyroid cancer. Initial data were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.

In April 2018, results from a window-of-opportunity study evaluating the effect of CDX-3379 on potential biomarkers in patients with head and neck squamous cell carcinoma (HNSCC) were presented at the American Association for Cancer Research (AACR) Annual Meeting. The study enrolled 12 patients with newly diagnosed HNSCC who received two doses of CDX-3379, at a two-week interval prior to tumor resection. CDX-3379 reduced phosphorylated ErbB3 (pErbB3) levels in 83% (10/12) of patient samples, with greater than or equal to 50% decreases in 58% of patients (7/12), which met the primary study objective. Stable disease was observed in 92% (11/12) of patients prior to surgery, and a patient with HPV-negative disease experienced significant tumor shrinkage (92% in primary tumor; 26% in metastatic lesion). CDX-3379 was well-tolerated, and no treatment-related adverse events were observed.

Preclinical data from the combination of CDX-3379 and Erbitux in xenograft models of head and neck squamous cell carcinoma were also presented at the AACR Annual Meeting in April 2018. Combining CDX-3379 and Erbitux inhibited tumor growth more potently than Erbitux alone. Mechanistic studies demonstrated a reduction of PD-L1 expression from the combination.

We have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The study employs a Simon two-stage design with an interim futility analysis following enrollment of the first 13 patients. According to the study's two-stage design, if at least one patient achieves an objective response in the first stage, enrollment may progress to the second stage. Enrollment to the first stage of the Phase 2 study (n=13) is complete. While a confirmed complete response has been documented, Celldex will conduct a comprehensive review, including the full data set, before making decisions on future development, as patients are still undergoing treatment and are eligible for evaluation. The primary objective of the study is objective response rate. Secondary objectives include assessments of clinical benefit response (CBR), duration of response (DOR), progression-free survival (PFS) and overall survival (OS), and safety and pharmacokinetics associated with the combination. We plan to present updated data from the study at a future medical meeting in 2019. CDX-3379 is also being studied in an investigator-sponsored study.

Varlilumab

Varlilumab is a fully human agonist monoclonal antibody that binds to and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. We believe varlilumab works primarily by stimulating T cells, an important component of a person's immune system, to attack cancer cells. Restricted expression and regulation of CD27 enables varlilumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, varlilumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *in vitro* and *in vivo* models. Varlilumab was initially studied as a single-agent to establish a safety profile and assess immunologic and clinical activity in patients with cancer,

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but we believe the greatest opportunity for varlilumab is as an immune activator in combination with other agents.

Single-Agent Phase 1 Study: In an open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers, varlilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients received varlilumab in the study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of an MTD. The majority of adverse events, or AEs, related to treatment were mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade were observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anti-cancer therapy. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

Phase 1/2 Varlilumab/Opdivo Combination Study: In 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb, or BMS, to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, BMS' PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. The Phase 1 portion of the study was initiated in January 2015 and conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo. It was followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts. Enrollment to the Phase 2 portion of the study was completed in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is objective response rate, or ORR, except glioblastoma, where the primary objective is the rate of 12-month OS.

Data from the ovarian and colorectal cancer cohorts were presented in an oral presentation at the 2018 ASCO Annual Meeting. Sixty-six patients with ovarian cancer were treated in the study (8 patients in Phase 1; 58 patients in Phase 2). Patients had a median of three prior lines of therapy, 91% had Stage IV disease and 66% had PD-L1 negative tumors. The overall response rate was 14% (n=9; 7 confirmed, 2 unconfirmed) across 64 response-evaluable patients. For patients with paired tumor samples (n=24) from before and during treatment, increases in tumor expression of PD-L1 and CD8+ TIL levels were observed. These increases were associated with improved clinical outcome, including improved PFS and response rate.

Forty-two patients with colorectal cancer were treated in the study (21 patients in Phase 1; 21 patients in Phase 2). Patients had a median of four prior lines of therapy, 100% had Stage IV disease and 87% had PD-L1 negative tumors. One patient had disease that was MSI-high and 21 patients had disease that was MSI-low/mismatch repair (MMR) proficient; MSI status for the remaining 20 patients was unknown. One patient with PD-L1 negative, MSI-high disease experienced a confirmed partial response in the Phase 2 study portion. Of note, a patient with PD-L1 negative disease, initially considered MMR proficient as determined by standard screening laboratory analysis, achieved a near complete response in the Phase 1 portion of the study, which continued at last follow-up at 39 months. This patient's tumor had a high mutational burden and mutations in genes regulating DNA repair, which together likely contributed to the response. Disease control rate for the response-evaluable population was 20% (8/41).

In the second quarter of 2018, we reported preliminary data from the head and neck squamous cell carcinoma (HNSCC) and renal cell carcinoma (RCC) cohorts. Twenty-seven patients with HNSCC were treated in the study (3 patients in Phase 1; 24 patients in Phase 2). Patients had a median of two prior lines of therapy, 96% had Stage IV disease, 63% had PD-L1 negative tumors and 52% had HPV positive tumors. The overall response rate was 15% (n=4 confirmed) across 27 response-evaluable

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patients. In this small sample size, no correlation between PDL-1 status and clinical outcome was observed. Given the changing treatment paradigm in renal cell carcinoma, only fourteen patients with RCC were treated in the study, all in Phase 2. All patients had experienced prior angiogenic therapy, with a range of 1 to 4 prior treatments, 100% had Stage IV disease and 50% had PD-L1 negative tumors. 39% of patients experienced stable disease.

Data from the GBM cohort were presented in November 2018 at the Society for Neuro-oncology (SNO) Annual Meeting. 22 patients with recurrent GBM were treated in the study. The median duration of disease prior to study entry was 13 months. Methylation status was determined in 21 patients (n=5 methylated; n=16 unmethylated). The combination was generally well-tolerated and the safety profile was consistent with that of each agent alone. Without taking into account MGMT status or other prognostic factors, overall results were similar to nivolumab monotherapy in recurrent GBM (OS12 = 42%). In the subset of patients with unmethylated MGMT promoter, a durable therapeutic benefit was achieved (OS at 12 months =50%).

Future development of varlilumab is focused on inclusion in internal combination studies, including potentially in the ongoing Phase 1 trial of CDX-1140, and several external investigator-initiated studies.

CDX-301

CDX-301, a recombinant FMS-like tyrosine kinase 3 ligand, or Flt3L, is a hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells, and in combination with other agents may potentiate anti-tumor responses. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. We believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio, as well as with approved or investigational therapies for the treatment of cancer.

A Phase 1 study of CDX-301 evaluated seven different dosing regimens of CDX-301 to determine the appropriate dose for further development based on safety, tolerability and biological activity. The data from the study were consistent with previous clinical experience and demonstrated that CDX-301 has an acceptable safety profile to date and can mobilize dendritic cell and hematopoietic stem cell populations in healthy volunteers. The study was published in the journal Bone Marrow Transplantation in 2015.

CDX-301 is being used as a priming agent to potentially increase the number of cells available to respond to CDX-1140 in the ongoing Phase 1 trial of CDX-1140. CDX-301 is also in clinical development for multiple cancers in ongoing investigator-sponsored and collaborative studies, including in combination with treatments that release tumor antigens, such as radiation therapy.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are described in Note 2 to the financial statements included in Item 8 of this Form 10-K. We believe our most critical accounting policies include accounting for business combinations, revenue recognition, intangible and long-lived assets, research and development expenses and stock-based compensation expense.

The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could materially change our reported results. We believe the following accounting policies are the most critical to us in that they are important to the portrayal of

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our financial statements and they require our most difficult, subjective or complex judgments in the preparation of our financial statements:

Business Combinations

We account for business combinations under the acquisition method of accounting. We record the fair value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. We assess the fair value of assets, including intangible assets such as IPR&D, using a variety of methods including present-value models. Each asset is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of IPR&D assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's assumptions regarding the probability of completing IPR&D projects, which would require obtaining regulatory approval for marketing of the associated drug candidate; a market participant's estimates regarding the timing of and the expected costs to complete IPR&D projects; a market participant's estimates of future cash flows from potential product sales; and the appropriate discount rates for a market participant. Transaction costs and restructuring costs associated with the transaction are expensed as incurred.

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is recorded to goodwill. Goodwill is evaluated for impairment on an annual basis during the third quarter, or earlier if impairment indicators are present. As a result of the discontinuation of the Glemba program, the Company evaluated goodwill for potential impairment in the first quarter of 2018. It was determined that the goodwill asset was fully impaired and an impairment charge of $91.0 million was recorded.

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- timing and probability of success of clinical events or regulatory approvals;
- timing and probability of success of meeting clinical and commercial milestones; and
- discount rates.

Our contingent consideration liabilities arose in connection with our acquisition of Kolltan. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Revenue Recognition

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

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The Company determines revenue recognition through the following steps:

Identification of the contract, or contracts, with a customer;

Identification of the performance obligations in the contract;

Determination of the transaction price;

Allocation of the transaction price to the performance obligations in the contract; and

Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company has historically been derived from biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation.

Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trial costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company owns and operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed-price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

Intangible and Long-Lived Assets

We evaluate the recoverability of our long-lived assets, including property and equipment, and finite-lived intangible assets when circumstances indicate that an event of impairment may have occurred. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values.

IPR&D assets acquired in a business combination initially are recorded at fair value and accounted for as indefinite-lived intangible assets. These assets are capitalized on our balance sheets until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. Discounted cash flow models

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are typically used in these tests, and the models require the use of significant estimates and assumptions including but not limited to:

- timing and costs to complete the in-process projects;
- timing and probability of success of clinical events or regulatory approvals;
- estimated future cash flows from product sales resulting from completed products and in-process projects; and
- discount rates

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. As a result of the discontinuation of the Glemba program, the Company concluded that the Glemba IPR&D asset was fully impaired, and a non-cash impairment charge of $11.8 million was recorded in the first quarter of 2018. The remaining IPR&D assets were assessed for impairment during 2018 and were determined not to be impaired.

Intangible assets acquired in a business combination with a finite life are recorded at fair value and amortized over the greater of economic consumption or on a straight-line basis over their estimated useful life. As a result of the discontinuation of the Glemba program, it was concluded that the Company's finite-lived intangible asset was fully impaired and a non-cash impairment charge of $6.9 million was recorded in the first quarter of 2018.

Research and Development Expenses

Research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, toxicology and other preclinical studies, personnel costs, depreciation, license fees and funding of outside contracted research.

Clinical trial expenses include expenses associated with clinical research organization, or CRO, services. Contract manufacturing expenses include expenses associated with contract manufacturing organization, or CMO, services. The invoicing from CROs and CMOs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO and CMO activities based on our estimate of costs incurred. We maintain regular communication with our CROs and CMOs to assess the reasonableness of our estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Stock-Based Compensation Expense

We record stock-based compensation expense for all stock-based awards made to employees, directors and non-employees based on the estimated fair values of the stock-based awards expected to vest at the grant date and adjust, if necessary, to reflect actual forfeitures. Our estimates of employee stock option values rely on estimates of future uncertain events. Significant assumptions include the use of historical volatility to estimate the expected stock price volatility. We also estimate expected term based on historical exercise patterns. For non-employee grants, we may elect to use the contractual term as the expected term in the option-pricing model. Actual volatility and lives of options may be significantly different from our estimates. Compensation expense for all stock-based awards to employees and directors is recognized using the straight-line method over the term of vesting or performance.

