CELLDEX THERAPEUTICS, INC.

FORM 10-K
(Annual Report)

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Symbol	CLDX
SIC Code	2835 - In Vitro and In Vivo Diagnostic Substances
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Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2016

or

☐ **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 Global Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 ☒ No ☐

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. ☒

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

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller Reporting Company ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2016 was $435 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 March 6, 2017 was 123,213,438 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

CELLDEX THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 2016

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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 ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of glembatumumab vedotin (also referred to as CDX-011) and other drug candidates and the growth of the markets for those drug candidates;

- our ability to raise sufficient capital to fund our 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;

- failure to obtain approval from our stockholders to issue additional shares of our common stock to Kolltan's former stockholders if any contingent milestones are achieved;

- our ability to negotiate strategic partnerships, where appropriate, for our programs, which may include, glembatumumab vedotin;

- our ability to successfully integrate our and Kolltan's businesses and to operate the combined business efficiently;

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

- 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 safety and efficacy trials of glembatumumab vedotin, and other preclinical and clinical testing;

- 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, who may be the sole source of supply;

- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- 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 adapt our proprietary antibody-targeted technology, or APC Targeting Technology™, to develop new, safe and effective therapeutics for oncology and infectious disease indications;
- 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; 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.

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 several immunotherapy technologies and other cancer-targeting biologics. Our drug candidates, including antibodies, antibody-drug conjugates and other protein-based therapeutics, 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.

Our latest stage drug candidate, glembatumumab vedotin (also referred to as CDX-011) is a targeted antibody-drug conjugate in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma. Varlilumab (also referred to as CDX-1127) is an immune modulating antibody that is designed to enhance a patient's immune response against cancer. We established proof of principal in a Phase 1 study with varlilumab, which supported the initiation of several combination studies in various indications. We also have a number of earlier stage drug candidates in clinical development, including CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APCs, for cancer indications; CDX-301, an immune cell mobilizing agent and dendritic cell growth factor; and CDX-014, an antibody-drug conjugate targeting renal and ovarian cancers. In November 2016, we completed the acquisition of Kolltan Pharmaceuticals, Inc. (Kolltan), a privately held company focused on the discovery and development of novel, antibody-based drugs targeting receptor tyrosine kinases (RTKs). This acquisition added the following drug candidates to our clinical pipeline: CDX-0158 (formerly KTN0158), a humanized monoclonal antibody (mAb) currently in a Phase 1 dose escalation study in refractory gastrointestinal stromal tumors (GIST) and other KIT positive tumors; and, CDX-3379 (formerly KTN3379; MEDI3379), a human monoclonal antibody which recently completed a Phase 1b study in patients with solid tumors. We also acquired the TAM program, a broad antibody discovery effort to generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AXL and MerTK, which are expressed on tumor-infiltrating macrophages, dendritic cells and some tumors. Our drug candidates address market opportunities for which we believe current cancer therapies are inadequate or non-existent.

We are building a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. 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.

The following table reflects Celldex-sponsored clinical studies that we are actively pursuing at this time. All programs are currently fully-owned by Celldex.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Triple negative breast cancer	Phase 2b	Celldex
Glembatumumab vedotin	Metastatic melanoma (with varlilumab or CPI*)	Phase 2	Celldex
Varlilumab	Multiple solid tumors (with nivolumab)	Phase 2	Celldex**
CDX-0158	Gastrointestinal and other KIT-postive tumors	Phase 1	Celldex
CDX-3379	Multiple solid tumors (in combination regimens)	Phase 1	Celldex
CDX-014	Renal cell carcinoma	Phase 1	Celldex

* checkpoint inhibitor

** BMS collaboration

We also routinely work with external parties, such as government agencies, to collaboratively advance our drug candidates. The following pipeline reflects clinical trials of our drug candidates being actively pursued by outside organizations. In addition to the studies listed below, we also have an Investigator Initiated Research (IIR) program with seven studies ongoing with our drug candidates and additional studies currently under consideration.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Uveal melanoma	Phase 2	NCI (CRADA)
Glembatumumab vedotin	Squamous cell lung cancer	Phase 2	PrECOG, LLC
CDX-1401/CDX-301	Multiple solid tumors	Phase 2	CITN

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, as well as any related companion diagnostic tests. 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."

Clinical Development Programs

As previously disclosed, it is our intention to integrate Kolltan without increasing our planned cash burn for 2017. Following the addition of the Kolltan programs, we undertook a full review of our pipeline and associated programs to identify priority areas that we believe have the highest probability of potentially impacting disease while also identifying areas for improved efficiency and cost savings. The adjustments are reflected in the following clinical pipeline program update.

Glembatumumab Vedotin

Glembatumumab vedotin is an antibody-drug conjugate, or ADC, that consists of a fully human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as gpNMB that is over-expressed in a variety of cancers including breast cancer, melanoma, non-small cell lung cancer, uveal melanoma and osteosarcoma, among others. The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. and is the same as that used in the marketed product Adcetris®. The ADC is designed to be stable in the bloodstream. Following intravenous administration, glembatumumab vedotin targets and binds to gpNMB, and upon internalization into the targeted cell, glembatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. Glembatumumab vedotin is being studied across multiple indications in company-sponsored trials and in collaborative studies with external parties. The Food and Drug Administration, or FDA, has granted Fast Track designation to glembatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer. A companion diagnostic is in development for certain indications, and we expect that, if necessary, such a companion diagnostic must be approved by the FDA or certain other foreign regulatory agencies before glembatumumab vedotin may be commercialized in those indications.

Treatment of Metastatic Breast Cancer: The Phase 1/2 study of glembatumumab vedotin administered intravenously once every three weeks evaluated patients with locally advanced or metastatic breast cancer (MBC) who had received prior therapy (median of seven prior regimens). Results were published in the *Journal of Clinical Oncology* in September 2014. The study began with a bridging phase to confirm the maximum tolerated dose, or MTD, and then expanded into a Phase 2 open-label, multi-center study. The study supported an acceptable safety profile of glembatumumab

vedotin at the pre-defined maximum dose level (1.88 mg/kg) in 6 patients. An additional 28 patients with MBC were enrolled in an expanded Phase 2 cohort (for a total of 34 treated patients at 1.88 mg/kg, the Phase 2 dose) to evaluate the progression-free survival (PFS) rate at 12 weeks. The 1.88 mg/kg dose exhibited an acceptable safety profile in this patient population with the most common adverse events being rash, neuropathy and fatigue. The primary anti-cancer activity endpoint, which called for at least 5 of 25 (20%) patients in the Phase 2 study portion to be progression-free at 12 weeks, was met as 9 of 27 (33%) evaluable patients were progression-free at 12 weeks. For all patients treated at the Phase 2 dose, median PFS was 9.1 weeks.

A subset of 10 patients had "triple negative disease," a more aggressive metastatic breast cancer subtype that carries a high risk of relapse and reduced survival as well as limited therapeutic options. In these patients, the 12-week PFS rate was 60% (6/10), and median PFS was 17.9 weeks. Tumor samples from a subset of patients across all dose groups were analyzed for gpNMB expression. The tumor samples from most patients showed evidence of stromal and/or tumor cell expression of gpNMB.

The subsequent EMERGE study was a randomized, multi-center Phase 2b study of glembatumumab vedotin in 124 patients with heavily pre-treated, advanced, gpNMB-positive breast cancer. Results from EMERGE were published in the *Journal of Clinical Oncology* in April 2015. Patients were randomized (2:1) to receive either glembatumumab vedotin or single-agent Investigator's Choice chemotherapy. Patients randomized to receive Investigator's Choice were allowed to cross over to receive glembatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and overall survival (OS). The final study results, as shown below, suggested that glembatumumab vedotin induced significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high gpNMB expression (expression in at least 25% of tumor cells) and in patients with triple negative breast cancer. The OS and PFS of patients treated with glembatumumab vedotin were also observed to be greatest in patients with high gpNMB expression and, in particular, in patients with triple negative breast cancer who also had high gpNMB expression.

EMERGE: Overall Response Rate and Disease Control Data (Intent-to-Treat Population)

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glembatumumab Vedotin (n=23)	Investigator's Choice (n=11)	Glembatumumab Vedotin (n=10)	Investigator's Choice (n=6)
Response Rate	30%	9%	40%	0%
Disease Control Rate	65%	27%	90%	17%

Tumor response assessed by RECIST 1.1, inclusive of response observed at a single time point.

EMERGE: Progression Free Survival (PFS) and Overall Survival (OS) Data

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glembatumumab Vedotin	Investigator's Choice	Glembatumumab Vedotin	Investigator's Choice
Median PFS (months)	2.8 p=0.18	1.5	3.5 p=0.0017	1.5
Median OS (months)	10.0 p=0.31	5.7	10.0 p=0.003	5.5

In December 2013, we initiated METRIC, a randomized, controlled Phase 2b study of glembatumumab vedotin in patients with triple negative breast cancer that over-expresses gpNMB. Clinical trial study sites are open to enrollment across the U.S., Canada, Australia and the European Union. The METRIC protocol was amended in late 2014 based on feedback from clinical investigators conducting the study that the eligibility criteria for study entry were limiting their ability to enroll patients they felt were clinically appropriate. In addition, we had spoken to country-specific members of the European Medicines Agency, or EMA, and believed an opportunity existed to expand the study into the EU. The amendment expanded patient entry criteria to position it for the possibility of full marketing approval with global regulators, including the EMA, and to support improved enrollment in the study. The primary endpoint of the study is PFS as PFS is an established endpoint for full approval registration studies in this patient population in both the U.S. and the EU. The sample size (n=300) and the secondary endpoint of OS remained unchanged. Since implementation of these changes, both the FDA and central European regulatory authorities have reviewed the protocol design, and we believe the METRIC study could potentially support marketing approval in both the U.S. and Europe dependent upon data results and review. Based on consistent improvements in enrollment trends to the METRIC study over the last several months, we anticipate that study enrollment will be completed by the end of September 2017. Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic, including partnering with a diagnostic company, are underway.

Treatment of Metastatic Melanoma: The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glembatumumab vedotin in 117 patients with unresectable stage III or IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD and resulting Phase 2 dose was determined to be 1.88 mg/kg administered intravenously once every three weeks. The study achieved its primary activity objective with an overall response rate (ORR) in the Phase 2 cohort of 15% (5/34). Median PFS was 3.3 months for patients treated with the Phase 2 dose. Glembatumumab vedotin was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, alopecia, pruritus, diarrhea and nausea. The development of rash, which may be associated with the presence of gpNMB in the skin, also seemed to correlate with greater PFS.

In December 2014, we initiated a single arm, single-agent, open-label Phase 2 study of glembatumumab vedotin in patients with unresectable stage III or IV melanoma (n=60) and enrollment has been completed. In May 2016, we amended the protocol to add a second cohort of patients to a glembatumumab vedotin and varlilumab combination arm to assess the potential clinical benefit of the combination and to explore varlilumab's potential biologic and immunologic effect when combined with an ADC. In November 2016, we amended the protocol again to add a third cohort of patients evaluating glembatumumab vedotin in combination with an approved checkpoint inhibitor (i.e., nivolumab or pembrolizumab) following progression on the checkpoint inhibitor alone. Both additional cohorts are open to enrollment. The primary endpoint for each cohort is ORR. Secondary endpoints include analyses of PFS, duration of response, OS, retrospective investigation of whether the anti-cancer activity of glembatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety of both the monotherapy and combination regimens.

We presented data from the single-agent cohort at the European Society for Medical Oncology (ESMO) Congress in October 2016. The cohort enrolled 62 evaluable patients with unresectable stage III (n=1; 2%) or stage IV (n=61; 98%) melanoma. All patients had progressed after checkpoint inhibitor therapy, and almost all patients had received both ipilimumab (n=58; 94%) and anti-PD-1/anti-PDL-1 (n=58; 94%) therapy. Twelve patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents. The primary endpoint of the cohort (6 or more objective responses in the first 52 patients enrolled) was exceeded. Seven of 62 (11%) patients experienced a confirmed response, and an additional three patients also experienced

single timepoint responses. The median duration of response was 6.0 months. A 52% disease control rate (patients without progression for greater than three months) was demonstrated and median PFS for all patients was 4.4 months. In addition, patients who experienced rash in the first cycle of treatment had a 20% confirmed response rate and a more prolonged PFS of 5.5 months [p=0.054; hazard rating=0.52 (0.27, 1.02)]. We also intend to conduct exploratory analyses of pre-entry skin biopsies in future patients to investigate potential predictors of response to glembatumumab vedotin, given the potential association of rash and outcome.

Treatment of Other Indications: We have entered into a collaborative relationship with PrECOG, LLC, which represents a research network established by the Eastern Cooperative Oncology Group (ECOG), under which PrECOG, LLC, is conducting an open-label Phase 1/2 study in patients with unresectable stage IIIB or IV, gpNMB-expressing, advanced or metastatic squamous cell carcinoma (SCC) of the lung, who have progressed on prior platinum-based chemotherapy. This study opened to enrollment in April 2016. The study includes a dose-escalation phase followed by a two-stage Phase 2 portion (Simon two-stage design). The Phase 1, dose-escalation portion of the study will assess the safety and tolerability of glembatumumab vedotin at the current dose of 1.9 mg/kg and then 2.2 mg/kg in order to determine whether higher dosing is feasible in this population. The first stage of the Phase 2 portion plans to enroll approximately 20 patients, and if at least two patients achieve a partial response or complete response, a second stage may enroll an additional 15 patients. The primary objective of the Phase 2 portion of the study is to assess the anti-tumor activity of glembatumumab vedotin in squamous cell lung cancer as measured by ORR. Secondary objectives of the study include analyses of safety and tolerability and further assessment of anti-tumor activity across a broad range of endpoints.

We have also entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, under which NCI is sponsoring two studies of glembatumumab vedotin—one in uveal melanoma and one in osteosarcoma. The uveal melanoma study is a single-arm, open-label study in patients with locally recurrent or metastatic uveal melanoma and is currently open to enrollment. The primary outcome measure is ORR. Secondary outcome measures include change in gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. We expect data from this study will be presented at a future medical meeting in the first half of 2017. The osteosarcoma study is a single-arm, open-label, evaluation of adolescent and adult patients with recurrent or refractory osteosarcoma. The co-primary objectives are to determine whether glembatumumab vedotin therapy either increases the disease control rate at 4 months in patients with recurrent measurable osteosarcoma as compared to historical experience and/or whether glembatumumab vedotin therapy produces an objective response rate greater than 20% in patients without previous eribulin (eribulin mesylate) treatment. Secondary outcome measures include safety, pharmacokinetics and the relation of gpNMB expression as measured by immunohistochemistry to clinical response. The study had a two stage design with a pre-specified activity threshold necessary in the first stage to progress enrollment to the second stage. The study did not meet the activity threshold for progressing to stage 2 and therefore no additional patients will be enrolled. We expect data from this study will be presented at a future medical meeting.

Varlilumab

Varlilumab is a fully human monoclonal agonist 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 *vitro* and *in vivo* models. We have entered into license agreements with

the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (acquired by Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. 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. Currently, we are focusing our efforts on a Phase 1/2 clinical trial being conducted in collaboration with BMS and their PD-1 immune checkpoint inhibitor, Opdivo. Varlilumab is also being explored in combination studies, including with glembatumumab vedotin, and in ongoing and planned investigator-sponsored studies.

Single-Agent Phase 1 Study: Data from the completed, open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers were presented in November 2014. Varlilumab to date has shown 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 were dosed in the study at multiple clinical sites in the U.S. of which 56 patients were dosed in dose escalation cohorts (various solid and hematologic B-cell tumors), and 34 patients were dosed in the expansion cohorts (melanoma and RCC) at 3 mg/kg. In both the solid tumor and hematologic dose-escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of a maximum tolerated dose. The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, with only three serious AEs related to treatment reported. No significant immune-mediated adverse events (colitis, hepatitis, etc.) typically associated with checkpoint blockade have been observed to date. Two patients experienced significant objective responses including a complete response in Hodgkin lymphoma (continued at 33.1+ months as of September 2016; patient no longer on study) and a partial response in renal cell carcinoma of 27.7+ months (as of September 2016). Thirteen patients experienced stable disease with a range of 3-47.3+ months (as of September 2016). As of December 2016, there are two patients continuing in long term follow-up.

Phase 1/2 Varlilumab/Opdivo® Combination Study: In May 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, Bristol-Myers Squibb made a one-time payment to us of $5.0 million, and the companies amended the terms of our existing license agreement with Medarex (acquired by Bristol-Myers Squibb) related to our CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from us to Medarex. In return, Bristol-Myers Squibb was granted a time-limited right of first negotiation if we wish to out-license varlilumab. The companies also agreed to work exclusively with each other to explore anti-PD-1 antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that we will be responsible for conducting the Phase 1/2 study.