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RESULTS OF OPERATIONS

Year Ended December 31, 2018 compared with Year Ended December 31, 2017

	Year Ended December 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2018	2017	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 3,341	$ 3,153	$ 188	6%
Contracts and Grants	6,197	9,590	(3,393)	(35)%
Total Revenue	$ 9,538	$ 12,743	$ (3,205)	(25)%
Operating Expenses:				
Research and Development	66,449	96,171	(29,722)	(31)%
General and Administrative	19,269	25,003	(5,734)	(23)%
Goodwill Impairment	90,976		90,976	n/a
Intangible Asset Impairment	18,677	13,000	5,677	44%
Gain on Fair Value Remeasurement of Contingent Consideration	(29,621)	(800)	28,821	3,603%
Amortization of Acquired Intangible Assets	224	896	(672)	(75)%
Total Operating Expense	165,974	134,270	31,704	24%
Operating Loss	(156,436)	(121,527)	34,909	29%
Investment and Other Income, Net	4,487	4,214	273	6%
Net Loss Before Income Tax Benefit	(151,949)	(117,313)	34,636	30%
Income Tax Benefit	765	24,282	(23,517)	(97)%
Net Loss	$ (151,184)	$ (93,031)	$ 58,153	63%

Net Loss

The $58.2 million increase in net loss for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily the result of the increase in the non-cash goodwill impairment and the decrease in the non-cash income tax benefit. This effect was partially offset by the increase in the non-cash gain on fair value remeasurement of contingent consideration and the decrease in research and development expenses.

Revenue

The $0.2 million increase in product development and licensing agreements revenue for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to an increase in reimbursable clinical trial expenses related to our BMS agreement. The $3.4 million decrease in contracts and grants revenue for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily related to a decrease in services performed under our contract manufacturing and research and development agreements with International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc.

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Research and Development Expense

Research and development expenses consist primarily of (i) personnel expenses, (ii) laboratory supply expenses relating to the development of our technology, (iii) facility expenses, (iv) license fees and (v) product development expenses associated with our drug candidates as follows:

	Year Ended December 31,		Increase/ (Decrease)	
	2018	2017	$	%
	(In thousands)			
Personnel	$ 28,045	$ 36,470	$ (8,425)	(23)%
Laboratory Supplies	4,176	4,514	(338)	(7)%
Facility	7,531	8,617	(1,086)	(13)%
License Fees	692	677	15	2%
Product Development	18,540	36,711	(18,171)	(49)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $8.4 million decrease in personnel expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to a decrease in headcount and lower stock-based compensation expense partially offset by severance expense of $1.0 million. We expect personnel expenses to decrease over the next twelve months due to our restructuring in April 2018.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.3 million decrease in laboratory supply expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to lower laboratory materials and supplies purchases. We expect laboratory supplies expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The $1.1 million decrease in facility expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to lower depreciation expense. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

License fee expenses include annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. License fee expense for the year ended December 31, 2018 was consistent with the year ended December 31, 2017. We expect license fee expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $18.2 million decrease in product development expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to a decrease in clinical trial expenses of $8.7 million and a decrease in contract manufacturing expenses of $7.2 million. The amount of product development expenses incurred over the next twelve months is expected to decrease due to the discontinuation of the Glemba and CDX-014 programs and our pipeline prioritization.

General and Administrative Expense

The $5.7 million decrease in general and administrative expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to a decrease in headcount and lower commercial planning costs. We expect general and administrative expenses to remain

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relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Goodwill Impairment

We recorded a non-cash goodwill impairment charge of $91.0 million during the year ended December 31, 2018 as a result of the discontinuation of the Glemba program.

Intangible Asset Impairment

We recorded a non-cash intangible asset impairment charge of $18.7 million on the Glemba program intangible assets during the year ended December 31, 2018 as a result of the discontinuation of the Glemba program. Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

Gain on Fair Value Remeasurement of Contingent Consideration

The $29.6 million gain on fair value remeasurement of contingent consideration for the year ended December 31, 2018 was due to discontinuation of the Glemba and CDX-014 programs, updated assumptions for the varlilumab program, and lower probability that milestones related to our anti-KIT program would be triggered by our current anti-KIT program development.

Amortization Expense

The $0.7 million decrease in amortization expenses for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was due to the full impairment of intangible assets subject to amortization recorded in the first quarter of 2018 as a result of the discontinuation of the Glemba program.

Investment and Other Income, Net

The $0.3 million increase in investment and other income, net for the year ended December 31, 2018, as compared to the year ended December 31, 2017, was primarily due to higher interest rates on fixed income investments. We anticipate investment income to decrease over the next twelve months due to lower levels of cash and investment balances.

Income Tax Benefit

We recorded a non-cash income tax benefit of $0.8 million related to the impairment of the Glemba IPR&D assets during the year ended December 31, 2018.

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Year Ended December 31, 2017 compared with Year Ended December 31, 2016

	Year Ended December 31,		Increase/ (Decrease)	Increase/ (Decrease)
	2017	2016	$	%
	(In thousands)			
Revenues:				
Product Development and Licensing Agreements	$ 3,153	$ 2,174	$ 979	45%
Contracts and Grants	9,590	4,612	4,978	108%
Total Revenue	$ 12,743	$ 6,786	$ 5,957	88%
Operating Expenses:				
Research and Development	96,171	102,726	(6,555)	(6)%
General and Administrative	25,003	35,979	(10,976)	(31)%
Intangible Asset Impairment	13,000		13,000	n/a
Gain on Fair Value Remeasurement of Contingent Consideration	(800)		800	n/a
Amortization of Acquired Intangible Assets	896	997	(101)	(10)%
Total Operating Expense	134,270	139,702	(5,432)	(4)%
Operating Loss	(121,527)	(132,916)	(11,389)	(9)%
Investment and Other Income, Net	4,214	4,386	(172)	(4)%
Net Loss Before Income Tax Benefit	(117,313)	(128,530)	(11,217)	(9)%
Income Tax Benefit	24,282		24,282	n/a
Net Loss	$ (93,031)	$ (128,530)	$ (35,499)	(28)%

Net Loss

The $35.5 million decrease in net loss for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily the result of a decrease in research and development expenses and general and administrative expenses and increases in contract revenues. The non-cash income tax benefit impacting net loss was partially offset by the non-cash in-process research and development impairment charge.

Revenue

The $1.0 million increase in product development and licensing agreements revenue for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to an increase in reimbursable clinical trial expenses related to our BMS agreement. The $5.0 million increase in contracts and grants revenue for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily related to our International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc. agreements executed in 2017.

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Research and Development Expense

Research and development expenses consist primarily of (i) personnel expenses, (ii) laboratory supply expenses relating to the development of our technology, (iii) facility expenses, (iv) license fees and (v) product development expenses associated with our drug candidates as follows:

	Year Ended December 31,		Increase/ (Decrease)	
	2017	2016	$	%
	(In thousands)			
Personnel	$ 36,470	$ 36,070	$ 400	1%
Laboratory Supplies	4,514	3,697	817	22%
Facility	8,617	6,314	2,303	36%
License Fees	677	1,614	(937)	(58)%
Product Development	36,711	46,852	(10,141)	(22)%

The $0.4 million increase in personnel expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to an increase in salaries expense and headcount related to the Kolltan acquisition partially offset by lower stock-based compensation expenses.

The $0.8 million increase in laboratory supply expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to higher laboratory materials and supplies purchases.

The $2.3 million increase in facility expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to the addition of our New Haven, CT facility that we acquired with the Kolltan acquisition and higher depreciation expense of $1.3 million. In March 2017, we terminated our lease in Branford, CT and consolidated our Connecticut operations in our New Haven facility.

The $0.9 million decrease in license fee expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates.

The $10.1 million decrease in product development expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to lower contract manufacturing and clinical trial costs of $9.9 and $7.6 million, respectively, related to varlilumab and Rintega. These decreases were partially offset by increases in (i) glembatumumab vedotin contract manufacturing expenses of $2.7 million and (ii) glembatumumab vedotin, anti-KIT and CDX-3379 clinical trial costs of $3.6 million.

General and Administrative Expense

The $11.0 million decrease in general and administrative expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to lower commercial planning costs of $4.5 million, lower stock-based compensation of $1.9 million and lower severance expense related to the Kolltan acquisition of $2.6 million.

Intangible Asset Impairment

We recorded a non-cash intangible asset impairment charge of $13.0 million on the anti-KIT program intangible assets acquired from Kolltan during the year ended December 31, 2017. This impairment charge was related to changes in projected development and regulatory timelines regarding the anti-KIT program.

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Gain on Fair Value Remeasurement of Contingent Consideration

The $0.8 million gain on fair value remeasurement of contingent consideration for the year ended December 31, 2017 was due to a reduction in fair value attributed to milestones related to our anti-KIT and TAM programs, partially offset by losses related to changes in discount rates, passage of time and probabilities affecting remaining milestones. See Note 4 to the financial statements included herein for a discussion of the contingent consideration that may be payable related to the Kolltan acquisition.

Amortization Expense

Amortization expense for the year ended December 31, 2017 was relatively consistent with the year ended December 31, 2016.

Investment and Other Income, Net

The $0.2 million decrease in investment and other income, net for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to lower levels of cash and investment balances, partially offset by higher interest rates on fixed income investments.

Income Tax Benefit

We recorded a non-cash income tax benefit of $19.1 million related to decreases in net deferred tax liabilities resulting from the Tax Cuts and Jobs Act of 2017 (TCJA). In addition, we recorded a non-cash income tax benefit of $5.2 million related to the partial impairment of the anti-KIT program IPR&D assets.

LIQUIDITY AND CAPITAL RESOURCES

Our cash equivalents are highly liquid investments with a maturity of three months or less at the date of purchase and consist primarily of investments in money market mutual funds with commercial banks and financial institutions. We maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. We invest our excess cash balances in marketable securities, including municipal bond securities, U.S. government agency securities and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees; facility and facility-related costs for our offices, laboratories and manufacturing facility; fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services; and consulting, legal and other professional fees. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At December 31, 2018, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $94.0 million. We have had recurring losses and incurred a loss of $151.2 million for the year ended December 31, 2018. Net cash used in operations for the year ended December 31, 2018 was $75.2 million. We believe that the cash, cash equivalents and marketable securities at December 31, 2018 combined with the (i) $2.3 million in net proceeds from sales of our common stock under the Cantor agreement from January 1, 2019 through February 28, 2019 and (ii) anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2020,

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although there is no assurance that future sales will occur. This could be impacted if we elected to pay Kolltan contingent milestones, if any, in cash.

During the next twelve months, we will take further steps to raise additional capital to meet our liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that we will be able to enter into further collaborative relationships. Additional equity financings may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from products under development. Our ability to continue funding our planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that we achieve the drug candidate milestones related to those payments. We may decide to pay those milestone payments in cash, shares of our common stock or a combination thereof. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of our business.

Operating Activities

Net cash used in operating activities was $75.2 million for the year ended December 31, 2018 compared to $99.9 million for the year ended December 31, 2017. The decrease in net cash used in operating activities was primarily due to decreases in both general and administrative and research and development expenses. We expect that cash used in operating activities will decrease over the next twelve months primarily due to our restructuring in April 2018, the discontinuation of the Glemba and CDX-014 programs, and our pipeline prioritization, although there may be fluctuations on a quarterly basis.

Net cash used in operating activities was $99.9 million for the year ended December 31, 2017 compared to $113.0 million for the year ended December 31, 2016. The decrease in net cash used in operating activities was primarily due to an increase in revenue and decreases in both general and administrative and research and development expenses.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials and clinical drug product manufacturing as our drug candidates are developed. We plan to spend significant amounts to progress our current drug candidates through the clinical trial processes as well as to develop additional drug candidates. As our drug candidates progress through the clinical trial process, we may be obligated to make significant milestone payments.

Investing Activities

Net cash provided by investing activities was $29.8 million for the year ended December 31, 2018 compared to net cash provided by investing activities of $46.5 million for the year ended December 31, 2017. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the year ended December 31, 2018 of $30.3 million as compared to net sales and maturities of marketable securities of $48.3 million for the year ended December 31,

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2017. We expect that cash provided by investing activities will remain relatively consistent over the next twelve months as we decrease cash used in operations which is funded mainly through the combination of net proceeds from the sales and maturities of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis.

Net cash provided by investing activities was $46.5 million for the year ended December 31, 2017 compared to net cash provided by investing activities of $68.9 million for the year ended December 31, 2016. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the year ended December 31, 2017 of $48.3 million as compared to net sales and maturities of marketable securities of $68.9 million for the year ended December 31, 2016.

Financing Activities

Net cash provided by financing activities was $29.4 million for the year ended December 31, 2018 compared to $51.3 million for the year ended December 31, 2017. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were $29.4 million during the year ended December 31, 2018 compared to $51.3 million for the year ended December 31, 2017.

Net cash provided by financing activities was $51.3 million for the year ended December 31, 2017 compared to $14.5 million for the year ended December 31, 2016. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were $51.3 million during the year ended December 31, 2017 compared to $14.5 million for the year ended December 31, 2016.

Equity Offerings

In December 2016, we filed a shelf registration statement with the Securities and Exchange Commission to register for sale any combination of the types of securities described in the shelf registration statement up to a maximum aggregate offering price of $250.0 million. Such registration statement was declared effective on February 13, 2017.

In May 2016, we entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow us to issue and sell shares of our common stock having an aggregate offering price of up to $60.0 million from time to time through Cantor, acting as agent. In November 2017, we filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the years ended December 31, 2018, 2017 and 2016, we issued 2,702,660, 1,181,524 and 220,253 shares of common stock, respectively, under this controlled equity offering sales agreement with Cantor resulting in net proceeds of $29.0 million, $51.0 million and $13.9 million, respectively, after deducting commission and offering expenses. At December 31, 2018, we had $37.6 million remaining in aggregate gross offering price available under the Cantor agreement. From January 1, 2019 through February 28, 2019, we issued 478,785 shares of our common stock resulting in net proceeds of $2.3 million.

AGGREGATE CONTRACTUAL OBLIGATIONS

We have entered into license agreements whereby we have received licenses or options to license technology, specified patents and/or patent applications. These license and collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain development, regulatory and/or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2018 such contingencies have not been recorded in our financial statements. We expect to incur approximately $0.3 million of license and milestone payments in 2019.

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The following table summarizes our contractual obligations (not including contingent royalty and milestone payments as described above) at December 31, 2018 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future years. These obligations, commitments and supporting arrangements represent expected payments based on current operating forecasts, which are subject to change:

	Total	2019	2020 - 2021	2022 - 2023	Thereafter
			(In thousands)		
Contractual obligations:					
Operating lease obligations(1)	$ 7,788	$ 4,648	$ 3,140	$	$
Other contractual obligations(2)(3)	1,160	1,160			
Total contractual obligations	$ 8,948	$ 5,808	$ 3,140	$	$

(1) Such amounts primarily consist of payments for our facility leases and do not assume the exercise of renewal terms or early termination provisions.

(2) We enter into agreements in the normal course of business with contract research organizations for clinical trials, contract manufacturing organizations, vendors for preclinical research studies and other services and products for operating purposes. We have included obligations in the table above if the contracts are not cancelable at any time by us, generally upon 30 days prior written notice to the vendor.

(3) In the event that certain specified preclinical and clinical development milestones related to Kolltan's development programs and/or our development programs and certain commercial milestones related to Kolltan's drug candidates are achieved, we will be required to pay Kolltan's stockholders milestone payments of up to $127.5 million as of December 31, 2018, which milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both, subject to NASDAQ listing requirements and provisions of the merger agreement. Because the timing and certainty of these milestones being achieved is unknown, these potential future obligations are not included within the table.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the financial statements for a discussion of recent accounting pronouncements.

OFF-BALANCE SHEET ARRANGEMENTS

None.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We own financial instruments that are sensitive to market risk as part of our investment portfolio. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds. These investments are evaluated quarterly to determine the fair value of the portfolio. From time to time, we invest our excess cash balances in marketable securities, including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. Because of the short-term nature of these investments, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from changes in interest rates is not material.

We do not utilize derivative financial instruments. The carrying amounts reflected in the balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at December 31, 2018 due to the short-term maturities of these instruments.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Celldex Therapeutics, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Celldex Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 7, 2019

We have served as the Company's auditor since 2008.

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CELLDEX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 24,310	$ 40,288
Marketable Securities	69,712	99,139
Accounts and Other Receivables	3,162	1,880
Prepaid and Other Current Assets	1,895	3,449
Total Current Assets	99,079	144,756
Property and Equipment, Net	6,111	10,372
Intangible Assets, Net	48,690	67,591
Other Assets	1,929	1,929
Goodwill		90,976
Total Assets	$ 155,809	$ 315,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,069	$ 1,715
Accrued Expenses	7,007	19,455
Current Portion of Long-Term Liabilities	4,526	6,566
Total Current Liabilities	12,602	27,736
Other Long-Term Liabilities	19,147	51,519
Total Liabilities	31,749	79,255
Commitments and Contingent Liabilities (Notes 13 and 15)		
Stockholders' Equity:		
Convertible Preferred Stock, $.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at December 31, 2018 and 2017		
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 11,957,635 and 9,234,693 Shares Issued and Outstanding at December 31, 2018 and 2017, Respectively	12	9
Additional Paid-In Capital	1,083,903	1,046,313
Accumulated Other Comprehensive Income	2,583	2,564
Accumulated Deficit	(962,438)	(812,517)
Total Stockholders' Equity	124,060	236,369
Total Liabilities and Stockholders' Equity	$ 155,809	$ 315,624

The accompanying notes are an integral part of the financial statements.

(Reflects one for fifteen reverse stock split effective February 8, 2019)

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CELLDEX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
REVENUES:			
Product Development and Licensing Agreements	$ 3,341	$ 3,153	$ 2,174
Contracts and Grants	6,197	9,590	4,612
Total Revenues	9,538	12,743	6,786
OPERATING EXPENSES:			
Research and Development	66,449	96,171	102,726
General and Administrative	19,269	25,003	35,979
Goodwill Impairment	90,976		
Intangible Asset Impairment	18,677	13,000	
Gain on Fair Value Remeasurement of Contingent Consideration	(29,621)	(800)	
Amortization of Acquired Intangible Assets	224	896	997
Total Operating Expenses	165,974	134,270	139,702
Operating Loss	(156,436)	(121,527)	(132,916)
Investment and Other Income, Net	4,487	4,214	4,386
Net Loss Before Income Tax Benefit	$ (151,949)	$ (117,313)	$ (128,530)
Income Tax Benefit	765	24,282	
Net Loss	$ (151,184)	$ (93,031)	$ (128,530)
Basic and Diluted Net Loss Per Common Share	$ (14.48)	$ (10.86)	$ (18.99)
Shares Used in Calculating Basic and Diluted Net Loss per Share	10,442	8,570	6,769
COMPREHENSIVE LOSS:			
Net Loss	$ (151,184)	$ (93,031)	$ (128,530)
Other Comprehensive Income (Loss):			
Foreign Currency Translation Adjustments			
Unrealized Gain (Loss) on Marketable Securities	19	23	234
Comprehensive Loss	$ (151,165)	$ (93,008)	$ (128,296)

The accompanying notes are an integral part of the financial statements.

(Reflects one for fifteen reverse stock split effective February 8, 2019)

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CELLDEX THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2015	**6,579,040**	**7**	**878,747**	**2,307**	**(590,956)**	**290,105**
Shares Issued under Stock Option and Employee Stock Purchase Plans	10,543		535			535
Shares Issued in Connection with Cantor Agreement	220,253		13,946			13,946
Shares Issued in Connection with the Kolltan Acquisition	1,217,200	1	73,396			73,397
Shares Issued in Connection with Kolltan Severance	7,407		427			427
Share-Based Compensation			15,317			15,317
Unrealized Gains on Marketable Securities				234		234
Net Loss					(128,530)	(128,530)
Consolidated Balance at December 31, 2016	**8,034,443**	**8**	**982,368**	**2,541**	**(719,486)**	**265,431**
Shares Issued under Stock Option and Employee Stock Purchase Plans	11,581		265			265
Shares Issued in Connection with Cantor Agreement	1,181,524	1	51,024			51,025
Shares Issued in Connection with Kolltan Severance	7,145		344			344
Share-Based Compensation			12,312			12,312
Unrealized Gains on Marketable Securities				23		23
Net Loss					(93,031)	(93,031)
Consolidated Balance at December 31, 2017	**9,234,693**	**9**	**1,046,313**	**2,564**	**(812,517)**	**236,369**
Shares Issued under Stock Option and Employee Stock Purchase Plans	16,047		419			419
Shares Issued in Connection with Cantor Agreement	2,702,660	3	29,019			29,022
Shares Issued in Connection with Kolltan Severance	4,235		71			71
Share-Based Compensation			8,081			8,081
Unrealized Gains on Marketable Securities				19		19
Adoption of ASC 606					1,263	1,263
Net Loss					(151,184)	(151,184)
Consolidated Balance at December 31, 2018	**11,957,635**	**$ 12**	**$ 1,083,903**	**$ 2,583**	**$ (962,438)**	**$ 124,060**

The accompanying notes are an integral part of the financial statements.
(Reflects one for fifteen reverse stock split effective February 8, 2019)