The Phase 1/2 study was initiated in January 2015 and is being conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts. The Phase 1 dose escalation portion of the study, conducted in patients with solid tumors, has completed enrollment (n=36) and primarily enrolled patients with colorectal and ovarian cancer.

Data were presented from the Phase 1 portion of the varlilumab and Opdivo study in a poster at the American Association for Cancer Research (AACR) Annual Meeting in April 2016. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination showed acceptable tolerability and safety across all dose levels without

any evidence of increased autoimmunity or inappropriate immune activation. Marked changes in the tumor microenvironment including increased infiltrating CD8+ T cells and increased PD-L1 expression, which have been shown to correlate with a greater magnitude of treatment effect from checkpoint inhibitors in other clinical studies were observed. Additional evidence of immune activity, such as increase in inflammatory chemokines and decrease in T regulatory cells, were also noted. In a subset of patients (n=17) on study who had both pre- and post-tumor biopsies available, preliminary evidence suggest a correlation between biomarker data and stable disease or better in seven of these patients (4 ovarian cancer, 2 colorectal cancer, 1 squamous cell carcinoma of the head and neck). All dose levels of the combination therapy showed an acceptable tolerability and safety profile, without identification of a maximum tolerated dose. In the Phase 2 portion of the study, varlilumab is administered at 3 mg/kg in the majority of cohorts, based upon cumulative data across multiple studies.

The Phase 2 portion of the study opened to enrollment in April 2016 and includes cohorts in colorectal cancer (n=18), ovarian cancer (n=54), head and neck squamous cell carcinoma (n=54), renal cell carcinoma (n=25) and glioblastoma (n=20). Based on a recent protocol amendments, additional dosing schedules are being explored in ovarian cancer (versus renal cell carcinoma) and, as previously disclosed, in head and neck squamous cell carcinoma, increasing the overall size of the study compared to the original study design. The primary objective of the Phase 2 cohorts is ORR, except glioblastoma, where the primary objective is the rate of 12-month overall survival. Secondary objectives include pharmacokinetics assessments, determining the immunogenicity of varlilumab when given in combination with Opdivo and further assessing the anti-tumor activity of combination treatment. We plan to complete enrollment across all cohorts in the Phase 2 portion of the study in the first quarter of 2018 and will work with BMS to present data from the study at a future medical meeting.

Phase 1/2 Varlilumab/Tecentriq® Combination Study: In March 2015, we entered into a clinical trial collaboration with Roche to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Tecentriq (anti-PDL1), Roche's cancer immunotherapy, in a Phase 1/2 study. Under the terms of this agreement, Roche is providing study drug, and we are responsible for conducting and funding the study. The Phase 1 portion of the study is being conducted in bladder cancer and renal cell carcinoma, and the primary outcome is safety and tolerability. The Phase 1 portion of the study completed enrollment in the third quarter of 2016. Patients continue to be followed, and we expect data from this study will be presented at a future medical meeting. Given the advancement of varlilumab into a broad Phase 2 study in combination with Opdivo and our efforts to identify areas for cost-containment, we will not be advancing the varlilumab/Tecentriq study to Phase 2.

Phase 1/2 Varlilumab/Sutent® Combination Study: In May 2015, we initiated a Phase 1/2 safety and tolerability study examining the combination of varlilumab and Sutent in patients with metastatic clear cell renal cell carcinoma. The Phase 1 portion of the study assesses the safety and tolerability of varlilumab at varying doses when administered with Sutent. The Phase 1 portion of the study completed enrollment in the fourth quarter of 2016. Patients continue to be followed, and data from this study will be presented at a future medical meeting. Given the advancement of varlilumab into a broad Phase 2 study in combination with Opdivo and our efforts to identify areas for cost-containment, we will not be advancing the varlilumab/Sutent study to Phase 2.

Phase 1/2 Varlilumab/Yervoy® +/- CDX-1401 Combination Study: In April 2015, we initiated a Phase 1/2 safety pilot and expansion study examining the combination of varlilumab and Yervoy in patients with stage III or IV metastatic melanoma. Since initiating the study, the standard of care has evolved, and there has been increasing physician reluctance to use Yervoy in this setting. As such, given the broad development strategy in place for varlilumab, as previously disclosed, this study was closed to enrollment in the third quarter of 2016.

CDX-0158

CDX-0158 (formerly KTN0158), is a humanized monoclonal antibody designed to inhibit KIT activation in tumor cells and mast cells. KIT is expressed in many tumor types including gastrointestinal stromal tumors (or GIST), sarcomas, small cell lung cancer, melanoma, acute myeloid leukemia (AML) and mast cell leukemia. It has also been implicated in asthma and neurofibromatosis. We are currently developing CDX-0158 for the treatment of GIST. Small molecule drugs currently approved to treat GIST inhibit mutant KIT, but acquired resistance develops via secondary, drug-resistant KIT mutations in the majority of patients over time. CDX-0158 is designed to uniquely prevent KIT activation by inhibiting both receptor dimerization and ligand binding. CDX-0158 has demonstrated preclinical activity versus the most common c-KIT mutations in human GIST, including treatment of mastocytoma in a canine model.

A Phase 1 dose escalation study in patients with advanced refractory GIST and other KIT positive tumors opened to enrollment in December 2015 to determine the maximum tolerated dose, recommend a dose for further study and characterize the safety profile. Enrollment is ongoing. Upon completion of Phase 1 assuming a successful outcome, we plan to develop CDX-0158 in patients with refractory GIST given the significant unmet need for these patients.

Preclinical data published in *Molecular Cancer Therapeutics* in January 2017 demonstrate that KIT inhibition in certain immune cells with CDX-0158 enhances the activity of checkpoint blockade, providing additional opportunities for combination therapy. This mechanism may also be effective with other immunotherapies, in particular with our CD27 agonist, varlilumab.

CDX-3379

CDX-3379 (formerly KTN3379 and MEDI3379) 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. 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.

A Phase 1a/1b study was conducted, including a single-agent dose-escalation portion and combination expansion cohorts. Data from the dose-escalation portion, which completed enrollment in September 2015, and initial data from the expansion cohorts (enrollment ongoing at the time) were presented at the American Society of Clinical Oncology Annual Meeting in June 2016. The single-agent dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. The most common adverse events included rash and diarrhea and were predominantly grade 1 or 2. 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=4) 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 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. We are currently exploring plans for advancement into Phase 2 study.

CDX-1401

CDX-1401, developed from our APC Targeting Technology, is an NY-ESO-1-antibody fusion protein for immunotherapy in multiple solid tumors. CDX-1401, which is administered with an adjuvant, is composed of the cancer-specific antigen NY-ESO-1 fused to a fully human antibody that binds to DEC-205 for efficient delivery to dendritic cells. Delivery of tumor-specific proteins directly to dendritic cells *in vivo* elicits potent, broad, anti-tumor immune responses across populations with different genetic backgrounds. In humans, NY-ESO-1 has been detected in 20% to 30% of melanoma, lung, esophageal, liver, gastric, ovarian and bladder cancers, and up to 70% of synovial sarcomas, thus representing a broad opportunity. We are developing CDX-1401 for the treatment of malignant melanoma and a variety of solid tumors which express the cancer antigen NY-ESO-1, which we licensed from the Ludwig Institute for Cancer Research in 2006. Preclinical studies have shown that CDX-1401 treatment results in activation of human T cell responses against NY-ESO-1.

We have completed a Phase 1 study of CDX-1401 which assessed the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 with TLR agonists (resiquimod and/or poly-ICLC) in 45 patients with advanced malignancies refractory to all available therapies. Results were published in *Science Translational Medicine* in April 2014. Sixty percent of patients had confirmed NY-ESO expression in archived tumor samples. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment indicates an acceptable safety profile to date, and there were no dose limiting toxicities. A variety of immune activation parameters were observed. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 56% of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and poly-ICLC alone and in combination. Long-term patient follow up suggested that treatment with CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. Of the 45 patients in the Phase 1 study, eight went on to receive subsequent therapy of either Yervoy or an investigational checkpoint inhibitor, and six of these patients had objective tumor regression. Six patients with melanoma received Yervoy within three months of treatment with CDX-1401, and four (67%) had objective tumor responses, including one complete response, which compares favorably to the overall response rate of 11% previously reported in metastatic melanoma patients treated with single-agent Yervoy. In addition, two patients with non-small cell lung cancer received an investigational checkpoint blockade within two months of completing treatment with CDX-1401, and both achieved partial responses. Together with Roche, we are

supporting an investigator initiated study of CDX-1401 in combination with Tecentriq® in patients with lung cancer.

CDX-1401's potential activity is being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-1401 in combination with CDX-301 is being conducted in metastatic melanoma by the Cancer Immunotherapy Trials Network (CITN) under a CRADA with the Cancer Therapy Evaluation Program of the NCI. This study was designed to determine the activity of CDX-1401 with or without CDX-301 in melanoma. The primary outcome measure of the study is immune response to NY-ESO-1. Secondary outcome measures include analysis and characterization of peripheral blood mononuclear cells (dendritic cells, T cells, natural killer cells, etc.), additional immune monitoring, safety and clinical outcomes (survival and time to tumor recurrence). Enrollment is complete and initial results were presented in June at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The data confirmed that CDX-1401 is capable of driving NY-ESO-1 immunity and further demonstrated the potential of CDX-301 as a combination agent for enhancing tumor specific immune responses. The NCI and CITN are planning to enroll additional cohorts to investigate alternative regimens of CDX-301. Other studies are being considered through investigator-sponsored and collaborative agreements.

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 in combination with other agents to potentiate the anti-tumor response. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. CDX-301 is in clinical development for multiple cancers, in combination with vaccines, adjuvants and other treatments that release tumor antigens. We licensed CDX-301 from Amgen Inc. in March 2009 and believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio.

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 hematopoietic stem cell (HSC) populations in healthy volunteers. Based on the safety profile and the clinical and preclinical data to date, we initiated a pilot clinical study of CDX-301 for the mobilization and transplantation of allogeneic hematopoietic stem cells in patients with hematological malignancies undergoing hematopoietic stem cell transplantation. Preliminary results from this Phase 2 study were presented at the annual meeting of the American Society for Blood and Marrow Transplantation in February 2016. These preliminary data from three donor/patient pairs showed that CDX-301 given as a single agent has an acceptable safety profile and mobilized hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naïve lymphocytes and plasmacytoid dendritic cells consistent with preclinical data suggesting a possible better outcome. Recipients experienced successful engraftment in an expected time frame. Given that hematopoietic stem cell transplantation is outside of our core focus, in an effort to prioritize human and capital resources, we announced in May 2016 that we decided not to advance CDX-301 in this particular indication at this time.

In June, at the 2016 ASCO Annual Meeting, initial results from a Phase 2 study of CDX-1401 in combination with CDX-301 in metastatic melanoma were presented that further demonstrated the value of CDX-301 as a combination agent for enhancing tumor specific immune responses. The Phase 2 study was conducted by the Cancer Immunotherapy Trials Network, or CITN, under a CRADA with the Cancer Therapy Evaluation Program of the NCI. Based on these results the CITN is planning to enroll additional cohorts to investigate alternative regimens of CDX-301. Other studies are being considered through investigator-sponsored and collaborative agreements.

CDX-014

CDX-014 is a human monoclonal ADC that targets T cell immunoglobulin and mucin domain 1, or TIM-1. TIM-1 expression is upregulated in several cancers, most notably renal cell and ovarian carcinomas, and is associated with a more malignant phenotype of renal cell carcinoma (RCC) and tumor progression. TIM-1 has restricted expression in healthy tissues, making it potentially amenable to an ADC approach. The TIM-1 antibody is linked to MMAE using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 has shown anti-tumor activity in preclinical models of ovarian and renal cancer. In July 2016, we announced that enrollment had opened in a Phase 1/2 study of CDX-014 to patients with both clear cell and papillary RCC. The Phase 1 dose-escalation portion of the study is evaluating cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study. We anticipate the Phase 1 dose-escalation portion of the study will complete enrollment by year-end 2017. The Phase 2 portion of the study plans to enroll approximately 25 patients to assess the anti-tumor activity of CDX-014 at the recommended dose in advanced renal cell carcinoma as measured by objective response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

Rintega

On March 7, 2016, we announced that our Phase 3 study of Rintega® in patients with newly diagnosed EGFRvIII-positive glioblastoma was being discontinued. This decision was made based on the outcome of a preplanned interim analysis conducted by an independent Data Safety and Monitoring Board (DSMB). The DSMB determined that continuation of the study would not result in reaching statistical significance for the primary endpoint of the study, overall survival in patients with minimal residual disease, as both the Rintega arm and the control arm were performing on par with each other. In the ACT IV study, Rintega performed consistently with prior Phase 2 studies but the control arm significantly outperformed expectations (Hazard ratio = 0.99; median OS: Rintega 20.4 months vs. control 21.1 months). Based on this recommendation, we discontinued the study. Data from the ACT IV study were presented at the Society for Neuro-Oncology Annual Meeting in November 2016. All patients on the Rintega arm of the ACT IV study, prior Phase 2 studies and existing compassionate use recipients have been offered ongoing access to Rintega on a compassionate use basis, and we continue to support new requests for compassionate use in recurrent glioblastoma on a limited basis. Study closure activities are complete, and we continue to anticipate that we will not incur substantial additional costs related to Rintega.

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.

Our intent is to leverage this knowledge and the availability of good, tested products that may not have optimal clinical activity as a monotherapy, but 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, including glembatumumab vedotin. 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 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

We and Medarex have entered into an assignment and license agreement, as amended, that provides for the assignment of certain patent and other intellectual property rights and a license to certain Medarex technology related to the Company's APC Targeting Technology™ and an anti-mannose receptor product. Under the terms of the agreement, we may be required to pay royalties

in the low-single digits on any net product sale of a Licensed Royalty-Bearing Product or Anti-Mannose Product to Medarex 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.

We and Medarex have also entered into a research and commercialization agreement, as amended, that provides that we may be required to pay Medarex milestones of up to $7.0 million upon obtaining first approval for commercial sale in a first indication of a product containing a licensed antibody and royalty payments in the low-to-mid single digits on any net product sales with respect to the development of any products containing such licensed antibodies 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. In September 2010, we exercised an option under our research and commercialization agreement, whereby we licensed from Medarex access to the UltiMab technology to develop and commercialize human antibodies to CD27, including varlilumab. In connection with the clinical trial collaboration we entered into with BMS in May 2014, we and BMS agreed to waive certain future milestone payments and to reduce future royalty rates that we may have owed Medarex in connection with any CD27 program.

Rockefeller University (Rockefeller)

In November 2005, we and Rockefeller entered into a license agreement for the exclusive worldwide rights to human DEC-205 receptor, with the right to sublicense the technology. The license grant is exclusive except that Rockefeller may use and permit other nonprofit organizations to use the human DEC-205 receptor patent rights for educational and research purposes. We may be required to pay Rockefeller milestones of up to $3.8 million upon obtaining first approval for commercial sale in a first indication of a product targeting the licensed receptor and royalty payments in the low-to-mid single digits on any net product sales with respect to development and commercialization of the human DEC-205 receptor.

University of Southampton, UK (Southampton)

In November 2008, we entered into a license agreement with Southampton 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)

In March 2009, we entered into a license agreement with Amgen to acquire 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.

Amgen Fremont (formerly Abgenix)

In connection with our acquisition of CuraGen Corporation in 2009, we assumed the license agreement between CuraGen and Amgen Fremont (successor in-interest to Abgenix) to develop fully-human monoclonal antibody therapeutics. In May 2009, an amendment to the license agreement was entered into related to CuraGen's exclusive rights to develop and commercialize glembatumumab vedotin, CDX-014 and antibodies to 10 other licensed antigens. Under the amendment, CuraGen and

Amgen Fremont agreed to modify the terms of their existing cross-license of antigens whereby our amended license is fully paid-up and royalty-free.

Seattle Genetics, Inc. (Seattle Genetics)

In connection with our acquisition of CuraGen, we assumed the license agreement between CuraGen and Seattle Genetics whereby CuraGen acquired the rights to proprietary ADC technology, with the right to sublicense, for use with its proprietary antibodies for the potential treatment of cancer. Under the terms of the agreement, we have the responsibility of using commercially reasonable efforts to develop, commercialize and market such treatment. In furtherance of these responsibilities, technical assistance from Seattle Genetics is available to us as necessary. We may be required to pay Seattle Genetics milestones of up to $5.0 million and $8.5 million for glembatumumab vedotin and CDX-014, respectively, upon obtaining first approval for commercial sale in a first indication and royalty payments in the mid-single digits on any net product sales with respect to development and commercialization of these drug candidates. The term of the agreement varies country to country and may be until the later of the expiration of the last relevant patent or the 10 th anniversary of the first commercial sale. The agreement allows us to terminate with prior written notice, with both parties being able to terminate the agreement for an uncured material breach or insolvency of the other party.