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CELLDEX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Cash Flows From Operating Activities:			
Net Loss	$ (151,184)	$ (93,031)	$ (128,530)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:			
Depreciation and Amortization	3,577	4,414	3,095
Amortization of Intangible Assets	224	896	997
Amortization and Premium of Marketable Securities, Net	(1,048)	(290)	926
Loss on Sale or Disposal of Assets	1,220	55	81
Goodwill Impairment	90,976		
Intangible Asset Impairment	18,677	13,000	
Gain on Fair Value Remeasurement of Contingent Consideration	(29,621)	(800)	
Non-Cash Income Tax Benefit	(765)	(24,282)	
Stock-Based Compensation Expense	8,081	12,312	15,317
Non-Cash Expense			1,638
Changes in Operating Assets and Liabilities:			
Accounts and Other Receivables	(777)	(96)	(814)
Prepaid and Other Current Assets	1,783	793	1,320
Other Assets		205	(89)
Accounts Payable and Accrued Expenses	(13,110)	(8,744)	(4,970)
Other Liabilities	(3,268)	(4,363)	(2,007)
Net Cash Used in Operating Activities	(75,235)	(99,931)	(113,036)
Cash Flows From Investing Activities:			
Sales and Maturities of Marketable Securities	201,469	219,236	242,792
Purchases of Marketable Securities	(171,182)	(170,980)	(173,925)
Investment in Other			(1,801)
Cash Acquired in Kolltan Acquisition, Net			4,592
Acquisition of Property and Equipment	(813)	(1,788)	(2,751)
Proceeds from Sale or Disposal of Assets	342		
Net Cash Provided by Investing Activities	29,816	46,468	68,907
Cash Flows From Financing Activities:			
Net Proceeds from Stock Issuances	29,022	51,025	13,946
Proceeds from Issuance of Stock from Employee Benefit Plans	419	265	536
Net Cash Provided by Financing Activities	29,441	51,290	14,482
Net Decrease in Cash and Cash Equivalents	(15,978)	(2,173)	(29,647)
Cash and Cash Equivalents at Beginning of Period	40,288	42,461	72,108
Cash and Cash Equivalents at End of Period	$ 24,310	$ 40,288	$ 42,461

Non-cash Investing Activities

Accrued construction in progress	$ 107	$ 20	$ 159
Non-cash Supplemental Disclosure			
Shares issued to former Kolltan executive for settlement of severance	$ 71	$ 344	$ 426
Shares issued in connection with Kolltan Acquisition	$	$	$ 73,397

The accompanying notes are an integral part of the financial statements.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

(1) Nature of Business and Overview

Celldex Therapeutics, Inc. (the "Company" or "Celldex") is a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies and other cancer-targeting biologics. The Company currently has four drug candidates in clinical development, including CDX-1140, CDX-3379, varlilumab (also referred to as CDX-1127), and CDX-301.

At December 31, 2018, the Company had cash, cash equivalents and marketable securities of $94.0 million. The Company has had recurring losses and incurred a loss of $151.2 million for the year ended December 31, 2018. Net cash used in operations for the year ended December 31, 2018 was $75.2 million. The Company believes that the cash, cash equivalents and marketable securities at March 7, 2019 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months from the date of issuance of these financial statements.

The Board of Directors of the Company approved a one for fifteen reverse stock split of the Company's outstanding common stock, which was effected on February 8, 2019. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

During the next twelve months and beyond, the Company will take further steps to raise additional capital to meet its liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While the Company may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and the Company's negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financings may be dilutive to the Company's stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company's ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company's economic potential from products under development. The Company's ability to continue funding its planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The balance sheets and statements of operations and comprehensive loss, stockholders' equity, and cash flows, are consolidated for the years ended December 31, 2018 and 2017. These consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

intercompany balances and transactions have been eliminated in consolidation. The Company operates in one segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) requires management to make estimates and use assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity date of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents consist principally of money market funds and debt securities.

Marketable Securities

The Company invests its excess cash balances in marketable securities, including municipal bond securities, U.S. government agency securities, and highly rated corporate bonds. The Company classifies all of its marketable securities as current assets on the balance sheets because they are available-for-sale and available to fund current operations. Marketable securities are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses are realized. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is reclassified from accumulated other comprehensive income (loss) to the statements of operations. Realized gains and losses are determined on the specific identification method and are included in investment and other income, net.

Concentration of Credit Risk and of Significant Customers and Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, marketable securities and accounts receivable. The Company invests its cash, cash equivalents and marketable securities in debt instruments and interest-bearing accounts at major financial institutions in excess of insured limits. The Company mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality. The Company has not historically experienced credit losses from its accounts receivable and therefore has not established an allowance for doubtful accounts.

Combined revenue from BMS, Rockefeller and International AIDS Vaccine Initiative represented 86% of total Company revenue for the year ended December 31, 2018 and 77% of total Company revenue for the year ended December 31, 2017. Combined revenue from Rockefeller and BMS represented 71% of total Company revenue for the year ended December 31, 2016.

The Company relies on contract manufacturing organizations (CMO) to manufacture drug substance and drug product as well as for future commercial supplies. The Company also relies on

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

CMOs for supply of raw materials as well as filling, packaging, storing and shipping our drug products. The Company relies on third-party collaborators to develop companion diagnostic tests.

Fair Value Measurements

The Company has certain assets and liabilities that are measured at fair value in the financial statements. The Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and liabilities) when measuring the fair value of its assets and liabilities. These assets and liabilities are classified into one of three levels of the following fair value hierarchy as defined by U.S. GAAP:

Level 1: Observable inputs such as quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Laboratory equipment and office furniture and equipment are depreciated over five years, and computer equipment is depreciated over three years. Manufacturing equipment is amortized over seven to ten years. Leasehold improvements are amortized over the shorter of the estimated useful life or the non-cancelable term of the related lease, including any renewals that are reasonably assured of occurring. Property and equipment under construction is classified as construction in progress and is depreciated or amortized only after the asset is placed in service. Expenditures for maintenance and repairs are charged to expense whereas the costs of significant improvements which extend the life of the underlying asset are capitalized. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are eliminated and any resulting gain or loss is reflected in the Company's statements of operations and comprehensive loss.

The treatment of costs to construct property and equipment depends on the nature of the costs and the stage of construction. Costs incurred in the project planning, design, construction and installation phases are capitalized as part of the cost of the asset. The Company stops capitalizing these costs when the asset is substantially complete and ready for its intended use. For manufacturing property and equipment, the Company also capitalizes the cost of validating these assets for the underlying manufacturing process. The Company completes the capitalization of validation costs when the asset is substantially complete and ready for its intended use. Costs capitalized include incremental labor and fringe benefits, and direct consultancy services.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

Other Assets

Other assets include a $1.8 million non-controlling investment in a privately-held company that is accounted for under the cost method of accounting as of December 31, 2018 and 2017. The Company periodically evaluates the carrying value of the investment if significant adverse events or circumstances indicate an impairment in value.

Business Combinations

The Company records the fair value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets such as in-process research and development (IPR&D), using a variety of methods including present-value models. Each asset is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of IPR&D assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's assumptions regarding the probability of completing IPR&D projects, which would require obtaining regulatory approval for marketing of the associated drug candidate; a market participant's estimates regarding the timing of and the expected costs to complete IPR&D projects; a market participant's estimates of future cash flows from potential product sales; and the appropriate discount rates for a market participant. Transaction costs and restructuring costs associated with the transaction are expensed as incurred.

The Company records contingent consideration resulting from a business combination at its fair value on the acquisition date. The Company determines the fair value of the contingent consideration based primarily on the (i) timing and probability of success of clinical events or regulatory approvals; (ii) timing and probability of success of meeting clinical and commercial milestones; and (iii) discount rates. The Company's contingent consideration liabilities arose in connection with its acquisition of Kolltan. On a quarterly basis, the Company revalues these obligations and records increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in the Company's estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval. The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Intangible Assets

IPR&D assets acquired in a business combination initially are recorded at fair value and accounted for as indefinite-lived intangible assets. These assets are capitalized on the Company's balance sheets until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. As a result of the discontinuation of the Glemba program, the Company concluded that the Glemba IPR&D asset was fully impaired, and a non-cash impairment charge of $11.8 million was recorded in the first quarter of 2018. The remaining IPR&D assets were assessed for impairment during 2018 and were determined not to be impaired. During the year ended December 31, 2017, the Company recorded a partial impairment charge of $13.0 million related to changes in projected development and regulatory timelines regarding the anti-KIT program.

Intangible assets acquired in a business combination with a finite life are recorded at fair value and amortized over the greater of economic consumption or on a straight-line basis over their estimated useful life. As a result of the discontinuation of the Glemba program, it was concluded that the Company's finite-lived intangible asset was fully impaired and a non-cash impairment charge of $6.9 million was recorded in the first quarter of 2018.

Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis during the third quarter, or earlier if impairment indicators are present. The Company has the option to assess qualitative factors to determine if it is more likely than not that goodwill might be impaired and whether it is necessary to perform a quantitative single-step goodwill impairment test required under U.S. GAAP. As a result of the discontinuation of the Glemba program, the Company evaluated goodwill for potential impairment in the first quarter of 2018. It was determined that the goodwill asset was fully impaired and an impairment charge of $91.0 million was recorded.

Impairment of Intangible and Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets, including property and equipment, and intangible assets when circumstances indicate that an event of impairment may have occurred. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values.

Revenue Recognition

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company determines revenue recognition through the following steps:

Identification of the contract, or contracts, with a customer;

Identification of the performance obligations in the contract;

Determination of the transaction price;

Allocation of the transaction price to the performance obligations in the contract; and

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company has historically been derived from biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation.

Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trial costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company owns and operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed-price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

Contract Assets and Liabilities

The Company classifies the right to consideration in exchange for products or services transferred to a client as either a receivable or a contract asset. A receivable is a right to consideration that is unconditional as compared to a contract asset which is a right to consideration that is conditional upon factors other than the passage of time.

The Company's contract liabilities result from arrangements where the Company has received payment in advance of performance under the contract. These amounts are included as deferred revenue within current portion of long-term liabilities on the condensed consolidated balance sheets.

Research and Development Expenses

Research and development costs, including internal and contract research costs, are expensed as incurred. Research and development expenses consist mainly of clinical trial costs, manufacturing of clinical material, toxicology and other preclinical studies, personnel costs, depreciation, license fees and funding of outside contracted research.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

Clinical trial expenses include expenses associated with clinical research organization, or CRO, services. Contract manufacturing expenses include expenses associated with contract manufacturing organization, or CMO, services. The invoicing from CROs and CMOs for services rendered can lag several months. The Company accrues the cost of services rendered in connection with CRO and CMO activities based on our estimate of costs incurred. The Company maintains regular communication with our CROs and CMOs to assess the reasonableness of its estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Patent Costs

Patent costs are expensed as incurred. Certain patent costs are reimbursed by the Company's product development and licensing partners. Any reimbursed patent costs are recorded as product development and licensing agreement revenues in the Company's financial statements.

Stock-Based Compensation

The Company records stock-based compensation expense for all stock-based awards made to employees, directors and non-employees based on the estimated fair values of the stock-based awards expected to vest at the grant date and adjust, if necessary, to reflect actual forfeitures. Compensation expense for all stock-based awards is recognized using the straight-line method over the term of vesting or performance.

Foreign Currency Translation

Net unrealized gains and losses resulting from foreign currency translation are included in accumulated other comprehensive income. At December 31, 2018 and 2017, accumulated other comprehensive income includes a net unrealized gain related to foreign currency translation of $2.6 million.

Income Taxes

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax basis. Quarterly, the Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change.

The Company records uncertain tax positions in the financial statements only if it is more likely than not that the uncertain tax position will be sustained upon examination by the taxing authorities. The Company records interest and penalties related to uncertain tax positions in income tax expense.

Comprehensive Loss

Comprehensive loss is comprised of net loss and certain changes in stockholders' equity that are excluded from net loss. The Company includes foreign currency translation adjustments and unrealized

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

gains and losses on marketable securities in other comprehensive loss. The statements of operations and comprehensive loss reflect total comprehensive loss for the years ended December 31, 2018, 2017 and 2016.

Net Loss Per Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common shares outstanding during the period when the effect is dilutive. The potentially dilutive common shares that have not been included in the net loss per common share calculations because the effect would have been anti-dilutive are as follows:

	Year Ended December 31,		
	2018	2017	2016
Stock options	866,132	723,747	681,248
Restricted stock	3,552	6,445	3,333
	869,684	730,192	684,581

Newly-Adopted Accounting Pronouncements

On January 1, 2018, the Company adopted the new U.S. GAAP standard "*Revenue from Contracts with Customers"* using a modified retrospective application method, recognizing an immaterial cumulative-effect adjustment to accumulated deficit. The Company applied the new guidance to (i) contracts not completed as of the date of adoption and (ii) all new revenue contracts entered into after January 1, 2018. Refer to Note 12 *"Revenue"* for additional details on this adoption and the Company's updated revenue accounting policy and disclosures.

On January 1, 2018, the Company adopted a U.S. GAAP standard update *"Classification of Certain Cash Receipts and Cash Payments"* which clarifies the classification of certain cash receipts and payments in the statement of cash flows. The adoption of this new standard did not impact the Company's consolidated financial statements.

On July 1, 2018, the Company adopted a U.S. GAAP standard that aligns the accounting for share-based payment awards issued to employees and nonemployees. Under the new guidance, the existing employee guidance is applied to nonemployee share-based transactions. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements upon adoption.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

In February 2016, the FASB issued a new U.S. GAAP accounting standard which requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The Company will adopt the new guidance for its fiscal year beginning January 1, 2019 using the modified retrospective transition method, which requires the Company to apply the standard as of the effective date and does not require restatement of prior periods. The Company intends to elect the package of practical expedients, which will allow the Company to not reassess: (i) whether expired or existing contracts contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. The Company also plans to make a policy election not to record short term leases on the balance sheet. Adoption of this standard will not have a material impact on the Company's Consolidated Statement of Operations and Comprehensive Loss or Statement of Cash Flow, however the Company expects to record a right-of-use asset of approximately $4.2 million and lease liability of approximately $4.7 million on its Consolidated Balance Sheet related to the Company's operating leases.

In June 2016, the FASB issued guidance on the Measurement of Credit Losses on Financial Instruments. The guidance requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard will be effective for the Company on January 1, 2020. We are currently evaluating the potential impact that this standard may have on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued amendments that modify certain disclosure requirements for fair value measurements. The amendments become effective, including interim periods, beginning January 1, 2020. Early adoption, of all the amendments or only the provisions that eliminate or modify the requirements, is permitted. The adoption of this new guidance is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2018, the FASB issued guidance to clarify the interaction between the accounting guidance for collaborative arrangements and revenue from contracts with customers. The amendments become effective, including interim periods, beginning January 1, 2020. Early adoption, including adoption in an interim period, is permitted. This guidance is required to be applied retrospectively as of the date of our adoption of the new revenue standard on January 1, 2018. We are currently evaluating the timing of our adoption and the expected impact this guidance could have on our consolidated financial statements and related disclosures.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(3) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the year ended December 31, 2018 are summarized below:

	Unrealized Gain (Loss) on Marketable Securities	Foreign Currency Items	Total
		(In thousands)	
Balance at December 31, 2017	$ (32)	$ 2,596	$ 2,564
Other comprehensive gain	19		19
Balance at December 31, 2018	$ (13)	$ 2,596	$ 2,583

No amounts were reclassified out of accumulated other comprehensive income during the years ended December 31, 2018, 2017 and 2016.

(4) Fair Value Measurements

The following tables set forth the Company's financial assets and liabilities subject to fair value measurements:

	As of December 31, 2018	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 15,755		$ 15,755	
Marketable securities	69,712		69,712	
	$ 85,467		$ 85,467	
Liabilities:				
Kolltan acquisition contingent consideration	$ 13,779			$ 13,779
	$ 13,779			$ 13,779

	As of December 31, 2017	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 24,061		$ 24,061	
Marketable securities	99,139		99,139	

	$	123,200	$	123,200
Liabilities:				
Kolltan acquisition contingent consideration	$	43,400	$	43,400
	$	43,400	$	43,400

The Company's financial assets consist mainly of cash and cash equivalents and marketable securities and are classified as Level 2 within the valuation hierarchy. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(4) Fair Value Measurements (Continued)

recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the year ended December 31, 2018 (in thousands):

	Other Liabilities: Contingent Consideration
Balance at December 31, 2017	$ 43,400
Fair value adjustments included in operating expenses	(29,621)
Balance at December 31, 2018	$ 13,779

The valuation technique used to measure fair value of the Company's Level 3 liabilities, which consist of contingent consideration related to the acquisition of Kolltan in 2016 (Note 17), was primarily an income approach. As of December 31, 2018, the Company may be required to pay future consideration of up to $127.5 million that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The significant unobservable inputs used in the fair value measurement of the contingent consideration are estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

During the year ended December 31, 2018, the Company recorded a $29.6 million gain on fair value remeasurement of contingent consideration, primarily due to discontinuation of the Glemba and CDX-014 programs, updated assumptions for the varlilumab program, and lower probability that milestones related to our anti-KIT program would be triggered by the Company's current anti-KIT program development.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the years ended December 31, 2018 and 2017.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(5) Marketable Securities

The following is a summary of marketable securities, classified as available-for-sale:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2018				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 27,355	$	$ (4)	$ 27,351
Maturing after one year through three years				
Total U.S. government and municipal obligations	$ 27,355	$	$ (4)	$ 27,351
Corporate debt securities				
Maturing in one year or less	$ 42,370	$	$ (9)	$ 42,361
Maturing after one year through three years				
Total corporate debt securities	$ 42,370	$	$ (9)	$ 42,361
Total marketable securities	$ 69,725	$	$ (13)	$ 69,712
December 31, 2017				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 26,164	$ 3	$ (9)	$ 26,158
Maturing after one year through three years				
Total U.S. government and municipal obligations	$ 26,164	$ 3	$ (9)	$ 26,158
Corporate debt securities				
Maturing in one year or less	$ 73,007	$ 1	$ (27)	$ 72,981
Maturing after one year through three years				
Total corporate debt securities	$ 73,007	$ 1	$ (27)	$ 72,981
Total marketable securities	$ 99,171	$ 4	$ (36)	$ 99,139

The Company holds investment grade marketable securities, and none were considered to be other-than-temporarily impaired as of December 31, 2018. Marketable securities include $0.1 million and $0.3 million in accrued interest at December 31, 2018 and December 31, 2017, respectively.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(6) Property and Equipment, Net

Property and Equipment, Net includes the following:

	December 31, 2018	December 31, 2017
	(In thousands)	
Laboratory Equipment	$ 8,272	$ 7,770
Manufacturing Equipment	2,497	4,354
Office Furniture and Equipment	3,791	3,764
Leasehold Improvements	17,408	17,164
Construction in Progress	327	932
Total Property and Equipment	32,295	33,984
Less: Accumulated Depreciation and Amortization	(26,184)	(23,612)
Property and Equipment, Net	$ 6,111	$ 10,372

Depreciation and amortization expense related to property and equipment was $3.6 million, $4.4 million, and $3.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

(7) Intangible Assets and Goodwill

Intangible Assets, Net

At December 31, 2018 and 2017, the Company recorded finite intangible assets of $0 and $7.1 million, respectively. Finite-lived intangible assets consisted solely of license rights amended under a 2009 agreement with Amgen Fremont related to developing and commercializing Glemba. As a result of the discontinuation of the Glemba program, the Company concluded that the finite-lived intangible asset was fully impaired and a non-cash impairment charge of $6.9 million was recorded in the first quarter of 2018. Amortization expense for finite intangible assets was $0.2 million, $0.9 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016.

At December 31, 2018 and 2017, the Company recorded indefinite-lived intangible assets of $48.7 million and $60.5 million, respectively. At December 31, 2018, indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of CDX-3379, the anti-KIT program and the TAM program. CDX-3379 is in Phase 2 development. The anti-KIT and TAM programs are in preclinical development. As of December 31, 2018, no IPR&D asset had reached technological feasibility nor did any have alternative future uses.

The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired. As a result of the discontinuation of the Glemba program, the Company concluded that the Glemba IPR&D asset was fully impaired and a non-cash impairment charge of $11.8 million was recorded in the first quarter of 2018. Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(7) Intangible Assets and Goodwill (Continued)

Goodwill

At December 31, 2018 and 2017, the Company recorded goodwill of $0 and $91.0 million, respectively. The Company evaluated goodwill for potential impairment due to the discontinuation of the Glemba program. The carrying amount of the Company was compared to the Company's fair value. The Company's fair value assessment reflected a number of significant management assumptions and estimates including the Company's probability forecasts for pipeline assets, income taxes, capital expenditures, market premium and changes in working capital requirements. Changes in these assumptions and/or discount rates could materially impact the Company's conclusions. Through this assessment, it was determined that the carrying amount of the Company exceeded its fair value by over $91.0 million. As such, the full goodwill asset was considered impaired and a charge of $91.0 million was recorded during the first quarter of 2018.

(8) Accrued Expenses

Accrued expenses include the following:

	December 31, 2018	December 31, 2017
	(In thousands)	
Accrued Payroll and Employee Benefits	$ 4,400	$ 6,348
Accrued Research and Development Contract Costs	1,766	11,399
Accrued Professional Fees	620	1,408
Other Accrued Expenses	221	300
	$ 7,007	$ 19,455

(9) Other Long-Term Liabilities

Other long-term liabilities include the following:

	December 31, 2018	December 31, 2017
	(In thousands)	
Net Deferred Tax Liabilities Related to IPR&D (Note 14)	$ 3,007	$ 3,772
Deferred Income From Sale of Tax Benefits	4,218	6,756
Other	1,083	1,344
Contingent Milestones (Note 4)	13,779	43,400
Deferred Revenue	1,586	2,813
Total	23,673	58,085
Less Current Portion	(4,526)	(6,566)
Long-Term Portion	$ 19,147	$ 51,519

In November 2015, December 2014 and January 2014, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $9.8 million, $1.9 million and $1.1 million to an independent third party for $9.2 million, $1.8 million and $1.0 million, respectively. Under the agreement, the Company must maintain a base of operations

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(9) Other Long-Term Liabilities (Continued)

in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. During the years ended December 31, 2018, 2017 and 2016, the Company recorded $2.5 million, $2.7 million and $2.8 million to other income related to the sale of these tax benefits, respectively.