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.

Competitors that we are aware of that have initiated a pivotal study or have obtained marketing approval for a potential competitive drug/device for glembatumumab vedotin in the treatment of breast cancer include AbbVie, Astellas, AstraZeneca, Bristol-Myers Squibb, Immunomedics, Merck, Nektar, Novartis, Pfizer, Roche, and Tesaro.

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 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 have limited experience in commercial manufacturing. Our ability to conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates will depend on the ability of such third parties to manufacture our drug candidates on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices, or cGMP, and U.S. and foreign regulatory requirements, if applicable. We rely on contract manufacturing organizations, or CMO, to manufacture mAb intermediate, drug substance, and drug candidate for our late-stage clinical study of glembatumumab vedotin as well as for potential future commercial supplies. We also rely on CMOs for packaging, labeling, 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. 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.

To date, we have utilized CMOs for the manufacture of clinical trial supplies of glembatumumab vedotin. In the second half of 2016, we established a relationship with Patheon Biologics in Brisbane, Australia to manufacture the glembatumumab vedotin mAb intermediate due to being informed by Lonza Biologics, our previous CMO, that the bioreactors used to manufacture glembatumumab vedotin will be decommissioned and would not be available for commercialization. We also have a relationship with Piramal Healthcare UK Ltd. to manufacture the antibody drug conjugate with the vcMMAE linker-toxin. The drug substance is then filled and packaged at Piramal Lexington or BSP Pharma. We rely on MilliporeSigma for supplying suitable quantities of vcMMAE. Any manufacturing failures or delays by our glembatumumab vedotin contract manufacturers or suppliers of materials could cause delays in our glembatumumab vedotin clinical studies, including the METRIC study and/or a BLA filing and, if regulatory approval is obtained, commercial launch of glembatumumab vedotin.

We also utilize CMOs for the manufacture of varlilumab for global clinical trials and potential commercialization. We have established relationships with Patheon Biologics in St. Louis for the manufacture of varlilumab drug substance and Vetter Pharma for the manufacture of varlilumab drug product. Any manufacturing failures or delays by our varlilumab CMOs could cause delays in our varlilumab clinical studies.

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-1401, CDX-301 and CDX-1140 drug substance and CDX-014 mAb intermediate in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials. CDX-014, an antibody-drug conjugate, is then manufactured by Lonza (Visp). We expect that our existing clinical supplies of CDX-3379 and CDX-0158 will be sufficient to carry out our current planned clinical development. Additional manufacturing is 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.

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.

We currently rely on sole suppliers for key components of our drug candidates, including vcMMAE for glembatumumab vedotin and Hiltonol® for CDX-1401. While we work with the suppliers of these key components to ensure continuity of supply, no assurance can be given that these efforts will be successful. In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. If our suppliers were to terminate our arrangements or fail to meet our supply needs we might be forced to delay our development programs or we could face disruptions in the distribution and sale of any drugs for which we obtain regulatory approval.

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 a focused commercial team with broad experience in marketing, sales, distribution and product reimbursement. We have also developed the capability to provide current and future market insights to our research and development organization regarding glembatumumab vedotin and our earlier-stage 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. We may also choose to enter into strategic partnerships to develop, sell, market and distribute our other drug candidates, including glembatumumab vedotin.

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 300 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 do not include any possible Patent Term Extensions (PTEs) or Supplementary Protection Certificates (SPCs), if these may be secured in due course):

- Our patent portfolio for glembatumumab vedotin includes issued patents in the U.S., Europe, Japan, Australia and Canada. If maintained to full term in due course, these would have estimated patent expiry dates in 2025. In addition, patent rights relating to the toxin and conjugation technology used in glembatumumab vedotin have been licensed from Seattle Genetics. The patent rights from Seattle Genetics include issued patents and pending applications in Australia, Canada, Europe, the U.S. and Japan which include composition of matter claims relating to the toxin and conjugation technology. If maintained to full term in due course, the main Seattle Genetics patent rights would have estimated patent expiry dates ranging from 2023 in Europe to 2026 in the U.S.

- 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. Further patent applications are also pending in the U.S., Europe and Japan. 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 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. We intend to appeal this decision and 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 patent applications in the major international territories which, if issued and maintained to full term in due course, would have estimated patent expiry dates in 2031.

- We have issued U.S. patents relating to the technology used in CDX-1401 which have estimated patent expiry dates in at least 2028 (not including increases of term due to Patent Term Adjustment). We have a corresponding issued European patent and further patents and pending patent applications in other international territories (including Japan, Australia, Canada, China, India, Republic of Korea and certain other countries) relating to the technology used in CDX-1401 which, if and where issued and maintained to full term in due course, would have estimated patent expiry dates in 2028.

- The U.S. patent for the technology used in CDX-301 has an estimated expiration date in 2020.

- Our patent portfolio for CDX-014 includes rights under issued U.S., European and Canadian patents and pending patent applications in Australia and Japan. If and where issued and maintained to full term in due course, these filings would have estimated patent expiry dates in at least 2024 (not including increases of term due to Patent Term Adjustment in the U.S.). In addition, patent rights relating to toxin and conjugation technology have been licensed from Seattle Genetics. The patent rights from Seattle Genetics include issued patents and pending patent applications in Australia, Canada, Europe, the U.S. and Japan which include composition of matter claims relating to the toxin and conjugation technology. If maintained to full term in due course, the main Seattle Genetics patent rights would have estimated patent expiry dates ranging from 2023 in Europe to 2026 in the U.S.

- We have exclusively licensed a portfolio of patent applications relating to particular ErbB3 inhibitors from MedImmune. These 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. A U.S. Patent has been issued which has an estimated patent expiry date in 2032. Patent applications in this portfolio are pending in Europe, Japan, Australia, Canada, China, 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. These are the estimated expirations if we continue to pay the maintenance fees and annuities when due, and do not include any possible additional terms for Patent Term Adjustments, Patent Term Extensions or SPCs if these may be secured in due course.

- We own a family of patents and patent applications directed to anti-KIT receptor antibody compositions of matter, including CDX-0158 compositions of matter, and methods of using such antibodies. U.S. patents have been issued and foreign counterparts to patent applications in this family are pending in Europe, Japan, Australia, Canada, China, India, Republic of Korea and certain other countries. If and where issued the foregoing would have estimated patent expiry dates ranging from at least 2032 to 2033. We also have pending U.S. and European patent applications directed to use of anti-KIT receptor antibodies, including CDX-0158 antibodies, for treatment of particular eosinophil or mast cell related disorders, including neurofibromatosis. Any patents that issue based on these patent applications would have estimated patent expiry dates in 2035. These are the estimated expirations if we continue to pay the maintenance fees and annuities when due, and do not include any possible additional terms for Patent Term Adjustments, Patent Term Extensions or SPCs if these may be secured in due course.

- 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 2028. These are the estimated expirations if we continue to pay the maintenance fees and annuities when due, and do not include any possible additional terms for Patent Term Adjustments, Patent Term Extensions or SPCs if these may be secured in due course.

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 applications in the United States and foreign countries covering particular antigens and antigenic fragments targeted by our current drug candidates, including CDX-1401;

- certain patents and pending applications related to particular receptors and other molecules on dendritic cells and macrophages that may be useful for generating monoclonal antibodies and can be employed in our APC Targeting Technology;

- a United States patent owned by Genentech, Inc., relating to the production of recombinant antibodies in host cells;

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

- a United States patent and certain pending applications assigned to Aduro Biotech Holdings relating to anti-CD27 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 has appealed the decision in the opposition proceeding. We do not know if the appeal will succeed, or, if successful, whether the scope of claims, post-appeal, would be relevant to our activities. Should the appeal be successful and a license be necessary for our program that targets ErbB3, we cannot predict whether we would be able to obtain such a license, or, if a license were available, whether it would be available on commercially reasonable terms. If the appeal results in patents having a valid claim relevant to our use of ErbB3 antibodies and a license under the patents is unavailable on commercially relevant terms, or at all, our ability to commercialize CDX-3379 in Europe may be impaired or delayed. We would vigorously defend ourselves, but we cannot predict whether the patents would be found valid, enforceable or infringed. We also continue to monitor counterparts in other jurisdictions which may entail comparable risks to us in these 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 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. 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 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 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 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.

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 a clinical trial 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.

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 product and establishment user 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 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 process requires 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, which 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, the FDA will 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, some 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 which demonstrate the potential to address unmet medical needs for the condition. 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 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 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 (iv) Rolling Review, which means that a drug company can submit completed sections of its BLA or NDA for review by 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 the FDA 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, or review 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 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 drugs or biologics 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.

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;
- 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 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 BPCI Act 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 BPCI Act provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCI Act, 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 BPCI Act establishes procedures by which the biosimilar applicant must 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 BPCI Act 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 may be applied to our drug candidates in the future and could be applied to allow approval of biosimilars to our products.

The FDA has not yet issued proposed regulations setting forth its interpretation of the BPCIA's provisions but has issued guidance documents related to BPCIA implementation. Because the BPCI Act 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 and decisions in the course of considering specific applications. Such evolution may significantly affect the impact of the BPCI Act 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 healthcare, 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 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 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 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

We expect that some of our drug candidates, including glembatumumab vedotin, will 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 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 privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare 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 healthcare 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 healthcare 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 healthcare 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 our products as 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.

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 healthcare 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 healthcare 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.

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 within, and over the long-term, of the Patient Protection and Affordable Care Act, or PPACA, 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, 2016, we employed 210 employees (205 full-time, 2 part-time and 3 interns), 40 of whom have Ph.D. and/or M.D. degrees. Of these employees, 177 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 $102.7 million, $100.2 million and $104.4 million during the years ended December 31, 2016, 2015 and 2014, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2017 as we continue to advance our drug candidates through clinical development.

Corporate and Available Information

We are incorporated in Delaware. In February 2016, we formed a wholly-owned subsidiary, Celldex Therapeutics Europe GmbH, in Zug, Switzerland. We are in the process of liquidating Celldex Therapeutics Europe GmbH. In July 2016, we formed a wholly-owned subsidiary, Celldex Australia Pty Ltd in Brisbane, Australia.

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.

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.

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 $719.5 million as of December 31, 2016. 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 $132.9 million, $129.5 million and $122.4 million during 2016, 2015 and 2014, respectively, and expect to incur an operating loss in 2017 and beyond. We believe that operating losses will continue in 2017 and beyond because we are planning to incur significant costs associated with the clinical development of our drug candidates and manufacturing of commercial supply to prepare for the potential commercial launch of glembatumumab vedotin if regulatory approval is obtained. During the years ended December 31, 2016, 2015 and 2014, we incurred $24.9 million, $36.3 million, and $45.6 million in clinical trial expense and $18.3 million, $14.8 million, and $21.2 million in contract manufacturing expense. We anticipate clinical trial expense to remain

relatively consistent over the next twelve months as decreases in Rintega costs are offset by increases in the CDX-0158 and CDX-3379 programs, although there may be fluctuations on a quarterly basis. We anticipate contract manufacturing expense to decrease over the next twelve months as decreases in Rintega costs are only partially offset by increases in the CDX-0158 and CDX-3379 programs. 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. In particular, the continuing development and commercialization of glembatumumab vedotin, varlilumab, CDX-0158, CDX-3379 and our other drug candidates requires additional capital beyond our current resources. As of December 31, 2016, we had cash, cash equivalents and marketable securities of $189.8 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
- 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 products under development. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay the build-out of our commercial infrastructure and our commercial planning and preparation activities, 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.

We may pay future milestone consideration to the former Kolltan stockholders. If we are unsuccessful in obtaining stockholder approval for the issuance of common stock, we would pay the milestone consideration to former Kolltan stockholders in cash, in which case we may 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 $172.5 million, which milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both (except with respect to non-accredited former shareholders of Kolltan to whom we will pay cash). Pursuant to applicable NASDAQ listing rules, we are required to

obtain stockholder approval of such issuances of our common stock to the extent that such issuances exceed 19.9% of our common stock outstanding prior to the merger. We plan to seek stockholder approval of such common stock issuances at our 2017 annual meeting. If we do not obtain stockholder approval of such common stock issuances, we may elect to pay the milestone consideration in cash to maintain compliance with applicable NASDAQ listing standards. We may still decide to pay cash even if we obtain stockholder approval although it is 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.

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, including our lead drug candidate, glembatumumab vedotin.

We are particularly dependent on the future success of glembatumumab vedotin because it is our most advanced drug candidate. 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 March 2016, we decided to discontinue ACT IV, a randomized Phase 3 clinical study of Rintega in patients with newly diagnosed EGFRvIII-positive glioblastoma, based on the determination by the independent Data Safety and Monitoring Board that continuation of the ACT IV study would not reach statistical significance for overall survival in patients with minimal residual disease, the primary endpoint of the study, because both the Rintega arm and the control arm were performing on par with each other. 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 glembatumumab vedotin, varlilumab, CDX-0158, CDX-3379 and our other drug candidates. Further, even if we complete the development of glembatumumab vedotin or any of our other 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 glembatumumab vedotin or any other drug candidate, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

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, including glembatumumab vedotin. 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.

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 prevention and 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.

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 product'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.

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 lead products 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.

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.

Product testing is critical to the success of our products 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.

We may have delays in 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 glembatumumab vedotin or any of our other drug candidates in development. Clinical trials for glembatumumab vedotin or any of our other products in development may be delayed or terminated as a result of many factors, including the following:

- difficulty in enrolling patients in our clinical trials;
- 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;
- treatment 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 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 for treating cancer 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 addition, when used in combination with other marketed therapies, our drug candidates may exacerbate adverse events associated with the marketed therapy.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for certain of our drug candidates, including our lead drug candidate glembatumumab vedotin, 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. For example, we have engaged third party collaborators to develop a commercially suitable companion diagnostic test to identify patients that over express gpNMB for use in certain indications with glembatumumab vedotin and such companion diagnostic may encounter technical hurdles to development and would require separate approval by the FDA, for which we must rely on our third party collaborator to obtain. 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 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. Glembatumumab vedotin has been granted Fast Track designation by the FDA. Fast Track designation does not change the standards for approval, guarantee a faster review time as compared to other drugs or ensure that the drug will ultimately obtain marketing approval. In addition, the FDA may withdraw these designations at any time. 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. Competitors that we are aware of that have initiated a pivotal study or have obtained marketing approval for a potential competitive drug/device for glembatumumab vedotin in the treatment of breast cancer include AbbVie, Astellas, AstraZeneca, Bristol-Myers Squibb, Immunomedics, Merck, Nektar, Novartis, Pfizer, Roche, and Tesaro.

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.

A 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.

In the United States, glembatumumab vedotin has received fast track designation and may be eligible for priority review status. If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this

disease or condition, the drug sponsor may apply for FDA fast track designation. If a drug offers major advances in treatment, the drug sponsor may apply for FDA priority review status. The FDA has broad discretion whether or not to grant fast track designation or priority review status, so even if we believe a particular drug candidate is eligible for such designation or status, the FDA could decide not to grant it. Even though glembatumumab vedotin has received fast track designation and may be eligible for priority review status, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Furthermore, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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. Competitors that we are aware of that have initiated a pivotal study or have obtained marketing approval for a potential competitive drug/device for glembatumumab vedotin in the treatment of breast cancer include AbbVie, Astellas, AstraZeneca, Bristol-Myers Squibb, Immunomedics, Merck, Nektar, Novartis, Pfizer, Roche, and Tesaro. 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 and 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.

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 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 for 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 healthcare 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.

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 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 plan to seek approval for glembatumumab vedotin in Europe and may seek approval of our other 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.

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.

The significant third parties who we currently rely on for clinical development activities include PPD Development, LLC for clinical studies including our METRIC study. If any of these third parties, including PPD Development, 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 and commercial grade 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 our late-stage clinical studies of glembatumumab vedotin 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 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.

For our most advanced programs, we are working 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. 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.

To date, we have utilized CMOs for the manufacture of clinical trial supplies of glembatumumab vedotin. In the second half of 2016, we established a relationship with Patheon Biologics in Brisbane to manufacture the glembatumumab vedotin mAb intermediate due to being informed by Lonza Biologics, our previous CMO, that the bioreactors used to manufacture glembatumumab vedotin will be decommissioned and would not be available for commercialization. We also have a relationship with Piramal Healthcare UK Ltd. to manufacture the antibody drug conjugate with the vcMMAE linker-toxin. The drug substance is then filled and packaged at Piramal Lexington or BSP Pharma. We rely on MilliporeSigma for supplying suitable quantities of vcMMAE. Any manufacturing failures or delays by our glembatumumab vedotin contract manufacturers or suppliers of materials could cause delays in our glembatumumab vedotin clinical studies including the METRIC study and/or a BLA filing and, if regulatory approval is obtained, commercial launch of glembatumumab vedotin.

We also utilize CMOs for the manufacture of varlilumab for global clinical trials and potential commercialization. We have established relationships with Patheon Biologics in St. Louis for the manufacture of varlilumab drug substance and Vetter Pharma for the manufacture of varlilumab drug

product. Any manufacturing failures or delays by our varlilumab CMOs could cause delays in our varlilumab clinical studies.

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 clinical trials. We currently manufacture CDX-1401, CDX-301, and CDX-1140 drug substance and CDX-014 mAb intermediate in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials. CDX-014, an antibody-drug conjugate, is then manufactured by Lonza (Visp). We expect our existing clinical supplies of CDX-3379 and CDX-0158 will be sufficient to carry out our current planned clinical development. Additional manufacturing is 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 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 sole suppliers for key components of our drug candidates. Any production problems with our suppliers or other disruptions in the supply of such components could adversely affect us

We currently rely on sole suppliers for key components of our drug candidates, including vcMMAE for glembatumumab vedotin and Hiltonol for CDX-1401. While we work with the suppliers of these key components to ensure continuity of supply, no assurance can be given that these efforts will be successful. In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. If our suppliers were to terminate our arrangements or fail to meet our supply needs we might be forced to delay our development programs or we could face disruptions in the distribution and sale of any drugs for which we obtain regulatory approval.

We currently rely on third party collaborators to develop and commercialize companion diagnostic tests for certain of our drug candidates, including our lead drug candidate glembatumumab vedotin.

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

The loss of Anthony S. Marucci, our President and Chief Executive Officer, or other executive officers or key members of our staff, including Avery W. Catlin, our Chief Financial Officer, Dr. Thomas Davis, our Chief Medical Officer, Dr. Tibor Keler, our Chief Scientific Officer, Dr. Ronald Pepin, our Chief Business Officer, Dr. Richard Wright, our Chief Commercial Officer, Elizabeth Crowley, our Chief Product Development Officer and Theresa LaVallee, our Senior Vice President, Regulatory and Precision Medicine, could harm us. We entered into employment agreements with Mr. Marucci and 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 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.

Integrating Kolltan's organization is expected to be costly and may divert management's attention away from our operations.

We are in the process of integrating Kolltan's organization and while we plan such integration to be cash neutral, we expect to incur significant costs integrating Kolltan's operations, facility, products and personnel. Furthermore, successful integration of Kolltan's preclinical and clinical programs, operations, and personnel may place a significant burden on our management and internal resources. The costs of integrating Kolltan's operations with ours and the diversion of management's attention and any difficulties encountered in the transition and integration process could result in delays in the

preclinical and clinical trial programs of Kolltan and/or Celldex and could otherwise harm our business, financial condition and operating results.

If we are unable to successfully integrate Kolltan's organization, we may not operate efficiently or realize the anticipated benefits of our acquisition of Kolltan.

The success of the merger will depend on, among other things, the combined company's ability to operate efficiently and to achieve its business objectives, including the successful development of its drug candidates. Achieving the benefits of the merger will depend in part on the successful integration of Kolltan's preclinical and clinical programs, operations and personnel in a timely and efficient manner. If we cannot successfully integrate Kolltan's preclinical and clinical programs, operations and personnel, we may not realize the expected benefits of the merger. The integration process may result in the disruption of each company's ongoing business, an adverse impact on the value of our assets, or inconsistencies in standards, controls, procedures or policies that could adversely affect our ability to comply with reporting obligations as a public company, to satisfy our obligations to third parties or to achieve the anticipated benefits of the merger.

Any delays in the integration process or inability to operate efficiently or to realize the full extent of the anticipated benefits of the merger could 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 and business arrangements in the healthcare 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 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 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 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, such as Kolltan's drug development programs and TAM technology, 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 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 oncology, inflammatory and infectious diseases by stimulating a patient's immune system against those disease organisms. If our immunotherapy technology portfolio cannot be used to create effective immunotherapeutic drugs against a variety of disease organisms, 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 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 produce 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 healthcare 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 licenses 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.

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. We intend to appeal this decision and 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 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. We do not know if the appeal will succeed, or, if successful, whether the scope of claims, post-appeal, would be relevant to our activities. Should the appeal be successful and a license be necessary for our program that targets ErbB3, we cannot predict whether we would be able to obtain such a license, or, if a license were available, whether it would be available on commercially reasonable terms. If the appeal results in such third party's patents having a valid claim relevant to our use of ErbB3 antibodies and a license under the patents is unavailable on commercially relevant terms, or at all, our ability to commercialize CDX-3379 in Europe may be impaired or delayed. We would vigorously defend ourselves, but we cannot predict whether the patents would be found valid, enforceable or infringed. We continue to monitor counterpart patent applications pending in other jurisdictions, including the United States. 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 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

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 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;
- 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 for 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 healthcare 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 may 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 healthcare 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, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes 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 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.

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 were 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 healthcare 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 rules with respect to cross-border transfers of such data out of the EU. 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 healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may have a material adverse effect on us.

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. PPACA aims to, among other things, expand coverage for the uninsured while at the same time containing overall healthcare costs. Many provisions of PPACA may 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. The required PHS discount on a given product is calculated based on the Average Manufacturers Price, or AMP, and Medicaid rebate amounts reported by the manufacturer. PPACA expanded the types of entities eligible to receive discounted PHS pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted PHS pricing on orphan drugs when used for the orphan indication. In addition, as PHS drug pricing is determined based on AMP and Medicaid rebate data, revisions, including the recently published AMP rule, to the Medicaid rebate formula and AMP definition described above could cause the required PHS discount to increase.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the

passage of legislation that would repeal certain aspects of PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of PPACA that are repealed. Because of the continued uncertainty about the implementation of PPACA, including the potential for further legal challenges or repeal of PPACA, we cannot quantify or predict with any certainty the likely impact of the PPACA or its repeal on our business, prospects, financial condition or results of operations.

In addition, other legislative changes have also been proposed and adopted since PPACA was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes a 2% reduction in Medicare provider payments paid under Medicare Part B to physicians for physician-administered drugs, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, legislation has been proposed to shorten the period of biologic data and market exclusivity granted by the FDA.

We also expect ongoing initiatives to increase pressure on drug pricing. For example, President Trump has indicated support for possible new measures related to drug pricing. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could negatively affect our revenue or sales of any drug candidates for which we obtain approval in the future.

We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes (or in some instances current regulations, guidance or interpretations) on the marketing approvals of our product candidates, if any, may be.

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 $719.5 million as of December 31, 2016. 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.

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 2016 through December 2016, the market price of our common stock has fluctuated from a high of $15.61 per share in the first quarter of 2016, to a low of $2.85 per share in the fourth quarter of 2016. 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.

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 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 $172.5 million, 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. 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. Pursuant to applicable NASDAQ listing rules, we are required to obtain stockholder approval of such issuances of our common stock to the extent that such issuances exceed 19.9% of its common stock outstanding prior to the merger. 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 the our net assets are 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) AVANT, CuraGen or Kolltan prior to our acquisitions, (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 15, "Income Taxes," in the accompanying notes to the financial statements for additional discussion on income taxes.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of December 31, 2016 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	April 2019(4)
Branford, Connecticut	10,300	Office	December 2019(5)

(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 two years.

(5) Lease includes two renewal options of three years. Lease also includes provision for early termination with 12 months notice.

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

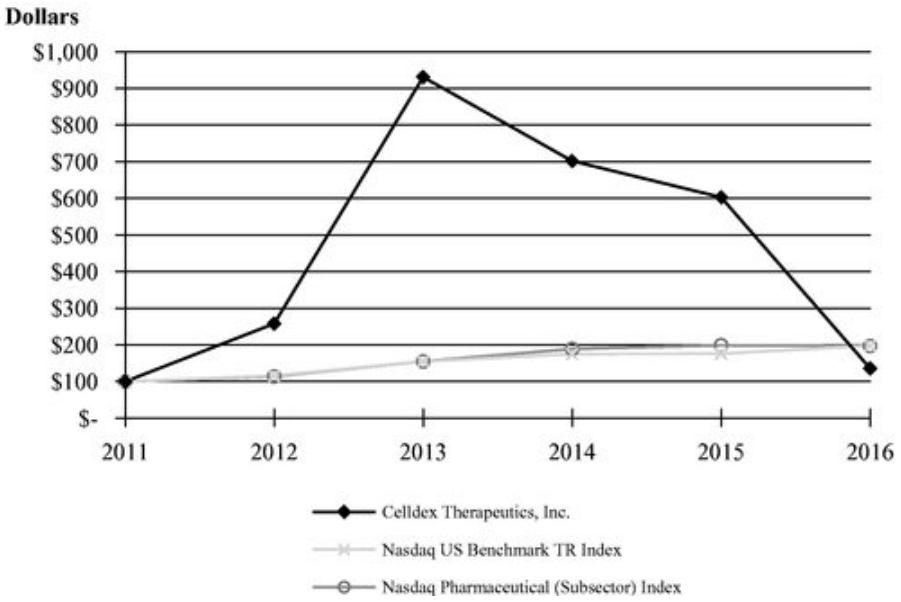
Our common stock currently trades on the Nasdaq Global Market (NASDAQ) under the symbol "CLDX". The following table sets forth for the periods indicated the high and low sale prices per share for our common stock, as reported by NASDAQ.

Fiscal Period	High	Low
Year Ended December 31, 2016		
First Quarter	$ 15.61	$ 2.96
Second Quarter	5.13	3.40
Third Quarter	4.83	3.23
Fourth Quarter	5.02	2.85
Year Ended December 31, 2015		
First Quarter	$ 32.82	$ 17.81
Second Quarter	30.28	23.62
Third Quarter	28.08	10.11
Fourth Quarter	18.62	10.15

As of March 6, 2017, there were approximately 356 shareholders of record of our common stock. On March 6, 2017 the closing price of our common stock, as reported by NASDAQ, was $3.81 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.

CELLDEX THEAPEUTICS, 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, 2011 through December 31, 2016, 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, 2011 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.



	2011	2012	2013	2014	2015	2016
Celldex Therapeutics, Inc.	$ 100	$ 258	$ 931	$ 702	$ 603	$ 136
NASDAQ U.S. Benchmark TR Index	$ 100	$ 116	$ 155	$ 175	$ 176	$ 198
NASDAQ Pharmaceutical (Subsector) Index	$ 100	$ 114	$ 155	$ 189	$ 199	$ 197

Unregistered Sales of Equity Securities

As more fully discussed in Note 17 to the Financial Statements and Supplementary Data in Item 8 of this Annual Report, effective November 29, 2016, the Company acquired Kolltan in accordance with the Agreement and Plan of Merger dated as of November 1, 2016 (the "Merger Agreement"). Under the terms of the Merger Agreement, Kolltan's investors received, in exchange for their share and debt interests in Kolltan, an aggregate of 18,257,996 shares of Celldex's common stock. All of the preceding shares were issued in reliance upon an exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 4(a)(2) thereof or Regulation D thereunder because the issuance did not involve a public offering.

Item 6. SELECTED FINANCIAL DATA

The following selected financial data are derived from our financial statements. The statement of operations data for the years ended December 31, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 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,				
	2016	2015	2014	2013	2012
REVENUE:					
Product Development and Licensing Agreements	$ 2,174	$ 1,442	$ 838	$ 160	$ 146
Contracts and Grants	4,612	4,038	2,748	1,617	281
Product Royalties	—	—	—	2,334	10,775
Total Revenue	6,786	5,480	3,586	4,111	11,202
OPERATING EXPENSE:					
Research and Development	102,726	100,171	104,381	67,401	47,398
Royalty	—	—	—	2,334	10,775
Other Operating Expense	36,976	34,850	21,635	15,818	11,106
Total Operating Expense	139,702	135,021	126,016	85,553	69,279
Operating Loss	(132,916)	(129,541)	(122,430)	(81,442)	(58,077)
Investment and Other Income, Net	4,386	2,344	4,350	819	530
Interest Expense	—	—	—	(927)	(1,576)
Net Loss	$ (128,530)	$ (127,197)	$ (118,080)	$ (81,550)	$ (59,123)
Basic and Diluted Net Loss Per Common Share	$ (1.27)	$ (1.31)	$ (1.32)	$ (1.02)	$ (1.02)
Shares Used in Calculating Basic and Diluted Net Loss Per Common Share	101,529	97,051	89,399	79,777	57,713

BALANCE SHEET DATA
(In thousands)

	December 31,				
	2016	2015	2014	2013	2012
Working Capital *	$ 160,346	$ 264,696	$ 180,494	$ 284,839	$ 67,429
Total Assets	383,358	337,584	248,014	347,095	125,541
Long-Term Liabilities	82,704	17,239	11,863	6,950	12,082
Accumulated Deficit	(719,486)	(590,956)	(463,759)	(345,679)	(264,129)
Total Stockholders' Equity	265,431	290,105	211,660	319,795	95,774

* Total current assets less total current liabilities

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

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies and other cancer-targeting biologics. Our drug candidates, including antibodies, antibody-drug conjugates and other protein-based therapeutics, 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.

Our latest stage drug candidate, glembatumumab vedotin (also referred to as CDX-011) is a targeted antibody-drug conjugate in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma. Varlilumab (also referred to as CDX-1127) is an immune modulating antibody that is designed to enhance a patient's immune response against cancer. We established proof of principal in a Phase 1 study with varlilumab, which supported the initiation of several combination studies in various indications. We also have a number of earlier stage drug candidates in clinical development, including CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APCs, for cancer indications; CDX-301, an immune cell mobilizing agent and dendritic cell growth factor; and CDX-014, an antibody-drug conjugate targeting renal and ovarian cancers. In November 2016, we completed the acquisition of Kolltan Pharmaceuticals, Inc. (Kolltan), a privately held company focused on the discovery and development of novel, antibody-based drugs targeting receptor tyrosine kinases (RTKs). This acquisition added the following drug candidates to our clinical pipeline: CDX-0158 (formerly KTN0158), a humanized monoclonal antibody (mAb) currently in a Phase 1 dose escalation study in refractory gastrointestinal stromal tumors (GIST) and other KIT positive tumors; and, CDX-3379 (formerly KTN3379; MEDI3379), a human monoclonal antibody which recently completed a Phase 1b study in patients with solid tumors. We also acquired the TAM program, a broad antibody discovery effort to generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AXL and MerTK, which are expressed on tumor-infiltrating macrophages, dendritic cells and some tumors. Our drug candidates address market opportunities for which we believe current cancer therapies are inadequate or non-existent.

We are building a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. 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.

The following table reflects Celldex-sponsored clinical studies that we are actively pursuing at this time. All programs are currently fully-owned by Celldex.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Triple negative breast cancer	Phase 2b	Celldex
Glembatumumab vedotin	Metastatic melanoma (with varlilumab or CPI*)	Phase 2	Celldex
Varlilumab	Multiple solid tumors (with nivolumab)	Phase 2	Celldex**
CDX-0158	Gastrointestinal and other KIT-postive tumors	Phase 1	Celldex
CDX-3379	Multiple solid tumors (in combination regimens)	Phase 1	Celldex
CDX-014	Renal cell carcinoma	Phase 1	Celldex

* *checkpoint inhibitor*

** BMS collaboration

We also routinely work with external parties, such as government agencies, to collaboratively advance our drug candidates. The following pipeline reflects clinical trials of our drug candidates being actively pursued by outside organizations. In addition to the studies listed below, we also have an Investigator Initiated Research (IIR) program with seven studies ongoing with our drug candidates and additional studies currently under consideration.