(10) Stockholders' Equity

Common Stock

In December 2016, the Company filed a new shelf registration statement with the Securities and Exchange Commission to register for sale any combination of the types of securities described in the shelf registration statement up to a maximum aggregate offering price of $250 million. Such registration statement was declared effective on February 13, 2017.

In May 2016, the Company entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to issue and sell shares of its common stock having an aggregate offering price of up to $60.0 million from time to time through Cantor, acting as agent. In November 2017, the Company filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the years ended December 31, 2018, 2017 and 2016, the Company issued 2,702,660, 1,181,524 and 220,253 shares of its common stock, respectively, under this controlled equity offering sales agreement with Cantor resulting in net proceeds to the Company of $29.0 million, $51.0 million and $13.9 million, respectively, after deducting commission and offering expenses. At December 31, 2018, the Company had $37.6 million remaining in aggregate gross offering price available under the Cantor agreement. From January 1, 2019 through February 28, 2019, the Company issued 478,785 shares of its common stock resulting in net proceeds to the Company of $2.3 million.

Convertible Preferred Stock

At December 31, 2018, the Company had authorized 3,000,000 shares of preferred stock all of which have been designated Class C Preferred Stock including 350,000 shares which have been designated Series C-1 Junior Participating Cumulative Preferred Stock (the "Series C-1 Preferred Stock"). No shares of Series C-1 Preferred Stock were outstanding at December 31, 2018 or 2017.

(11) Stock-Based Compensation

The Company has the following stock-based compensation plans: the 2004 Employee Stock Purchase Plan (the "2004 ESPP Plan") and the 2008 Stock Option and Incentive Plan (the "2008 Plan").

Employee Stock Purchase Plan

At December 31, 2018, a total of 26,667 shares of common stock are reserved for issuance under the 2004 ESPP Plan. Under the 2004 ESPP Plan, each participating employee may purchase shares of common stock through payroll deductions at a purchase price equal to 85% of the lower of the fair market value of the common stock at either the beginning of the offering period or the applicable exercise date. During the years ended December 31, 2018, 2017 and 2016, the Company issued 9,524,

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(11) Stock-Based Compensation (Continued)

5,359 and 3,956 shares under the 2004 ESPP Plan, respectively. At December 31, 2018, 3,666 shares were available for issuance under the 2004 ESPP Plan.

Employee Stock Option and Incentive Plan

The 2008 Plan permits the granting of incentive stock options (intended to qualify as such under Section 422A of the Internal Revenue Code of 1986, as amended), non-qualified stock options, stock appreciation rights, performance share units, restricted stock and other awards of restricted stock in lieu of cash bonuses to employees, consultants and non-employee directors.

At December 31, 2018, the 2008 Plan allowed for a maximum of 1,333,333 shares of common stock to be issued for grants of new awards until June 9, 2025 and grants of incentive stock options until April 16, 2025. The Company's Board of Directors determines the term of each option, option price, and number of shares for which each option is granted and the rate at which each option vests. Options generally vest over a period not to exceed four years. The term of each option cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of the Company), and the exercise price of stock options cannot be less than the fair market value of the common stock at the date of grant (110% of fair market value for incentive stock options granted to holders of more than 10% of the voting stock of the Company). Vesting of all employee and non-employee director stock option awards may accelerate upon a change in control as defined in the 2008 Plan.

A summary of stock option activity for the year ended December 31, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2017	723,747	$ 141.00	6.1
Granted	338,517	$ 9.11	
Exercised	(6,967)	$ 42.00	
Canceled	(189,165)	$ 125.38	
Options Outstanding at December 31, 2018	866,132	$ 93.70	7.1
Options Vested and Expected to Vest at December 31, 2018	846,352	$ 95.47	7.0
Options Exercisable at December 31, 2018	426,612	$ 162.83	5.1
Shares Available for Grant Under the 2008 Plan	356,913		

The total intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $0.0 million, $0.0 million and $0.1 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2018, 2017 and 2016 was $6.60, $23.70 and $47.70, respectively. The total fair value of stock options vested during the years ended December 31, 2018, 2017 and 2016 was $8.0 million, $13.4 million and $17.0 million, respectively.

The aggregate intrinsic value of stock options outstanding at December 31, 2018 was $0.0 million. The aggregate intrinsic value of stock options vested and expected to vest at December 31, 2018 was $0.0 million. As of December 31, 2018, total compensation cost related to non-vested employee and

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(11) Stock-Based Compensation (Continued)

non-employee director stock options not yet recognized was approximately $6.8 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.6 years.

Restricted Stock

A summary of restricted stock activity under the 2008 Plan for the year ended December 31, 2018 is as follows:

	Shares	Weighted Average Grant Date Fair Value (per share)
Outstanding and unvested at December 31, 2017	6,445	$ 44.70
Granted		$
Vested	(2,449)	$ 47.94
Canceled	(444)	$ 34.83
Outstanding and unvested at December 31, 2018	3,552	$ 43.84

Valuation and Expenses Information

Stock-based compensation expense for the years ended December 31, 2018, 2017 and 2016 was recorded as follows:

	2018	2017	2016
	(In thousands)		
Research and development	$ 3,874	$ 6,693	$ 7,821
General and administrative	4,207	5,619	7,496
Total stock-based compensation expense	$ 8,081	$ 12,312	$ 15,317

The fair values of employee and director stock options granted during the years ended December 31, 2018, 2017 and 2016 were valued using the Black-Scholes option pricing model with the following assumptions:

	2018	2017	2016
Expected stock price volatility	73 - 85%	75 - 77%	70 - 77%
Expected option term	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	2.8 - 3.1%	2.0 - 2.3%	1.4 - 2.3%
Expected dividend yield	None	None	None

The Company estimates expected term based on historical exercise patterns. The Company uses its historical stock price volatility consistent with the expected term of grant as the basis for its expected volatility assumption. The risk-free interest rate is based upon the yield of U.S. Treasury securities consistent with the expected term of the option. The dividend yield assumption is based on the Company's history of zero dividend payouts and expectation that no dividends will be paid in the foreseeable future.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(12) Revenue

On January 1, 2018, the Company adopted a new revenue accounting standard, "*Revenue from Contracts with Customers" (ASC 606)*. Upon adoption using the modified retrospective application, the Company recognized a $1.3 million decrease to accumulated deficit, a $0.8 million decrease in deferred revenue and $0.5 million increase in accounts receivable due to the cumulative impact of adopting *ASC 606*. This impact was driven by the acceleration of revenue using a percentage-of-completion method of accounting under *ASC 606* for an open contract that had previously been accounted for using the Contingency Adjusted Performance Model ("CAPM") under previous guidance.

Results for reporting periods beginning after January 1, 2018 are presented under *ASC 606* while prior period amounts were not adjusted and continue to be reported in accordance with historic accounting under previous guidance. There was not a material impact to revenues as a result of applying *ASC 606* for the year ended December 31, 2018, and there have not been significant changes to the Company's business processes, systems or internal controls as a result of adopting the new standard. Revenue recognition remained largely unchanged under the new standard.

Contract Assets and Liabilities

At January 1, 2018 and December 31, 2018, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets.

Revenue recognized from contract liabilities as of January 1, 2018 during the year ended December 31, 2018 was $1.9 million. Revenue expected to be recognized in the future from contract liabilities as performance obligations are satisfied are not expected to be material.

Product Development and Licensing Revenue

The Company's primary product development and licensing revenue is associated with a clinical collaboration agreement with BMS entered into in 2014 to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo®, BMS's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under this agreement, BMS made an upfront payment to Celldex of $5.0 million and provides funding for 50% of the external costs incurred by the Company in connection with the clinical trial. The performance obligations under the collaboration agreement consist of intellectual property licenses and the performance of research and development services. The Company determined that the performance obligations were not separately identifiable and were not distinct (and did not have standalone value) due to the specialized nature of the services to be provided, the dependent relationship between the performance obligations and the Company's proprietary technology that makes them uniquely qualified to perform the R&D services. Therefore, the Company concluded that the collaboration agreement has a single identified or combined performance obligation. As of December 31, 2018, deferred revenue related to the Company's remaining performance obligation under this arrangement is not material. The Company recorded $3.3 million, $2.8 million and $2.1 million in revenue related to this agreement during the years ended December 31, 2018, 2017 and 2016, respectively.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(12) Revenue (Continued)

Contract and Grants Revenue

In 2017, the Company entered into fixed-fee manufacturing and research and development arrangements with both the International AIDS Vaccine Initiative (IAVI) and Frontier Biotechnologies, Inc (Frontier). The Company recognized $3.0 million and $6.6 million in revenue under these agreements during the years ended December 31, 2018 and 2017, respectively.

In 2013, the Company entered into an agreement, as amended, with Rockefeller University pursuant to which the Company performs manufacturing and research and development services for Rockefeller University. The Company recognized $2.6 million, $2.2 million and $2.7 million in revenue for labor hours and direct costs incurred related to the Rockefeller University agreement during years ended December 31, 2018, 2017 and 2016, respectively.

(13) Collaboration Agreements

The Company has entered into license agreements whereby the Company has received licenses or options to license technology, specified patents or patent applications. The Company's licensing and development collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain developmental, regulatory and/or commercial milestones. Nonrefundable license fee expense of $0.7 million, $0.7 million and $1.6 million was recorded to research and development expense for the years ended December 31, 2018, 2017 and 2016, respectively.

Medarex, Inc. (Medarex), which was acquired by Bristol-Myers Squibb

Under a license agreement with Medarex, as amended, the Company acquired access to the UltiMab technology to develop and commercialize human antibodies to CD27, including varlilumab. The Company may be required to pay Medarex royalty payments in the low-to-mid single digits on any net product sales with respect to the development and commercialization of varlilumab until the later of (i) the expiration of the last to expire applicable patent and (ii) the tenth anniversary of the first commercial sale of such licensed product.

University of Southampton, UK (Southampton)

Under a license agreement with Southampton, the Company acquired the rights to develop human antibodies towards CD27, a potentially important target for immunotherapy of various cancers. The Company may be required to pay Southampton milestones of up to approximately $1.0 million upon obtaining first approval for commercial sale in a first indication and royalty payments in the low-single digits on any net product sales with respect to development and commercialization of varlilumab.

Amgen Inc. (Amgen)

Under a license agreement with Amgen, the Company acquired the exclusive rights to CDX-301 and CD40 ligand, or CD40L. CDX-301 and CD40L are immune modulating molecules that increase the numbers and activity of immune cells that control immune responses. The Company may be required to pay Amgen milestones of up to $0.9 million upon obtaining first approval for commercial sale in a first indication and royalty payments in the low-single digits on any net product sales with

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(13) Collaboration Agreements (Continued)

respect to development and commercialization of the technology licensed from Amgen, including CDX-301.