Product (generic)	Indication/Field	Status	Sponsor
Glembatumumab vedotin	Uveal melanoma	Phase 2	NCI (CRADA)
Glembatumumab vedotin	Squamous cell lung cancer	Phase 2	PrECOG, LLC
CDX-1401/CDX-301	Multiple solid tumors	Phase 2	CITN

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 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 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 is 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 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, 2016, we incurred an aggregate of $422.1 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, 2016, 2015 and 2014. 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, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
		(In thousands)	
Glembatumumab vedotin	$ 30,156	$ 19,124	$ 26,907
Varlilumab	28,554	18,484	9,459
CDX-0158	279	—	—
CDX-3379	416	—	—
CDX-014	3,623	5,724	3,722
CDX-1401	4,323	3,385	4,144
CDX-301	4,053	2,206	1,238
CDX-1140	3,802	—	—
TAM	438	—	—
Rintega	15,337	43,038	52,861
Other Programs	11,745	8,210	6,050
Total R&D Expense	$ 102,726	$ 100,171	$ 104,381

Clinical Development Programs

As previously disclosed, it is our intention to integrate Kolltan without increasing our planned cash burn for 2017. Following the addition of the Kolltan programs, we undertook a full review of our pipeline and associated programs to identify priority areas that we believe have the highest probability of potentially impacting disease while also identifying areas for improved efficiency and cost savings. The adjustments are reflected in the following clinical pipeline program update.

Glembatumumab Vedotin

Glembatumumab vedotin is an antibody-drug conjugate, or ADC, that consists of a fully human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as gpNMB that is over-expressed in a variety of cancers including breast cancer, melanoma, non-small cell lung cancer, uveal melanoma and osteosarcoma, among others. The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. and is the same as that used in the marketed product Adcetris®. The ADC is designed to be stable in the bloodstream. Following intravenous administration, glembatumumab vedotin targets and binds to gpNMB, and upon internalization into the targeted cell, glembatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. Glembatumumab vedotin is being studied across multiple indications in company-sponsored trials and in collaborative studies with external parties. The Food and Drug Administration, or FDA, has granted Fast Track designation to glembatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer. A companion diagnostic is in development for certain indications, and we expect that, if necessary, such a companion diagnostic must be approved by the FDA or certain other foreign regulatory agencies before glembatumumab vedotin may be commercialized in those indications.

Treatment of Metastatic Breast Cancer: The Phase 1/2 study of glembatumumab vedotin administered intravenously once every three weeks evaluated patients with locally advanced or metastatic breast cancer (MBC) who had received prior therapy (median of seven prior regimens). Results were published in the *Journal of Clinical Oncology* in September 2014. The study began with a bridging phase to confirm the maximum tolerated dose, or MTD, and then expanded into a Phase 2 open-label, multi-center study. The study supported an acceptable safety profile of glembatumumab vedotin at the pre-defined maximum dose level (1.88 mg/kg) in 6 patients. An additional 28 patients with MBC were enrolled in an expanded Phase 2 cohort (for a total of 34 treated patients at 1.88 mg/kg, the Phase 2 dose) to evaluate the progression-free survival (PFS) rate at 12 weeks. The 1.88 mg/kg dose exhibited an acceptable safety profile in this patient population with the most common adverse events being rash, neuropathy and fatigue. The primary anti-cancer activity endpoint, which called for at least 5 of 25 (20%) patients in the Phase 2 study portion to be progression-free at 12 weeks, was met as 9 of 27 (33%) evaluable patients were progression-free at 12 weeks. For all patients treated at the Phase 2 dose, median PFS was 9.1 weeks.

A subset of 10 patients had "triple negative disease," a more aggressive metastatic breast cancer subtype that carries a high risk of relapse and reduced survival as well as limited therapeutic options. In these patients, the 12-week PFS rate was 60% (6/10), and median PFS was 17.9 weeks. Tumor samples from a subset of patients across all dose groups were analyzed for gpNMB expression. The tumor samples from most patients showed evidence of stromal and/or tumor cell expression of gpNMB.

The subsequent EMERGE study was a randomized, multi-center Phase 2b study of glembatumumab vedotin in 124 patients with heavily pre-treated, advanced, gpNMB-positive breast cancer. Results from EMERGE were published in the *Journal of Clinical Oncology* in April 2015. Patients were randomized (2:1) to receive either glembatumumab vedotin or single-agent Investigator's Choice chemotherapy. Patients randomized to receive Investigator's Choice were allowed to cross over to receive glembatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and overall survival (OS). The final study results, as shown below, suggested that glembatumumab vedotin induced significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high gpNMB expression (expression in at least 25% of tumor cells) and in patients with triple negative breast cancer. The OS and PFS of patients treated with glembatumumab vedotin were also observed to be greatest in patients with high gpNMB expression and, in particular, in patients with triple negative breast cancer who also had high gpNMB expression.

EMERGE: Overall Response Rate and Disease Control Data (Intent-to-Treat Population)

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glembatumumab Vedotin (n=23)	Investigator's Choice (n=11)	Glembatumumab Vedotin (n=10)	Investigator's Choice (n=6)
Response Rate	30%	9%	40%	0%
Disease Control Rate	65%	27%	90%	17%

Tumor response assessed by RECIST 1.1, inclusive of response observed at a single time point.

EMERGE: Progression Free Survival (PFS) and Overall Survival (OS) Data

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression	
	Glembatumumab Vedotin	Investigator's Choice	Glembatumumab Vedotin	Investigator's Choice
Median PFS (months)	2.8	1.5	3.5	1.5
	p=0.18		p=0.0017	
Median OS (months)	10.0	5.7	10.0	5.5
	p=0.31		p=0.003	

In December 2013, we initiated METRIC, a randomized, controlled Phase 2b study of glembatumumab vedotin in patients with triple negative breast cancer that over-expresses gpNMB. Clinical trial study sites are open to enrollment across the U.S., Canada, Australia and the European Union. The METRIC protocol was amended in late 2014 based on feedback from clinical investigators conducting the study that the eligibility criteria for study entry were limiting their ability to enroll patients they felt were clinically appropriate. In addition, we had spoken to country-specific members of the European Medicines Agency, or EMA, and believed an opportunity existed to expand the study into the EU. The amendment expanded patient entry criteria to position it for the possibility of full marketing approval with global regulators, including the EMA, and to support improved enrollment in the study. The primary endpoint of the study is PFS as PFS is an established endpoint for full approval registration studies in this patient population in both the U.S. and the EU. The sample size (n=300) and the secondary endpoint of OS remained unchanged. Since implementation of these changes, both the FDA and central European regulatory authorities have reviewed the protocol design, and we believe the METRIC study could potentially support marketing approval in both the U.S. and Europe dependent upon data results and review. Based on consistent improvements in enrollment trends to the METRIC study over the last several months, we anticipate that study enrollment will be completed by the end of September 2017. Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic, including partnering with a diagnostic company, are underway.

Treatment of Metastatic Melanoma: The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glembatumumab vedotin in 117 patients with unresectable stage III or IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD and resulting Phase 2 dose was determined to be 1.88 mg/kg administered intravenously once every three weeks. The study achieved its primary activity objective with an overall response rate (ORR) in the Phase 2 cohort of 15% (5/34). Median PFS was 3.3 months for patients treated with the Phase 2 dose. Glembatumumab vedotin was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, alopecia, pruritus, diarrhea and nausea.

The development of rash, which may be associated with the presence of gpNMB in the skin, also seemed to correlate with greater PFS.

In December 2014, we initiated a single arm, single-agent, open-label Phase 2 study of glembatumumab vedotin in patients with unresectable stage III or IV melanoma (n=60) and enrollment has been completed. In May 2016, we amended the protocol to add a second cohort of patients to a glembatumumab vedotin and varlilumab combination arm to assess the potential clinical benefit of the combination and to explore varlilumab's potential biologic and immunologic effect when combined with an ADC. In November 2016, we amended the protocol again to add a third cohort of patients evaluating glembatumumab vedotin in combination with an approved checkpoint inhibitor (i.e., nivolumab or pembrolizumab) following progression on the checkpoint inhibitor alone. Both additional cohorts are open to enrollment. The primary endpoint for each cohort is ORR. Secondary endpoints include analyses of PFS, duration of response, OS, retrospective investigation of whether the anti-cancer activity of glembatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety of both the monotherapy and combination regimens.

We presented data from the single-agent cohort at the European Society for Medical Oncology (ESMO) Congress in October 2016. The cohort enrolled 62 evaluable patients with unresectable stage III (n=1; 2%) or stage IV (n=61; 98%) melanoma. All patients had progressed after checkpoint inhibitor therapy, and almost all patients had received both ipilimumab (n=58; 94%) and anti-PD-1/anti-PDL-1 (n=58; 94%) therapy. Twelve patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents. The primary endpoint of the cohort (6 or more objective responses in the first 52 patients enrolled) was exceeded. Seven of 62 (11%) patients experienced a confirmed response, and an additional three patients also experienced single timepoint responses. The median duration of response was 6.0 months. A 52% disease control rate (patients without progression for greater than three months) was demonstrated and median PFS for all patients was 4.4 months. In addition, patients who experienced rash in the first cycle of treatment had a 20% confirmed response rate and a more prolonged PFS of 5.5 months [p=0.054; hazard rating=0.52 (0.27, 1.02)]. We also intend to conduct exploratory analyses of pre-entry skin biopsies in future patients to investigate potential predictors of response to glembatumumab vedotin, given the potential association of rash and outcome.

Treatment of Other Indications: We have entered into a collaborative relationship with PrECOG, LLC, which represents a research network established by the Eastern Cooperative Oncology Group (ECOG), under which PrECOG, LLC, is conducting an open-label Phase 1/2 study in patients with unresectable stage IIIB or IV, gpNMB-expressing, advanced or metastatic squamous cell carcinoma (SCC) of the lung, who have progressed on prior platinum-based chemotherapy. This study opened to enrollment in April 2016. The study includes a dose-escalation phase followed by a two-stage Phase 2 portion (Simon two-stage design). The Phase 1, dose-escalation portion of the study will assess the safety and tolerability of glembatumumab vedotin at the current dose of 1.9 mg/kg and then 2.2 mg/kg in order to determine whether higher dosing is feasible in this population. The first stage of the Phase 2 portion plans to enroll approximately 20 patients, and if at least two patients achieve a partial response or complete response, a second stage may enroll an additional 15 patients. The primary objective of the Phase 2 portion of the study is to assess the anti-tumor activity of glembatumumab vedotin in squamous cell lung cancer as measured by ORR. Secondary objectives of the study include analyses of safety and tolerability and further assessment of anti-tumor activity across a broad range of endpoints.

We have also entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, under which NCI is sponsoring two studies of glembatumumab vedotin—one in uveal melanoma and one in osteosarcoma. The uveal melanoma study is a single-arm, open-label study in patients with locally recurrent or metastatic uveal melanoma and is currently open to enrollment. The primary outcome measure is ORR. Secondary outcome measures include change in

gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. We expect data from this study will be presented at a future medical meeting in the first half of 2017. The osteosarcoma study is a single-arm, open-label, evaluation of adolescent and adult patients with recurrent or refractory osteosarcoma. The co-primary objectives are to determine whether glembatumumab vedotin therapy either increases the disease control rate at 4 months in patients with recurrent measurable osteosarcoma as compared to historical experience and/or whether glembatumumab vedotin therapy produces an objective response rate greater than 20% in patients without previous eribulin (eribulin mesylate) treatment. Secondary outcome measures include safety, pharmacokinetics and the relation of gpNMB expression as measured by immunohistochemistry to clinical response. The study had a two stage design with a pre-specified activity threshold necessary in the first stage to progress enrollment to the second stage. The study did not meet the activity threshold for progressing to stage 2 and therefore no additional patients will be enrolled. We expect data from this study will be presented at a future medical meeting.

Varlilumab

Varlilumab is a fully human monoclonal agonist 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 *vitro* and *in vivo* models. We have entered into license agreements with the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (acquired by Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. 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. Currently, we are focusing our efforts on a Phase 1/2 clinical trial being conducted in collaboration with BMS and their PD-1 immune checkpoint inhibitor, Opdivo. Varlilumab is also being explored in combination studies, including with glembatumumab vedotin, and in ongoing and planned investigator-sponsored studies.

Single-Agent Phase 1 Study: Data from the completed, open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers were presented in November 2014. Varlilumab to date has shown 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 were dosed in the study at multiple clinical sites in the U.S. of which 56 patients were dosed in dose escalation cohorts (various solid and hematologic B-cell tumors), and 34 patients were dosed in the expansion cohorts (melanoma and RCC) at 3 mg/kg. In both the solid tumor and hematologic dose-escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of a maximum tolerated dose. The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, with only three serious AEs related to treatment reported. No significant immune-mediated adverse events (colitis, hepatitis, etc.) typically associated with checkpoint blockade have been observed to date. Two patients experienced significant objective responses including a complete response in Hodgkin lymphoma (continued at 33.1+ months as of September 2016; patient no longer on study) and a partial response in renal cell carcinoma of 27.7+ months (as of September 2016). Thirteen patients experienced stable disease with a range of 3-47.3+ months (as of September 2016). As of December 2016, there are two patients continuing in long term follow-up.

Phase 1/2 Varlilumab/Opdivo® Combination Study: In May 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, Bristol-Myers Squibb made a one-time payment to us of $5.0 million, and the companies amended the terms of our existing license agreement with Medarex (acquired by Bristol-Myers Squibb) related to our CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from us to Medarex. In return, Bristol-Myers Squibb was granted a time-limited right of first negotiation if we wish to out-license varlilumab. The companies also agreed to work exclusively with each other to explore anti-PD-1 antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that we will be responsible for conducting the Phase 1/2 study.

The Phase 1/2 study was initiated in January 2015 and is being conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts. The Phase 1 dose escalation portion of the study, conducted in patients with solid tumors, has completed enrollment (n=36) and primarily enrolled patients with colorectal and ovarian cancer.

Data were presented from the Phase 1 portion of the varlilumab and Opdivo study in a poster at the American Association for Cancer Research (AACR) Annual Meeting in April 2016. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination showed acceptable tolerability and safety across all dose levels without any evidence of increased autoimmunity or inappropriate immune activation. Marked changes in the tumor microenvironment including increased infiltrating CD8+ T cells and increased PD-L1 expression, which have been shown to correlate with a greater magnitude of treatment effect from checkpoint inhibitors in other clinical studies were observed. Additional evidence of immune activity, such as increase in inflammatory chemokines and decrease in T regulatory cells, were also noted. In a subset of patients (n=17) on study who had both pre- and post-tumor biopsies available, preliminary evidence suggest a correlation between biomarker data and stable disease or better in seven of these patients (4 ovarian cancer, 2 colorectal cancer, 1 squamous cell carcinoma of the head and neck). All dose levels of the combination therapy showed an acceptable tolerability and safety profile, without identification of a maximum tolerated dose. In the Phase 2 portion of the study, varlilumab is administered at 3 mg/kg in the majority of cohorts, based upon cumulative data across multiple studies.

The Phase 2 portion of the study opened to enrollment in April 2016 and includes cohorts in colorectal cancer (n=18), ovarian cancer (n=54), head and neck squamous cell carcinoma (n=54), renal cell carcinoma (n=25) and glioblastoma (n=20). Based on a recent protocol amendments, additional dosing schedules are being explored in ovarian cancer (versus renal cell carcinoma) and, as previously disclosed, in head and neck squamous cell carcinoma, increasing the overall size of the study compared to the original study design. The primary objective of the Phase 2 cohorts is ORR, except glioblastoma, where the primary objective is the rate of 12-month overall survival. Secondary objectives include pharmacokinetics assessments, determining the immunogenicity of varlilumab when given in combination with Opdivo and further assessing the anti-tumor activity of combination treatment. We plan to complete enrollment across all cohorts in the Phase 2 portion of the study in the first quarter of 2018 and will work with BMS to present data from the study at a future medical meeting.

Phase 1/2 Varlilumab/Tecentriq® Combination Study: In March 2015, we entered into a clinical trial collaboration with Roche to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Tecentriq (anti-PDL1), Roche's cancer immunotherapy, in a Phase 1/2 study. Under the terms of this agreement, Roche is providing study drug, and we are responsible for conducting and funding the study. The Phase 1 portion of the study is being conducted in bladder cancer and renal cell carcinoma,

and the primary outcome is safety and tolerability. The Phase 1 portion of the study completed enrollment in the third quarter of 2016. Patients continue to be followed, and we expect data from this study will be presented at a future medical meeting. Given the advancement of varlilumab into a broad Phase 2 study in combination with Opdivo and our efforts to identify areas for cost-containment, we will not be advancing the varlilumab/Tecentriq study to Phase 2.

Phase 1/2 Varlilumab/Sutent® Combination Study: In May 2015, we initiated a Phase 1/2 safety and tolerability study examining the combination of varlilumab and Sutent in patients with metastatic clear cell renal cell carcinoma. The Phase 1 portion of the study assesses the safety and tolerability of varlilumab at varying doses when administered with Sutent. The Phase 1 portion of the study completed enrollment in the fourth quarter of 2016. Patients continue to be followed, and data from this study will be presented at a future medical meeting. Given the advancement of varlilumab into a broad Phase 2 study in combination with Opdivo and our efforts to identify areas for cost-containment, we will not be advancing the varlilumab/Sutent study to Phase 2.

Phase 1/2 Varlilumab/Yervoy® +/– CDX–1401 Combination Study: In April 2015, we initiated a Phase 1/2 safety pilot and expansion study examining the combination of varlilumab and Yervoy in patients with stage III or IV metastatic melanoma. Since initiating the study, the standard of care has evolved, and there has been increasing physician reluctance to use Yervoy in this setting. As such, given the broad development strategy in place for varlilumab, as previously disclosed, this study was closed to enrollment in the third quarter of 2016.

CDX-0158

CDX-0158 (formerly KTN0158), is a humanized monoclonal antibody designed to inhibit KIT activation in tumor cells and mast cells. KIT is expressed in many tumor types including gastrointestinal stromal tumors (or GIST), sarcomas, small cell lung cancer, melanoma, acute myeloid leukemia (AML) and mast cell leukemia. It has also been implicated in asthma and neurofibromatosis. We are currently developing CDX-0158 for the treatment of GIST. Small molecule drugs currently approved to treat GIST inhibit mutant KIT, but acquired resistance develops via secondary, drug-resistant KIT mutations in the majority of patients over time. CDX-0158 is designed to uniquely prevent KIT activation by inhibiting both receptor dimerization and ligand binding. CDX-0158 has demonstrated preclinical activity versus the most common c-KIT mutations in human GIST, including treatment of mastocytoma in a canine model.

A Phase 1 dose escalation study in patients with advanced refractory GIST and other KIT positive tumors opened to enrollment in December 2015 to determine the maximum tolerated dose, recommend a dose for further study and characterize the safety profile. Enrollment is ongoing. Upon completion of Phase 1 assuming a successful outcome, we plan to develop CDX-0158 in patients with refractory GIST given the significant unmet need for these patients.

Preclinical data published in *Molecular Cancer Therapeutics* in January 2017 demonstrate that KIT inhibition in certain immune cells with CDX-0158 enhances the activity of checkpoint blockade, providing additional opportunities for combination therapy. This mechanism may also be effective with other immunotherapies, in particular with our CD27 agonist, varlilumab.

CDX-3379

CDX-3379 (formerly KTN3379 and MEDI3379) 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. 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.

A Phase 1a/1b study was conducted, including a single-agent dose-escalation portion and combination expansion cohorts. Data from the dose-escalation portion, which completed enrollment in September 2015, and initial data from the expansion cohorts (enrollment ongoing at the time) were presented at the American Society of Clinical Oncology Annual Meeting in June 2016. The single-agent dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. The most common adverse events included rash and diarrhea and were predominantly grade 1 or 2. 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=4) 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 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. We are currently exploring plans for advancement into Phase 2 study.

CDX-1401

CDX-1401, developed from our APC Targeting Technology, is an NY-ESO-1-antibody fusion protein for immunotherapy in multiple solid tumors. CDX-1401, which is administered with an adjuvant, is composed of the cancer-specific antigen NY-ESO-1 fused to a fully human antibody that binds to DEC-205 for efficient delivery to dendritic cells. Delivery of tumor-specific proteins directly to dendritic cells *in vivo* elicits potent, broad, anti-tumor immune responses across populations with different genetic backgrounds. In humans, NY-ESO-1 has been detected in 20% to 30% of melanoma, lung, esophageal, liver, gastric, ovarian and bladder cancers, and up to 70% of synovial sarcomas, thus representing a broad opportunity. We are developing CDX-1401 for the treatment of malignant melanoma and a variety of solid tumors which express the cancer antigen NY-ESO-1, which we licensed from the Ludwig Institute for Cancer Research in 2006. Preclinical studies have shown that CDX-1401 treatment results in activation of human T cell responses against NY-ESO-1.

We have completed a Phase 1 study of CDX-1401 which assessed the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 with TLR agonists (resiquimod and/or poly-ICLC) in 45 patients with advanced malignancies refractory to all available therapies. Results were published in *Science Translational Medicine* in April 2014. Sixty percent of patients had confirmed NY-ESO expression in archived tumor samples. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment indicates an acceptable safety profile to date, and there were no dose limiting toxicities. A variety of immune activation parameters were observed. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 56% of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and poly-ICLC alone and in combination. Long-term patient follow up suggested that treatment with CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. Of the 45 patients in the Phase 1 study, eight went on to receive

subsequent therapy of either Yervoy or an investigational checkpoint inhibitor, and six of these patients had objective tumor regression. Six patients with melanoma received Yervoy within three months of treatment with CDX-1401, and four (67%) had objective tumor responses, including one complete response, which compares favorably to the overall response rate of 11% previously reported in metastatic melanoma patients treated with single-agent Yervoy. In addition, two patients with non-small cell lung cancer received an investigational checkpoint blockade within two months of completing treatment with CDX-1401, and both achieved partial responses. Together with Roche, we are supporting an investigator initiated study of CDX-1401 in combination with Tecentriq® in patients with lung cancer.

CDX-1401's potential activity is being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-1401 in combination with CDX-301 is being conducted in metastatic melanoma by the Cancer Immunotherapy Trials Network (CITN) under a CRADA with the Cancer Therapy Evaluation Program of the NCI. This study was designed to determine the activity of CDX-1401 with or without CDX-301 in melanoma. The primary outcome measure of the study is immune response to NY-ESO-1. Secondary outcome measures include analysis and characterization of peripheral blood mononuclear cells (dendritic cells, T cells, natural killer cells, etc.), additional immune monitoring, safety and clinical outcomes (survival and time to tumor recurrence). Enrollment is complete and initial results were presented in June at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. The data confirmed that CDX-1401 is capable of driving NY-ESO-1 immunity and further demonstrated the potential of CDX-301 as a combination agent for enhancing tumor specific immune responses. The NCI and CITN are planning to enroll additional cohorts to investigate alternative regimens of CDX-301. Other studies are being considered through investigator-sponsored and collaborative agreements.

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 in combination with other agents to potentiate the anti-tumor response. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. CDX-301 is in clinical development for multiple cancers, in combination with vaccines, adjuvants and other treatments that release tumor antigens. We licensed CDX-301 from Amgen Inc. in March 2009 and believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio.

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 hematopoietic stem cell (HSC) populations in healthy volunteers. Based on the safety profile and the clinical and preclinical data to date, we initiated a pilot clinical study of CDX-301 for the mobilization and transplantation of allogeneic hematopoietic stem cells in patients with hematological malignancies undergoing hematopoietic stem cell transplantation. Preliminary results from this Phase 2 study were presented at the annual meeting of the American Society for Blood and Marrow Transplantation in February 2016. These preliminary data from three donor/patient pairs showed that CDX-301 given as a single agent has an acceptable safety profile and mobilized hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naïve lymphocytes and plasmacytoid dendritic cells consistent with preclinical data suggesting a possible better outcome. Recipients experienced successful engraftment in an expected time frame. Given that hematopoietic stem cell transplantation is outside of our core focus, in an effort to prioritize human and capital resources, we announced in May 2016 that we decided not to advance CDX-301 in this particular indication at this time.

In June, at the 2016 ASCO Annual Meeting, initial results from a Phase 2 study of CDX-1401 in combination with CDX-301 in metastatic melanoma were presented that further demonstrated the value of CDX-301 as a combination agent for enhancing tumor specific immune responses. The Phase 2 study was conducted by the Cancer Immunotherapy Trials Network, or CITN, under a CRADA with the Cancer Therapy Evaluation Program of the NCI. Based on these results the CITN is planning to enroll additional cohorts to investigate alternative regimens of CDX-301. Other studies are being considered through investigator-sponsored and collaborative agreements.

CDX-014

CDX-014 is a human monoclonal ADC that targets T cell immunoglobulin and mucin domain 1, or TIM-1. TIM-1 expression is upregulated in several cancers, most notably renal cell and ovarian carcinomas, and is associated with a more malignant phenotype of renal cell carcinoma (RCC) and tumor progression. TIM-1 has restricted expression in healthy tissues, making it potentially amenable to an ADC approach. The TIM-1 antibody is linked to MMAE using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 has shown anti-tumor activity in preclinical models of ovarian and renal cancer. In July 2016, we announced that enrollment had opened in a Phase 1/2 study of CDX-014 to patients with both clear cell and papillary RCC. The Phase 1 dose-escalation portion of the study is evaluating cohorts of patients receiving increasing doses of CDX-014 to determine the maximum tolerated dose and a recommended dose for Phase 2 study. We anticipate the Phase 1 dose-escalation portion of the study will complete enrollment by year-end 2017. The Phase 2 portion of the study plans to enroll approximately 25 patients to assess the anti-tumor activity of CDX-014 at the recommended dose in advanced renal cell carcinoma as measured by objective response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

Rintega

On March 7, 2016, we announced that our Phase 3 study of Rintega® in patients with newly diagnosed EGFRvIII-positive glioblastoma was being discontinued. This decision was made based on the outcome of a preplanned interim analysis conducted by an independent Data Safety and Monitoring Board (DSMB). The DSMB determined that continuation of the study would not result in reaching statistical significance for the primary endpoint of the study, overall survival in patients with minimal residual disease, as both the Rintega arm and the control arm were performing on par with each other. In the ACT IV study, Rintega performed consistently with prior Phase 2 studies but the control arm significantly outperformed expectations (Hazard ratio = 0.99; median OS: Rintega 20.4 months vs. control 21.1 months). Based on this recommendation, we discontinued the study. Data from the ACT IV study were presented at the Society for Neuro-Oncology Annual Meeting in November 2016. All patients on the Rintega arm of the ACT IV study, prior Phase 2 studies and existing compassionate use recipients have been offered ongoing access to Rintega on a compassionate use basis, and we continue to support new requests for compassionate use in recurrent glioblastoma on a limited basis. Study closure activities are complete, and we continue to anticipate that we will not incur substantial additional costs related to Rintega.

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 on-going 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 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. We performed an annual impairment test of the goodwill asset as of July 1, 2016 and concluded that the goodwill asset was not impaired.

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

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured.

We have entered into and in the future may enter into 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. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. In accounting for these transactions, we allocate revenue to the various elements based on their relative fair value. The fair value of a revenue generating element can be based on current selling prices offered by us or another party for current products or our best estimate of a selling price for future products. Revenue allocated to an individual element is recognized when all other revenue recognition criteria are met for that element.

These collaborative and other agreements may contain milestone payments. Revenues from milestones, if they are considered substantive, are recognized upon successful accomplishment of the milestones. Determining whether a milestone is substantive involves judgment, including an assessment of our involvement in achieving the milestones and whether the amount of the payment is commensurate to our performance. If not considered substantive, milestones are initially deferred and recognized over the remaining period of the performance obligation.

Payments received to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Revenue from contracts and grants is recognized as the services are performed and recorded as effort is expended on the contracted work and billed to the government or our contractual partner. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed.

Product royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize our licensed technologies and are recognized when the amount of and basis for such royalty payments are reported to us in accurate and appropriate form and in accordance with the related license agreement.

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. IPR&D assets are tested for impairment on an annual basis during the third quarter, or earlier if impairment indicators are present.

Discounted cash flow models 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

We performed an annual impairment test of the IPR&D assets as of July 1, 2016 and concluded that the IPR&D assets were not 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.

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. We performed an annual impairment test of the goodwill asset as of July 1, 2016 and concluded that goodwill was not impaired.

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 organizations, or CRO, services. Contract manufacturing expenses include expenses associated with contract manufacturing organizations, 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 and directors based on the estimated fair values of the stock-based awards expected to vest at the grant date and is adjusted, 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. 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.

We record stock-based compensation expense for stock options granted to non-employees based on the fair value of the stock options which is re-measured over the vesting term resulting in periodic adjustments to stock-based compensation expense.

RESULTS OF OPERATIONS

Year Ended December 31, 2016 compared with Year Ended December 31, 2015

	Year Ended December 31		Increase/ (Decrease)	
	2016	2015	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 2,174	$ 1,442	$ 732	51%
Contracts and Grants	4,612	4,038	574	14%
Total Revenue	6,786	5,480	1,306	24%
Operating Expense:				
Research and Development	102,726	100,171	2,555	3%
General and Administrative	35,979	33,837	2,142	6%
Amortization of Acquired Intangible Assets	997	1,013	(16)	(2)%
Total Operating Expense	139,702	135,021	4,681	3%
Operating Loss	(132,916)	(129,541)	3,375	3%
Investment and Other Income, Net	4,386	2,344	2,042	87%
Net Loss	$ (128,530)	$ (127,197)	$ 1,333	1%

Net Loss

The $1.3 million increase in net loss for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily the result of an increase in research and development expenses and general and administrative expenses, offset by an increase in investment and other income and revenue.

Revenue

The $0.7 million increase in product development and licensing agreements revenue for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily related to our BMS agreement. In May 2014, we entered into a clinical trial collaboration with BMS whereby BMS made a one-time payment to us of $5.0 million which we are recognizing as revenue along with BMS's 50% share of the clinical trial cost over our estimated performance period of five years. The $0.6 million increase in contracts and grants revenue for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily related to an increase in grant revenue of $1.2 million, partially offset by a decrease of $0.7 million in revenue from our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller.

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)	
	2016	2015	$	%
	(In thousands)			
Personnel	$ 36,070	$ 29,774	$ 6,296	21%
Laboratory Supplies	3,697	4,355	(658)	(15)%
Facility	6,314	5,756	558	10%
License Fees	1,614	896	718	80%
Product Development	46,852	52,776	(5,924)	(11)%

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $6.3 million increase in personnel expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to Kolltan-related severance expense and higher stock-based compensation of $0.7 million and $1.6 million, respectively, and increased headcount. We expect personnel expenses, not including the Kolltan-related severance expenses, to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.7 million decrease in laboratory supply expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to lower manufacturing supply purchases. We expect supply 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 $0.6 million increase in facility expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to an increase in rent. 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. The $0.7 million increase in license fee expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. 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 $5.9 million decrease in product development expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to a $19.9 million decrease in Rintega program costs. That decrease was partially offset by increases in glembatumumab vedotin and varlilumab program costs of $4.6 million and $9.6 million, respectively. We expect product development expenses to decrease over the next twelve months as decreases in Rintega costs are only partially offset by increases in the CDX-0158 and CDX-3379 programs, although there may be fluctuations on a quarterly basis.

General and Administrative Expense

The $2.1 million increase in general and administrative expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to Kolltan-related severance expense, restructuring expense related to our decision to not occupy our Needham, MA expansion space and higher stock-based compensation of $2.4 million, $1.2 million and $0.9 million, respectively. Those increases were partially offset by lower commercial planning costs of $2.8 million. We expect general and administrative expense, not including the Kolltan-related severance and restructuring expenses, to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Amortization Expense

Amortization expenses for the year ended December 31, 2016 were consistent compared to the year ended December 31, 2015. We expect amortization expense of acquired intangible assets to remain relatively consistent over the next twelve months.

Investment and Other Income, Net

The $2.0 million increase in investment and other income, net for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to higher other income of $1.8 million related to our sale of New Jersey tax benefits. We anticipate investment income to decrease over the next twelve months.

Year Ended December 31, 2015 compared with Year Ended December 31, 2014

	Year Ended December 31		Increase/ (Decrease)	
	2015	2014	$	%
	(In thousands)			
Revenue:				
Product Development and Licensing Agreements	$ 1,442	$ 838	$ 604	72%
Contracts and Grants	4,038	2,748	1,290	47%
Total Revenue	5,480	3,586	1,894	53%
Operating Expense:				
Research and Development	100,171	104,381	(4,210)	(4)%
General and Administrative	33,837	20,622	13,215	64%
Amortization of Acquired Intangible Assets	1,013	1,013	—	0%
Total Operating Expense	135,021	126,016	9,005	7%
Operating Loss	(129,541)	(122,430)	7,111	6%
Investment and Other Income, Net	2,344	4,350	(2,006)	(46)%
Net Loss	$ (127,197)	$ (118,080)	$ 9,117	8%

Net Loss

The $9.1 million increase in net loss for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily the result of an increase in general and administrative expenses, partially offset by a decrease in research and development expenses.

Revenue

The $0.6 million increase in product development and licensing agreements revenue for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily related to our BMS agreement. In May 2014, we entered into a clinical trial collaboration with BMS whereby BMS made a one-time payment to us of $5.0 million which we are recognizing as revenue along with BMS's 50% share of the clinical trial cost over our estimated performance period of five years. The $1.3 million increase in contracts and grants revenue for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily related to our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller.