Yale University (Yale)

Under a license agreement with Yale, the Company may be required to make a one-time payment to Yale of $3.0 million with respect to each therapeutic or prophylactic RTK royalty-bearing product, including CDX-3379, that achieves a specified commercial milestone. In addition, the Company may be required to pay a low single-digit royalty on annual worldwide net sales of each RTK royalty-bearing product, including CDX-3379.

MedImmune, LLC (MedImmune)

Under a license agreement with MedImmune, the Company acquired exclusive rights to specified patent rights and know-how that are controlled by MedImmune and relate to the research, development, manufacture and commercialization of CDX-3379. The Company may be required to pay Medimmune up to $45.0 million upon obtaining specified regulatory and development milestones in the first indication of CDX-3379. In addition, the Company may be required to pay MedImmune one-time milestone payments of up to $125.0 million if specified annual net sale thresholds are met related to the first indication of CDX-3379. The Company may also be required to pay MedImmune a tiered royalty on annual net sales of CDX-3379 at rates ranging from high single-digit to low teens percentages. The Company may also be required to pay specified royalties on annual net sales of CDX-3379 at a rate in the low single digits to certain other third parties from whom MedImmune licensed certain intellectual property.

(14) Income Taxes

The components of income tax benefit (provision) are as follows:

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Income Tax Benefit (Provision):			
Federal	$ 22,255	$ 57,547	$ 45,518
State	6,406	(2,479)	7,268
Foreign	913	2,448	1,124
Income Tax Rate Change		(99,528)	
	29,574	(42,012)	53,910
Deferred Tax Valuation Allowance	(28,809)	66,294	(53,910)
	$ 765	$ 24,282	$

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) Income Taxes (Continued)

A reconciliation between the amount of reported income tax and the amount computed using the U.S. Statutory rate is as follows:

	2018	2017	2016
		(In thousands)	
Pre-Tax Loss	$ (151,949)	$ (117,313)	$ (128,530)
Loss at Statutory Rates	(31,909)	(39,887)	(43,700)
Difference in Foreign Tax Rates		326	150
Research and Development Credits	(2,056)	(2,847)	(5,203)
State Taxes	(6,406)	(6,283)	(7,268)
Income Tax Rate Change		99,528	
Other	(1,175)	(321)	2,111
Milestone Abandonment	(6,220)		
Intangible Impairment	19,105		
Recognition of APIC NOLs		(5,729)	
Impact of Pass-through Entities	(913)	(2,775)	
Change in Valuation Allowance	28,809	(66,294)	53,910
Income Tax (Benefit) Provision	$ (765)	$ (24,282)	$

Deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. The

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) Income Taxes (Continued)

principal components of the deferred tax assets and liabilities at December 31, 2018 and 2017, respectively, are as follows:

	December 31, 2018	December 31, 2017
	(In thousands)	
Gross Deferred Tax Assets		
Net Operating Loss Carryforwards	$ 168,239	$ 146,228
Foreign Net Operating Loss Carryforwards	4,485	3,572
Tax Credit Carryforwards	39,761	36,458
Deferred Research and Development Expenses	76,555	79,272
Stock-based Compensation	11,977	10,718
Fixed Assets	1,761	1,305
Deferred Revenue	13	686
Accrued Expenses and Other	183	316
	302,974	278,555
Gross Deferred Tax Liabilities		
Other Acquired Intangibles	120	(1,792)
IPR&D Intangibles	(12,748)	(15,992)
Total Deferred Tax Assets and Liabilities	290,346	260,771
Valuation Allowance	(293,353)	(264,543)
Net Deferred Tax Liability	$ (3,007)	$ (3,772)

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and considered its history of losses, ultimately concluding that it is "more likely than not" that the Company will not recognize the benefits of federal, state and foreign deferred tax assets and, as such, has maintained a full valuation allowance on its deferred tax assets.

During year ended December 31, 2017, the Company's gross deferred tax assets and corresponding valuation allowance each increased by $17.7 million. This was a one-time increase due to the adoption of a new accounting standard removing the requirement to recognize excess tax benefits from the exercise of stock options in additional paid-in-capital when realized.

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted, leading to significant changes to U.S. tax law. Among other provisions, the TCJA lowered the U.S. federal corporate income tax rate from 35% to 21%, limited the deduction for net operating losses to 80% of taxable income while providing that net operating loss carryovers for years after 2017 will not expire, imposed a mandatory one-time transition tax on previously deferred foreign earnings and eliminated or reduced certain income tax deductions.

As a result of the TCJA, the Company revalued its deferred tax liabilities at the new federal rate of 21%, resulting in a $6.9 million decrease and a corresponding income tax benefit. The Company also scheduled out reversals of its deferred tax assets and liabilities, determining that their reversal would create future indefinite-lived net operating losses under the TCJA. As such, the valuation allowance was reduced relating to the remaining indefinite-lived federal deferred tax liabilities balance, leading to

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) Income Taxes (Continued)

an additional income tax benefit of $12.2 million. The Company's deferred tax asset balance was also revalued at the new 21% rate resulting in a $99.5 million decrease in the balance with a corresponding decrease to the valuation allowance. Finally, the one-time transition tax on previously deferred foreign earnings under the TCJA is not expected to impact the Company due to a net deficit in the Australian subsidiary. The Company's accounting for the tax effects of the TCJA is complete.

The net deferred tax liability of $3.0 million and $3.8 million at December 31, 2018 and 2017, respectively, relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and are not deductible for tax purposes. The Company recorded an income tax benefit of $0.8 million during the year ended December 31, 2018 due to a decrease in deferred tax liabilities resulting from the partial impairment of the anti-KIT program.

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of $636.8 million and $532.4 million, respectively, which may be available to offset certain future income tax liabilities and begin to expire in 2019 and 2028, respectively. Of the federal net operating loss carryforwards of $636.8 million, approximately $75 million are from 2018 and have no expiration date. As of December 31, 2018, the Company also had federal and state research and development tax credit carryforwards of $31.0 million and $11.1 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2018 and 2017, respectively.

Utilization of the net operating loss carryforwards and research and credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, or Section 382, due to ownership changes that occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has estimated the amounts of net operating loss and research and development tax credit carryforwards which will expire unutilized as a result of its estimated annual limitations under Section 382 and has excluded those amounts from the carryforward amounts disclosed above and in the deferred tax assets and liabilities table included in this footnote. The Company has concluded Section 382 studies through 2015 for Celldex generated NOLs.

The Company incurred a foreign pre-tax loss of $3.0 million and $8.2 million during the years ended December 31, 2018 and 2017, respectively. Beginning with the 2016 tax returns, the Company elected to classify the Australian entity as a disregarded entity for income tax purposes. The foreign pre-tax losses have been included with the Federal net operating loss carryforwards.

As of December 31, 2018 and 2017, the Company did not have any unrecognized tax benefits.

Massachusetts, New Jersey, New York, Connecticut and Australia are the jurisdictions in which the Company primarily operates or has operated and has income tax nexus. The Company is not currently under examination by these or any other jurisdictions for any tax year. Generally, in U.S. federal and state taxing jurisdictions, all years which generated net operating losses and/or tax credit carryforwards remain subject to examination to the extent those carryforwards are utilized in a subsequent period.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(15) Commitments and Contingencies

The Company has facility and equipment leases that expire at various dates through 2020. Certain of these facility leases contain renewal options, early termination provisions, and provisions that escalate the base rent payments and require the Company to pay common area maintenance costs ("CAM") during the lease term. The following obligations for base rent and CAM costs under facility and other non-cancelable operating leases as of December 31, 2018 do not include the exercise of renewal terms or early termination provisions (in thousands):

2019	$	4,648
2020		3,140
2021		
2022		
2023		
Thereafter		
Total minimum lease payments	$	7,788

The Company's total rent and CAM expense for all facility leases was $4.0 million, $4.1 million and $4.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

(16) Retirement Savings Plan

The Company maintains a 401(k) Plan which is available to substantially all employees. Under the terms of the 401(k) Plan, participants may elect to contribute up to 60% of their compensation or the statutory prescribed limits. The Company may make 50% matching contributions on up to 4% of a participant's annual salary. Benefit expense for the 401(k) Plan was $0.4 million, $0.5 million and $0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

(17) Kolltan Acquisition

On November 29, 2016, the Company acquired all of the share and debt interests of Kolltan Pharmaceuticals, Inc. ("Kolltan"), a clinical-stage biopharmaceutical company, in exchange for 1,217,200 shares of the Company's common stock plus contingent consideration in the form of development and approval milestones. As of December 31, 2018, the Company may be required to pay future consideration of up to $127.5 million that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The Company completed this acquisition in order to gain access to Kolltan's antibody-based drug development programs targeting receptor tyrosine kinases (RTKs) for the treatment of cancer and other diseases with significant unmet needs.

Purchase Price

The purchase price for Kolltan was calculated based on the closing price of the Company's common stock of $60.30 per share on November 29, 2016. The Company also recorded a liability of $44.2 million which represented the initial fair value of the contingent consideration. This fair value measurement used significant unobservable inputs representing a Level 3 measurement more fully described in Note 4, *Fair Value Measurements* to these consolidated financial statements. Subsequent changes to the fair value of the contingent consideration will be recognized as adjustments to operating

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(17) Kolltan Acquisition (Continued)

earnings. The acquisition was accounted for using the acquisition method of accounting which requires all assets acquired and liabilities assumed recognized at their acquisition-date fair values.

The total consideration transferred consisted of the following (in thousands):

Fair value of common stock issued for upfront payment	$	73,397
Fair value of contingent consideration		44,200
Kolltan transaction expenses paid in cash by the Company		3,768
Total consideration transferred	$	121,365

Allocations of Assets and Liabilities

The purchase price allocation was finalized in the fourth quarter of 2017 with no adjustments made to the initial purchase price allocation. The following table summarizes the fair values of the assets acquired and liabilities assumed as of November 29, 2016 (in thousands):

Cash and cash equivalents	$	8,160
Other current and long-term assets		799
Property and equipment, net		2,072
In-process research and development (IPR&D)		61,690
Goodwill		82,011
Deferred tax liabilities, net		(23,393)
Other assumed liabilities		(9,974)
Total	$	121,365

IPR&D primarily represents the initial estimated fair value of $40.0 million, $3.5 million and $18.0 million for the anti-KIT program, CDX-3379 and TAM programs, respectively, using probability adjusted discounted cash flow analyses. The expected future net cash flows for the anti-KIT program, CDX-3379 and TAM programs were based on the expectation that a Biologics License Application ("BLA") would be filed with the FDA no earlier than the end of 2023, 2024 and 2028, respectively, with an expected commercial launch as promptly as practicable after necessary regulatory approvals are received. The estimated development costs included in the expected future net cash flows were approximately $132 million combined.

The deferred tax liability, net of $23.4 million primarily relates to the temporary differences associated with the IPR&D intangible assets, which are not deductible for tax purposes.

The excess of purchase price over the fair value amounts assigned to the identifiable assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The value of the goodwill can be attributable to the synergies related to the combined antibody-based platform and a deferred tax liability related to acquired IPR&D intangible assets. None of the goodwill is expected to be deductible for income tax purposes.

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CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(17) Kolltan Acquisition (Continued)

Acquisition-Related Expenses, Including Severance

The Company incurred $0.7 million in acquisition-related expenses in the consolidated statements of operations for the year ended December 31, 2016. From the acquisition date through December 31, 2016, the consolidated statements of operations also include $2.4 and $0.7 million in Kolltan related severance expense within general and administrative and research and development expenses, respectively.

Pro Forma Financial Information

The operating results of Kolltan and pro forma adjustments including severance expense and transaction expenses of $3.1 million and $0.7 million, respectively, have been included in the accompanying consolidated financial statements from November 29, 2016 to December 31, 2016. Kolltan had no revenues from November 29, 2016 through December 31, 2016. The following unaudited pro forma financial summary is presented as if the operations of the Company and Kolltan were combined as of January 1, 2015. The unaudited pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisition been consummated at that date or of the future operations of the combined entities.

	Unaudited Years Ended December 31, 2016
	(In thousands)
Revenue	$ 6,786
Net loss	$ (146,905)

(18) Selected Quarterly Financial Data (Unaudited)

2018	Q1 2018	Q2 2018	Q3 2018	Q4 2018
	(In thousands, except per share amounts)			
Total revenue	$ 4,068	$ 2,763	$ 941	$ 1,764
Net loss	(118,132)	(16,407)	(7,243)	(9,402)
Basic and diluted net loss per common share	(12.61)	(1.67)	(0.66)	(0.81)

2017	Q1 2017	Q2 2017	Q3 2017	Q4 2017
	(In thousands, except per share amounts)			
Total revenue	$ 1,534	$ 3,829	$ 3,924	$ 3,456
Net loss	(34,261)	(28,566)	(26,363)	(3,841)
Basic and diluted net loss per common share	(4.19)	(3.42)	(3.05)	(0.42)

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Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2018, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2018. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and

provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

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The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, or the 2019 Proxy Statement, under "Information Regarding the Current Directors and Executive Officers of Celldex Therapeutic, Inc.," "Section 16(a) Beneficial Ownership Reporting Compliance," "Code of Business Conduct and Ethics" and "The Board of Directors and Its Committees" and is incorporated herein by reference. If the 2019 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in the 2019 Proxy Statement under "Executive Compensation," and "Compensation Committee Interlocks and Insider Participation," and is incorporated herein by reference. If the 2019 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in the 2019 Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference. If the 2019 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in the 2019 Proxy Statement under "Election of Directors" and "Approval of Related Person Transactions and Transactions with Related Persons" and is incorporated herein by reference. If the 2019 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

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Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in the 2019 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference. If the 2019 Proxy Statement is not filed with the SEC within 120 days after the end of our most recent fiscal year, we will provide such information by means of an amendment to this Annual Report on Form 10-K.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(A)

The following documents are filed as part of this Form 10-K:

(1)

Financial Statements:

The Financial Statements and Supplementary Data are included in Part II Item 8 of this report.

(2)

Financial Statement Schedules:

Schedules are omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the Financial Statements or Notes thereto.

(3)

Exhibits:

		Incorporated by Reference to		
No.	**Description**	**Form and SEC File No.**	**Exhibit No.**	**SEC Filing Date**
Plan of Acquisition, Reorganization, Arrangement, Liquidation or Succession				
2.1	Agreement and Plan of Merger, dated as of November 1, 2016, by and among Kolltan Pharmaceuticals, Inc., Celldex Therapeutics, Inc., Connemara Merger Sub 1 Inc. and Connemara Merger Sub 2 LLC.	8-K (000-15006)	2.1	11/1/16
Articles of Incorporation and By-Laws				
3.1	Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.2	7/16/98
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.1	5/10/02
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.1	3/11/08
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.2	3/11/08
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.7	11/10/08
3.8	Amended and Restated By-Laws, dated April 7, 2014	8-K (000-15006)	3.1	4/8/14
3.9	Seventh Certificate of Amendment of Third Restated Certificate of Incorporation	8-K	3.1	2/8/19

			(000-15006)		
Instruments Defining the Rights of Security Holders					
4.1	Specimen of Common Stock Certificate		8-K (000-15006)	4.1	2/8/19

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No.	Description	Incorporated by Reference to Form and SEC File No.	Exhibit No.	SEC Filing Date
4.2	Certificate of Designations, Preferences and Rights of a Series of Preferred Stock classifying and designating the Series C-1 Junior Participating Cumulative Preferred Stock	8-A (000-15006)	3.1	11/8/04
Material Contracts Leases				
10.1	Commercial Lease Agreement of May 1, 1996 between the Company and Fourth Avenue Ventures Limited Partnership	10-Q/A (000-15006)	10.11	8/23/96
10.2	Extension of Lease Agreement of May 1, 1997 between the Company and DIV Needham 53 LLC (successor in interest to Fourth Avenue Ventures Limited Partnership) dated as of August 23, 2001	10-K (000-15006)	10.9	3/27/02
10.3	First Amendment to Lease by and between the Company and DIV Needham 115 LLC (successor in interest to Fourth Avenue Ventures Limited Partnership) dated November 29, 2005	10-K (000-15006)	10.40	3/16/06
10.4	Second Amendment to Lease by and between the Company and DIV Needham 115 LLC dated as of August 1, 2015	10-K/A (000-15006)	10.4	2/25/16
*10.5	Lease Agreement, by and between the Company and the Massachusetts Development Finance Agency, dated as of December 22, 2003	10-Q (000-15006)	10.1	4/30/04
10.6	First Amendment to Lease between Massachusetts Development Finance Agency and the Company dated March 17, 2005	10-K/A (000-15006)	10.6	12/23/10
10.7	Second Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of November 4, 2005	10-K (000-15006)	10.41	3/16/06
10.8	Third Amendment to Lease between Massachusetts Development Finance Agency and the Company dated December 20, 2006	10-K/A (000-15006)	10.7	12/23/10
10.9	Fifth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated October 3, 2008	10-K/A (000-15006)	10.8	12/23/10
10.10	Sixth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated August 20, 2009	10-K/A (000-15006)	10.9	12/23/10
10.11	Seventh Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of June 22, 2010	10-Q (000-15006)	10.1	8/5/10
10.12	Eighth Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of November 1, 2015	10-K/A (000-15006)	10.12	2/25/16

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No.	Description	Incorporated by Reference to Form and SEC File No.	Exhibit No.	SEC Filing Date
10.13	Lease Agreement dated as of May 1, 2013 by and between Crown Perryville, LLC and the Company.	10-Q (000-15006)	10.1	5/03/13
10.14	First Amendment to Lease between Company and Crown Perryville, LLC dated as of June 17, 2015	10-Q (000-15006)	10.2	8/10/15
Material Contracts License, Collaboration, Supply and Distribution Agreements				
*10.15	Research and Commercialization Agreement, as amended, dated as of April 6, 2004 by and among Medarex, Inc., GenPharm International, Inc. and the Company	S-4 (333-148291)	10.5	1/18/08
*10.16	Exclusive Patent and Know-How License Agreement dated as of November 5, 2008 between the Company and the University of Southampton	10-K (000-15006)	10.47	3/2/09
*10.17	License and Assignment Agreement, between Amgen Inc. and the Company dated March 16, 2009	10-K/A (000-15006)	10.1	12/23/10
*10.18	License Agreement between Medarex and Company dated September 17, 2010	10-Q/A (000-15006)	10.3	12/23/10
*10.19	License and Option Agreement by and between MedImmune, LLC and the Company, dated July 24, 2013, as amended by the Amendment, dated October 27, 2015	10-K (000-15006)	10.24	3/7/18
*10.20	Third Amended and Restated License Agreement by and between Yale University and the Company, dated March 14, 2013, as amended by the Amendments, dated March 21, 2014 and December 1, 2014	10-K (000-15006)	10.25	3/7/18
Material Contracts Stock Purchase, Financing and Credit Agreements				
10.21	Sales Agreement, dated May 19, 2016, by and between Celldex Therapeutics, Inc. and Cantor Fitzgerald & Co.	8-K (000-15006)	1.1	5/19/16
Material Contracts Management Contracts and Compensatory Plans				
10.22	2008 Stock Option and Incentive Plan, as amended and restated	10-K (000-15006)	10.27	3/7/18
10.23	2004 Employee Stock Purchase Plan, as amended and restated	10-K (000-15006)	10.28	3/7/18
10.24	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Anthony S. Marucci	8-K (000-15006)	10.1	12/29/17
10.25	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Sam Martin	8-K (000-15006)	10.2	12/29/17
10.26	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Tibor Keler, Ph.D.	8-K (000-15006)	10.3	12/29/17

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No.	Description	Incorporated by Reference to Form and SEC File No.	Exhibit No.	SEC Filing Date
10.27	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Ronald Pepin, Ph.D.	8-K (000-15006)	10.4	12/29/17
10.28	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Sarah Cavanaugh	8-K (000-15006)	10.5	12/29/17
10.29	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Margo Heath-Chiozzi, M.D.	8-K (000-15006)	10.6	12/29/17
10.30	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Elizabeth Crowley	8-K (000-15006)	10.7	12/29/17
10.31	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Richard Wright, Ph.D.	8-K (000-15006)	10.8	12/29/17
10.32	Form of Stock Option Agreement	10-Q (000-15006)	10.1	8/08/18
10.33	Form of Restricted Stock Award	10-K (000-15006)	10.42	3/12/10
21.1	Subsidiaries of Celldex Therapeutics, Inc.	Filed herewith		
23.1	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm	Filed herewith		
31.1	Certification of President and Chief Executive Officer	Filed herewith		
31.2	Certification of Senior Vice President and Chief Financial Officer	Filed herewith		
32	Section 1350 Certifications	Furnished herewith		
101	XBRL Instance Document	Filed herewith		
101	XBRL Taxonomy Extension Schema Document	Filed herewith		
101	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith		
101	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		

*

Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

Indicates a management contract or compensation plan, contract or arrangement.

Item 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CELLDEX THERAPEUTICS, INC.
By: /s/ ANTHONY S. MARUCCI

Date
March 7, 2019

Anthony S. Marucci
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ANTHONY S. MARUCCI Anthony S. Marucci	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 7, 2019
/s/ SAM MARTIN Sam Martin	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 7, 2019
/s/ LARRY ELLBERGER Larry Ellberger	Director, Chairman of the Board of Directors	March 7, 2019
/s/ KEITH L. BROWNLIE Keith L. Brownlie	Director	March 7, 2019
/s/ HERBERT J. CONRAD Herbert J. Conrad	Director	March 7, 2019
/s/ JAMES J. MARINO James J. Marino	Director	March 7, 2019
/s/ HARRY H. PENNER, JR. Harry H. Penner, Jr.	Director	March 7, 2019
/s/ KAREN L. SHOOS Karen L. Shoos	Director	March 7, 2019