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)	
	2015	2014	$	%
	(In thousands)			
Personnel	$ 29,774	$ 20,666	$ 9,108	44%
Laboratory Supplies	4,355	3,598	757	21%
Facility	5,756	5,062	694	14%
License Fees	896	3,150	(2,254)	(72)%
Product Development	52,776	67,205	(14,429)	(21)%

The $0.8 million increase in laboratory supply expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to higher manufacturing supply purchases.

The $0.7 million increase in facility expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to an increase in rent and depreciation and amortization expense.

The $2.3 million decrease in license fee expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to the one-time $2.5 million milestone incurred and paid to Seattle Genetics in 2014 as a result of the METRIC study initiation.

The $14.4 million decrease in product development expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to a $13.5 million decrease in ACT IV costs. Increases in glembatumumab vedotin and varlilumab clinical trial costs of $2.4 million and $3.0 million, respectively, were offset by decreases in contract manufacturing costs of $6.4 million.

General and Administrative Expense

The $13.2 million increase in general and administrative expenses for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to higher headcount, stock-based compensation of $3.2 million and a $6.5 million increase in Rintega and glembatumumab vedotin commercial planning costs.

Amortization Expense

Amortization expenses for the year ended December 31, 2015 were consistent compared to the year ended December 31, 2014.

Investment and Other Income, Net

The $2.0 million decrease in investment and other income, net for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to other income of $3.0 million received in 2014 in connection with our TopoTarget agreement. These payments are the last milestone payments we were owed from TopoTarget.

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, 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, 2016, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $189.8 million. We have had recurring losses and incurred a loss of $128.5 million for the year ended December 31, 2016. Net cash used in operations for the year ended December 31, 2016 was $113.0 million. We believe that the cash, cash equivalents and marketable securities at December 31, 2016 combined with the 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 2018, however, this could be impacted if we elected to pay Kolltan contingent milestones, if any, in cash.

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 $172.5 million, 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.

During the next twelve months and beyond, 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. Further, if we do not obtain shareholder approval to issue shares in lieu of cash payments, we would need to make those payments in cash in order to meet our NASDAQ listing requirements. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay on-going 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 $113.0 million for the year ended December 31, 2016 compared to $98.9 million for the year ended December 31, 2015. The increase in net cash used in operating activities was primarily due to an increase in net loss of $1.3 million and changes in working capital. We expect that cash used in operating activities will remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Net cash used in operating activities was $98.9 million for the year ended December 31, 2015 compared to $101.5 million for the year ended December 31, 2014. The decrease in net cash used in operating activities was primarily due to increases in accounts payable and other accrued expenses of $3.4 million and stock-based compensation expense of $5.9 million, offset by an increase in net loss of $9.1 million.

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 and commercialization 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 $68.9 million for the year ended December 31, 2016 compared to net cash used by investing activities of $50.2 million for the year ended December 31, 2015. The increase in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the year ended December 31, 2016 of $68.9 million as compared to net purchases of marketable securities of $45.3 million for the year ended December 31, 2015. We expect that cash provided by investing activities will increase over the next twelve months as we fund our operations through the net proceeds from the sale and maturity of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis.

Net cash used in investing activities was $50.2 million for the year ended December 31, 2015 compared to $41.0 million for the year ended December 31, 2014. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the year ended December 31, 2015 of $45.3 million as compared to $39.1 million for the year ended December 31, 2014.

Financing Activities

Net cash provided by financing activities was $14.5 million for the year ended December 31, 2016 compared to $193.2 million for the year ended December 31, 2015. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were $14.5 million during the year ended December 31, 2016 compared to $193.2 million for the year ended December 31, 2015.

Net cash provided by financing activities was $193.2 million for the year ended December 31, 2015 compared to $1.2 million for the year ended December 31, 2014. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were $193.2 million during the year ended December 31, 2015 compared to $1.2 million for the year ended December 31, 2014.

Equity Offerings

In December 2013, we filed an automatic 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. In December 2016, we 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, 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. During the year ended December 31, 2016, we issued 3,303,800 shares of our common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds to us of $13.9 million, after deducting commission and offering expenses.

During the years ended December 31, 2015, we issued 8,337,500 shares of our common stock in underwritten public offerings resulting in net proceeds to us of $188.8 million, after deducting underwriting fees and offering expenses.

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, 2016 such contingencies have not been recorded in our financial statements. We expect to incur approximately $0.9 million of license and milestone payments in 2017.

The following table summarizes our contractual obligations (not including contingent royalty and milestone payments as described above) at December 31, 2016 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	2017	2018 - 2019	2020 - 2021	Thereafter
			(In thousands)		
Contractual obligations:					
Operating lease obligations(1)	$ 15,830	$ 4,319	$ 9,163	$ 2,348	$ —
Other contractual obligations(2)(3)	9,408	7,661	1,747	—	—
Total contractual obligations	$ 25,238	$ 11,980	$ 10,910	$ 2,348	$ —

(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 $172.5 million, 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 likely 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, 2016 due to the short-term maturities of these instruments.

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.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders' equity, and of cash flows present fairly, in all material respects, the financial position of Celldex Therapeutics, Inc. and its subsidiaries at December 31, 2016 and December 31, 2015 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these 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 these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

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 14, 2017

CELLDEX THERAPEUTICS, INC.

BALANCE SHEETS

(In thousands, except share and per share amounts)

	Consolidated December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 42,461	$ 72,108
Marketable Securities	147,315	217,781
Accounts and Other Receivables	1,784	970
Prepaid and Other Current Assets	4,009	4,077
Total Current Assets	195,569	294,936
Property and Equipment, Net	13,192	11,461
Intangible Assets, Net	81,487	20,794
Other Assets	2,134	1,428
Goodwill	90,976	8,965
Total Assets	$ 383,358	$ 337,584
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 1,740	$ 1,506
Accrued Expenses	28,657	24,316
Current Portion of Long-Term Liabilities	4,826	4,418
Total Current Liabilities	35,223	30,240
Other Long-Term Liabilities	82,704	17,239
Total Liabilities	117,927	47,479
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, 2016 and 2015	—	—
Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 120,516,654 and 98,685,595 Shares Issued and Outstanding at December 31, 2016 and 2015, respectively	121	99
Additional Paid-In Capital	982,255	878,655
Accumulated Other Comprehensive Income	2,541	2,307
Accumulated Deficit	(719,486)	(590,956)
Total Stockholders' Equity	265,431	290,105
Total Liabilities and Stockholders' Equity	$ 383,358	$ 337,584

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

CELLDEX THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Consolidated Year Ended December 31, 2016	Year Ended December 31, 2015	Consolidated Year Ended December 31, 2014
REVENUE:			
Product Development and Licensing Agreements	$ 2,174	$ 1,442	$ 838
Contracts and Grants	4,612	4,038	2,748
Total Revenue	6,786	5,480	3,586
OPERATING EXPENSE:			
Research and Development	102,726	100,171	104,381
General and Administrative	35,979	33,837	20,622
Amortization of Acquired Intangible Assets	997	1,013	1,013
Total Operating Expense	139,702	135,021	126,016
Operating Loss	(132,916)	(129,541)	(122,430)
Investment and Other Income, Net	4,386	2,344	4,350
Net Loss	$ (128,530)	$ (127,197)	$ (118,080)
Basic and Diluted Net Loss Per Common Share	$ (1.27)	$ (1.31)	$ (1.32)
Shares Used in Calculating Basic and Diluted Net Loss per Share	101,529	97,051	89,399
COMPREHENSIVE LOSS:			
Net Loss	$ (128,530)	$ (127,197)	$ (118,080)
Other Comprehensive Income (Loss):			
Foreign Currency Translation Adjustments	—	15	(5)
Unrealized Gain (Loss) on Marketable Securities	234	(298)	(73)
Comprehensive Loss	$ (128,296)	$ (127,480)	$ (118,158)

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

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
Consolidated Balance at December 31, 2013	**89,246,832**	**$ 89**	**$ 662,717**	**$ 2,668**	**$ (345,679)**	**$ 319,795**
Shares Issued under Stock Option and Employee Stock Purchase Plans	193,775	1	1,170	—	—	1,171
Shares Issued in Connection with Supply Agreement	152,172	—	2,000	—	—	2,000
Share-Based Compensation	—	—	6,852	—	—	6,852
Foreign Currency Translation Adjustments	—	—	—	(5)	—	(5)
Unrealized Losses on Marketable Securities	—	—	—	(73)	—	(73)
Net Loss	—	—	—	—	(118,080)	(118,080)
Consolidated Balance at December 31, 2014	**89,592,779**	**90**	**672,739**	**2,590**	**(463,759)**	**211,660**
Shares Issued under Stock Option and Employee Stock Purchase Plans	755,316	1	4,310	—	—	4,311
Shares Issued in Underwritten Offering	8,337,500	8	188,832	—	—	188,840
Share-Based Compensation	—	—	12,774	—	—	12,774
Foreign Currency Translation Adjustments	—	—	—	15	—	15
Unrealized Losses on Marketable Securities	—	—	—	(298)	—	(298)
Net Loss	—	—	—	—	(127,197)	(127,197)
Balance at December 31, 2015	**98,685,595**	**99**	**878,655**	**2,307**	**(590,956)**	**290,105**
Shares Issued under Stock Option and Employee Stock Purchase Plans	158,152	1	534	—	—	535
Shares Issued in Connection with Cantor Agreement	3,303,800	3	13,943	—	—	13,946
Shares Issued in Connection with the Kolltan Acquisition	18,257,996	18	73,379	—	—	73,397
Shares Issued in Connection with Kolltan Severance	111,111	—	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	**120,516,654**	**$ 121**	**$ 982,255**	**$ 2,541**	**$ (719,486)**	**$ 265,431**

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

CELLDEX THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(In thousands)

	Consolidated Year Ended December 31, 2016	Year Ended December 31, 2015	Consolidated Year Ended December 31, 2014
Cash Flows From Operating Activities:			
Net Loss	$ (128,530)	$ (127,197)	$ (118,080)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:			
Depreciation and Amortization	3,095	2,998	2,388
Amortization of Intangible Assets	997	1,013	1,013
Amortization and Premium of Marketable Securities, Net	926	350	95
Realized Gain on Sales and Maturities of Marketable Securities	—	—	(11)
Loss on Sale or Disposal of Assets	81	—	6
Stock-Based Compensation Expense	15,317	12,774	6,852
Non-Cash Expense	1,638	288	72
Changes in Operating Assets and Liabilities:			
Accounts and Other Receivables	(814)	(543)	62
Prepaid and Other Current Assets	1,320	(653)	(2,026)
Other Assets	(89)	6	65
Accounts Payable and Accrued Expenses	(4,970)	4,875	1,450
Other Liabilities	(2,007)	7,202	6,577
Net Cash Used in Operating Activities	(113,036)	(98,887)	(101,537)
Cash Flows From Investing Activities:			
Sales and Maturities of Marketable Securities	242,792	161,090	109,232
Purchases of Marketable Securities	(173,925)	(206,405)	(148,314)
Investment in Other	(1,801)	—	—
Cash Acquired in Kolltan Acquisition, net	4,592	—	—
Acquisition of Property and Equipment	(2,751)	(4,876)	(1,929)
Net Cash Provided by (Used in) Investing Activities	68,907	(50,191)	(41,011)
Cash Flows From Financing Activities:			
Net Proceeds from Stock Issuances	13,946	188,840	—
Proceeds from Issuance of Stock from Employee Benefit Plans	536	4,311	1,171
Net Cash Provided by Financing Activities	14,482	193,151	1,171
Effect of Exchange Rate Changes on Cash and Cash Equivalents	—	15	(5)
Net (Decrease) Increase in Cash and Cash Equivalents	(29,647)	44,088	(141,382)
Cash and Cash Equivalents at Beginning of Period	72,108	28,020	169,402
Cash and Cash Equivalents at End of Period	$ 42,461	$ 72,108	$ 28,020
Non-cash Investing Activities			
Accrued construction in progress	$ 159	$ 75	$ 1,027
Non-cash Supplemental Disclosure			
Shares issued to former Kolltan executive for settlement of severance	$ 426	$ —	$ —
Shares issued in connection with Kolltan Acquisition	$ 73,397	$ —	$ —

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

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 for the treatment of cancer and other difficult-to-treat diseases. The Company currently has seven drug candidates in clinical development including glembatumumab vedotin (also referred to as CDX-011), varlilumab (also referred to as CDX-1127), CDX-0158, CDX-3379, CDX-1401, CDX-301 and CDX-014.

As more fully discussed in Note 17, on November 29, 2016, the Company acquired (the "Kolltan Acquisition") Kolltan Pharmaceuticals, Inc. ("Kolltan"), a privately held clinical-stage biotechnology company based in New Haven, Connecticut in accordance with the Agreement and Plan of Merger dated as of November 1, 2016 (the "Merger Agreement"). Under the terms of the Merger Agreement, Kolltan's investors received, in exchange for their share and debt interests in Kolltan, an aggregate of 18,257,996 shares of Celldex's common stock. In addition, following closing, certain officers of Kolltan will receive an aggregate of 437,901 shares of Celldex's common stock in lieu of cash severance obligations, less tax withholdings. In December 2016, the Company issued 111,111 shares of Celldex's common stock as partial payment of this obligation. In addition, 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, Celldex will be required to pay Kolltan's stockholders milestone payments of up to $172.5 million, which milestone payments may be made, at Celldex's sole election, in cash, in shares of Celldex's common stock or a combination of both, subject to NASDAQ listing requirements and provisions of the Merger Agreement. The number of shares of Celldex common stock issuable in connection with a milestone payment, if any, will be determined based on the average closing price per share of Celldex common stock for the five trading day period ending three calendar days prior to the achievement of such milestone. Pursuant to applicable NASDAQ listing rules, Celldex is required to obtain stockholder approval of such issuances of Celldex's common stock to the extent that such issuances exceed 19.9% of its common stock outstanding prior to the merger. If Celldex does not obtain stockholder approval of such common stock issuances, Celldex may elect to pay the milestone consideration in cash to maintain compliance with applicable NASDAQ listing standards. Celldex may still decide to pay cash even if Celldex obtains stockholder approval although it is required to maintain a certain percentage of the overall consideration paid in Celldex common stock to satisfy certain tax requirements under the Merger Agreement.

At December 31, 2016, the Company had cash, cash equivalents and marketable securities of $189.8 million. The Company has had recurring losses and incurred a loss of $128.5 million for the year ended December 31, 2016. Net cash used in operations for the year ended December 31, 2016 was $113.0 million. The Company believes that the cash, cash equivalents and marketable securities at March 14, 2017 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.

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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(1) NATURE OF BUSINESS AND OVERVIEW (Continued)

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 may decide to pay those milestone payments in cash. Further, if the Company does not obtain shareholder approval to issue shares in lieu of cash payments, the Company would need to make those payments in cash in order to meet its NASDAQ listing requirements. If the Company is unable to raise the funds necessary to meet its long-term liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay on-going 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

Following the Kolltan Acquisition, the consolidated financial statements reflect the financial position, results of operation and cash flows of the combined companies. Accordingly, this report reflects the financial condition as of December 31, 2016 and the results of operations and cash flows for the period from the Kolltan Acquisition on November 29, 2016 through December 31, 2016. On December 31, 2016, the Company completed the merger of Kolltan with and into Celldex pursuant to a short-form merger effected under Delaware law. As a result, the separate corporate existence of Kolltan has ceased and the Company has succeeded to all rights, privileges, powers and franchises of Kolltan.

On December 31, 2014, the Company's wholly-owned subsidiary, Celldex Research Corporation, merged into Celldex Therapeutics, Inc. In February 2016, the Company formed a wholly-owned subsidiary, Celldex Therapeutics Europe GmbH, in Zug, Switzerland. In July 2016, we formed a wholly-owned subsidiary, Celldex Australia Pty Ltd, in Brisbane, Australia. The statements of operations and comprehensive loss, of stockholders' equity, and of cash flows, are consolidated for the years ended December 31, 2016 and 2014. These consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary prior to the merger. All 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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 high-grade 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 their 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 transferred from 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.

Revenue from Rockefeller and BMS represented 40% and 31% for the year ended December 31, 2016, 62% and 24% for the year ended December 31, 2015, and 75% and 20% for the year ended December 31, 2014, of total Company revenue, respectively.

The Company relies on contract manufacturing organizations (CMO) to manufacture drug substance and drug product for its late-stage clinical study of glembatumumab vedotin as well as for future commercial supplies. The Company also relies on CMOs for supply of raw materials as well as filling, packaging, storage and shipping of drug product. These clinical studies would be adversely affected by a significant interruption in the supply of glembatumumab vedotin. The Company also relies on third-party collaborators to develop companion diagnostic tests for certain of its drug candidates, including glembatumumab vedotin.

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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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 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.

IPR&D assets are tested for impairment on an annual basis during the third quarter, or earlier if impairment indicators are present. As part of the annual impairment test of the IPR&D assets as of July 1, 2016, the Company performed a calculation of the fair value of the asset and concluded that the IPR&D assets were not 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.

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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 the two-step goodwill impairment test required under U.S. GAAP. As part of its annual impairment test of the goodwill asset as of July 1, 2016, the Company bypassed the optional qualitative assessment and performed the two-step impairment test. The Company concluded that goodwill was not impaired.

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

The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured.

The Company has entered into and in the future may enter into 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. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. In accounting for these transactions, the Company allocates revenue to the various elements based on their relative fair value. The fair value of a revenue generating element can be based on current selling prices offered by the Company or another party for current products or the Company's best estimate of a selling price for future products. Revenue allocated to an individual element is recognized when all other revenue recognition criteria are met for that element.

These collaborative and other agreements may contain milestone payments. Revenues from milestones, if they are considered substantive, are recognized upon successful accomplishment of the milestones. Determining whether a milestone is substantive involves judgment, including an assessment of the Company's involvement in achieving the milestones and whether the amount of the payment is commensurate to the Company's performance. If not considered substantive, milestones are initially deferred and recognized over the period of the remaining performance obligation.

Payments received to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Revenue from contracts and grants is recognized as the services are performed and recorded as effort is expended on the contracted work and billed to the government or the Company's contractual partner. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed.

Product royalty revenue consists of payments received from licensees for a portion of sales proceeds from products that utilize the Company's licensed technologies and are recognized when the

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

amount of and basis for such royalty payments are reported to the Company in accurate and appropriate form and in accordance with the related license agreement.

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 organizations, or CRO, services. Contract manufacturing expenses include expenses associated with contract manufacturing organizations, 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 and directors based on the estimated fair values of the stock-based awards expected to vest at the grant date and is adjusted, if necessary, to reflect actual forfeitures. 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.

The Company records stock-based compensation expense for stock options granted to non-employees based on the fair value of the stock options which is re-measured over the graded vesting term resulting in periodic adjustments to stock-based compensation expense.

Foreign Currency Translation

Net unrealized gains and losses resulting from foreign currency translation are included in other comprehensive income (loss). At December 31, 2016 and December 31, 2015, 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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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, 2016, 2015 and 2014.

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,		
	2016	2015	2014
Stock options	10,218,710	8,110,239	7,015,350
Restricted stock	50,000	19,500	7,000
	10,268,710	8,129,739	7,022,350

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 financial position or results of operations upon adoption.

In May 2014, the FASB issued a new U.S. GAAP accounting standard that creates modifications to various other revenue accounting standards for specialized transactions and industries. The new U.S. GAAP accounting standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

for those goods or services. In August 2015, the FASB deferred the effective date of the new standard from January 1, 2017 to January 1, 2018. The amendment allows for two methods of adoption, a full retrospective method or a modified retrospective approach with the cumulative effect recognized at the date of initial application. The Company will further study the implications of this standard in order to evaluate the expected impact on the financial statements.

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 new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that this standard may have on the Company's financial statements.

In March 2016, the FASB issued a new U.S. GAAP accounting standard which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for the Company on January 1, 2017. The adoption of this standard is not expected to have a material impact on our financial statements.

In June 2016, the FASB issued a new U.S. GAAP accounting standard which changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. The new standard will be effective for the Company on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In August 2016, the FASB issued a new U.S. GAAP accounting standard which clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The new standard will be effective for us on January 1, 2018. The Company is currently evaluating the potential impact that this standard may have on the Company's financial statements.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(3) COMPREHENSIVE LOSS

The changes in accumulated other comprehensive income (loss) by component for the years ended December 31, 2016, 2015 and 2014 are summarized below. No amounts were reclassified out of accumulated other comprehensive income during the years ended December 31, 2016, 2015 and 2014.

	Unrealized Gain (Loss) on Marketable Securities	Foreign Currency Items	Total
	(In thousands)		
Balance at December 31, 2013	**$ 82**	**$ 2,586**	**$ 2,668**
Other comprehensive loss before reclassifications	(73)	(5)	(78)
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive loss	(73)	(5)	(78)
Balance at December 31, 2014	**9**	**2,581**	**2,590**
Other comprehensive (loss) gain before reclassifications	(298)	15	(283)
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive (loss) gain	(298)	15	(283)
Balance at December 31, 2015	**$ (289)**	**$ 2,596**	**$ 2,307**
Other comprehensive gain before reclassifications	234	—	234
Amounts reclassified from other comprehensive income	—	—	—
Net current-period other comprehensive gain	234	—	234
Balance at December 31, 2016	**$ (55)**	**$ 2,596**	**$ 2,541**

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(4) FAIR VALUE MEASUREMENTS

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

	As of December 31, 2015	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 59,831	—	$ 59,831	—
Marketable securities	$ 217,781	—	$ 217,781	—
	$ 277,612	—	$ 277,612	—

	As of December 31, 2016	Level 1	Level 2	Level 3
		(In thousands)		
Assets:				
Money market funds and cash equivalents	$ 20,445	—	$ 20,445	—
Marketable securities	$ 147,315	—	$ 147,315	—
	$ 167,760	—	$ 167,760	—
Liabilities:				
Kolltan acquisition contingent consideration	$ 44,200	—	—	$ 44,200
	$ 44,200	—	—	$ 44,200

Contingent consideration liabilities related to acquisitions are classified as Level 3 within the valuation hierarchy and are valued based on various estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met. In connection with the Kolltan acquisition, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. We determine the fair value of these obligations on the acquisition date using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. The following table represents a roll-forward of our acquisition-related contingent consideration (in thousands):

	December 31, 2016
Balance at beginning of period	$ —
Milestone payments	—
Changes in fair value	—
Kolltan acquisition contingent consideration	$ 44,200
Balance at end of period	$ 44,200

There have been no transfers of assets or liabilities between the fair value measurement classifications. The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable and accounts payable. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from 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

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(4) FAIR VALUE MEASUREMENTS (Continued)

information, broker or dealer quotes, bids, offers or a combination of these data sources. Short-term accounts receivable and accounts payable are reflected in the accompanying financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

(5) MARKETABLE SECURITIES

A summary of marketable securities is shown below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2016				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 52,754	$ 5	$ (12)	$ 52,747
Maturing after one year through three years	296	8	—	304
Total U.S. government and municipal obligations	$ 53,050	$ 13	$ (12)	$ 53,051
Corporate debt securities				
Maturing in one year or less	$ 94,320	$ —	$ (56)	$ 94,264
Maturing after one year through three years	—	—	—	—
Total corporate debt securities	$ 94,320	$ —	$ (56)	$ 94,264
Total marketable securities	$ 147,370	$ 13	$ (68)	$ 147,315
December 31, 2015				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	$ 48,871	$ 4	$ (20)	$ 48,855
Maturing after one year through three years	15,940	24	(57)	15,907
Total U.S. government and municipal obligations	$ 64,811	$ 28	$ (77)	$ 64,762
Corporate debt securities				
Maturing in one year or less	$ 129,327	$ 2	$ (141)	$ 129,188
Maturing after one year through three years	23,932	1	(102)	23,831
Total corporate debt securities	$ 153,259	$ 3	$ (243)	$ 153,019
Total marketable securities	$ 218,070	$ 31	$ (320)	$ 217,781

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of December 31, 2016. Marketable securities include $0.6 million and $1.5 million in accrued interest at December 31, 2016 and December 31, 2015, respectively.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(6) PROPERTY AND EQUIPMENT, NET

Property and equipment include the following:

	December 31, 2016	December 31, 2015
	(In thousands)	
Laboratory Equipment	$ 6,771	$ 5,432
Manufacturing Equipment	4,312	4,178
Office Furniture and Equipment	3,677	3,088
Leasehold Improvements	17,115	15,371
Construction in Progress	1,283	451
Total Property and Equipment	33,158	28,520
Less Accumulated Depreciation and Amortization	(19,966)	(17,059)
	$ 13,192	$ 11,461

Depreciation and amortization expense related to property and equipment was $3.1 million, $3.0 million and $2.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

(7) INTANGIBLE ASSETS AND GOODWILL

Intangible assets, net of accumulated amortization, and goodwill are as follows:

		December 31, 2016			December 31, 2015		
	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
		(In thousands)					
Intangible Assets:							
IPR&D	Indefinite	$ 73,490	$ —	$ 73,490	$ 11,800	$ —	$ 11,800
Amgen Amendment	16 years	14,500	(6,503)	7,997	14,500	(5,605)	8,895
Core Technology	11 years	1,296	(1,296)	—	1,296	(1,197)	99
Total Intangible Assets		$ 89,286	$ (7,799)	$ 81,487	$ 27,596	$ (6,802)	$ 20,794
Goodwill	Indefinite	$ 90,976	$ —	$ 90,976	$ 8,965	$ —	$ 8,965

The IPR&D intangible asset recorded in connection with the CuraGen acquisition of $11.8 million relates to the development of glembatumumab vedotin. At the date of acquisition and at December 31, 2016, glembatumumab vedotin had not yet reached technological feasibility nor did it have any alternative future use. Glembatumumab vedotin is in a randomized, Phase 2b study for the treatment of triple negative breast cancer and a Phase 2 study for the treatment of metastatic melanoma.

The IPR&D intangible asset recorded in connection with the Kolltan acquisition of $61.7 million relates to the development of the CDX-1058, CDX-3379 and TAM programs. At the date of acquisition and at December 31, 2016, the CDX-1058, CDX-3379 and TAM programs had not yet reached technological feasibility nor did they have any alternative future use. CDX-0158 is a humanized monoclonal antibody currently in a Phase 1 dose escalation study in refractory gastrointestinal stromal tumors and CDX-3379 is a human monoclonal antibody which recently completed a Phase 1b study in patients with solid tumors. The TAM program is a multi-faceted broad antibody discovery effort to

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(7) INTANGIBLE ASSETS AND GOODWILL (Continued)

generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AXL and MerTK, which are expressed on tumor-infiltrating macrophages, dendritic cells and some tumors.

Amortization expense for intangible assets was $1.0 million for the years ended December 31, 2016, 2015 and 2014. The estimated future amortization expense of intangible assets for the years ending December 31, 2017, 2018, 2019, 2020 and 2021 is $0.9 million, $0.9 million, $0.9 million, $0.9 million and $0.9 million, respectively.

(8) ACCRUED EXPENSES

Accrued expenses include the following:

	December 31, 2016	December 31, 2015
	(In thousands)	
Accrued Payroll and Employee Benefits	$ 7,132	$ 5,601
Accrued Research and Development Contract Costs	17,742	14,548
Accrued Professional Fees	1,146	399
Other Accrued Expenses	2,637	3,768
	$ 28,657	$ 24,316

(9) OTHER LONG-TERM LIABILITIES

Other long-term liabilities include the following:

	December 31, 2016	December 31, 2015
	(In thousands)	
Deferred Rent	$ 398	$ 409
Net Deferred Tax Liability related to IPR&D (Note 17)	28,054	4,661
Deferred Income from Sale of Tax Benefits	9,436	12,219
Needham Expansion Restructuring (Note 18)	1,154	—
Long-Term Severance (Note 17)	539	—
Contingent Milestones (Note 17)	44,200	—
Deferred Revenue	3,749	4,368
Total	87,530	21,657
Less Current Portion	(4,826)	(4,418)
Long-Term Portion	$ 82,704	$ 17,239

In November 2015, December 2014, January 2014, January 2013 and January 2012, 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, $1.1 million, $0.8 million and $0.8 million to an independent third party for $9.2 million, $1.8 million, $1.0 million, $0.8 million and $0.7 million, respectively. Under the agreement, the Company must maintain a base of operations 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, 2016, 2015 and 2014, the Company recorded $2.8 million, $1.0 million and $0.4 million to other income related to the sale of these tax benefits, respectively.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(10) STOCKHOLDERS' EQUITY

Common Stock

In December 2013, the Company filed an automatic 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. 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.

During the year ended December 31, 2014, the Company entered into an amended and restated supply agreement with Biosyn Corporation. Under the supply agreement, Biosyn will manufacture and supply keyhole limpet hemocyanin (KLH) to the Company for use in connection with the development, manufacture or commercial sale of Rintega. In connection with the supply agreement, the Company issued to Biosyn 152,172 shares of its common stock having a value of $2.0 million. During the years ended December 31, 2016, 2015 and 2014, the Company recorded $1.6 million, $0.3 million and $0.1 million to research and development expense related to this supply agreement, respectively.

During the year ended December 31, 2015, the Company issued 8,337,500 shares of its common stock in underwritten public offerings resulting in net proceeds to the Company of $188.8 million, after deducting underwriting fees and offering expenses.

During the year ended December 31, 2016, the Company entered into a research and collaboration agreement with an undisclosed private company to access novel technologies and paid $3.5 million to support research activities and make an investment in the private company. The Company initially recorded $1.8 million to other assets related to this investment and $1.7 million was recorded to prepaid and other currents assets and is being amortized over the term of the agreement. At December 31, 2016, $0.7 million remained recorded to prepaid research related to this collaboration.

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. During the year ended December 31, 2016, Company issued 3,303,800 shares of its common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds to the Company of $13.9 million, after deducting commission and offering expenses.

Convertible Preferred Stock

At December 31, 2016, 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").

(11) STOCK-BASED COMPENSATION

The Company has the following stock-based compensation plans: the 2004 Employee Stock Purchase Plan (the "2004 ESPP Plan"), the 2008 Stock Option and Incentive Plan (the "2008 Plan") and Celldex Research's 2005 Equity Incentive Plan (the "Celldex Research 2005 Plan"). There are no shares available for future grant under the Celldex Research 2005 Plan.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(11) STOCK-BASED COMPENSATION (Continued)

Employee Stock Purchase Plan

At December 31, 2016, a total of 200,000 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, 2016 and 2015, the Company issued 59,335 and 15,755 shares under the 2004 ESPP Plan, respectively. At December 31, 2016, 78,236 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, 2016, the 2008 Plan allowed for a maximum of 14,350,000 shares of common stock to be issued for grants of Stock Options and other Awards made prior to June 9, 2025 and grants of Incentive Stock Options made prior to 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, 2016 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2015	8,110,239	$ 13.13	6.7
Granted	2,464,750	$ 4.78	
Exercised	(48,817)	$ 2.90	
Canceled	(307,462)	$ 14.05	
Options Outstanding at December 31, 2016	10,218,710	$ 11.14	6.5
Options Vested and Expected to Vest at December 31, 2016	10,148,728	$ 11.14	6.5
Options Exercisable at December 31, 2016	6,086,840	$ 10.86	5.0
Shares Available for Grant under the 2008 Plan	3,577,635		

The total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was $0.1 million, $14.4 million and $2.7 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2016, 2015 and

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(11) STOCK-BASED COMPENSATION (Continued)

2014 was $3.18, $15.25 and $8.82, respectively. The total fair value of stock options vested during the years ended December 31, 2016, 2015 and 2014 was $17.0 million, $10.0 million and $5.7 million, respectively.

The aggregate intrinsic value of stock options outstanding at December 31, 2016 was $0.4 million. The aggregate intrinsic value of stock options vested and expected to vest at December 31, 2016 was $0.4 million. As of December 31, 2016, total compensation cost related to non-vested employee and non-employee director stock options not yet recognized was approximately $27.4 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.8 years.

Restricted Stock

A summary of restricted stock activity under the 2008 Plan for the year ended December 31, 2016 is as follows:

	Shares	Weighted Average Grant Date Fair Value (per share)
Outstanding and unvested at December 31, 2015	19,500	$ 25.41
Granted	60,000	$ 4.72
Vested	(19,500)	$ 25.41
Canceled	(10,000)	$ 4.72
Outstanding and unvested at December 31, 2016	50,000	$ 4.72

Valuation and Expenses Information

Stock-based compensation expense for the years ended December 31, 2016, 2015 and 2014 was recorded as follows:

	2016	2015	2014
		(In thousands)	
Research and development	$ 7,821	$ 6,186	$ 3,459
General and administrative	7,496	6,588	3,393
Total stock-based compensation expense	$ 15,317	$ 12,774	$ 6,852

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(11) STOCK-BASED COMPENSATION (Continued)

The fair values of employee stock options granted during the years ended December 31, 2016, 2015 and 2014 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Expected stock price volatility	70 - 77%	67 - 69%	70 - 72%
Expected option term	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	1.4 - 2.3%	1.8 - 2.2%	1.9 - 2.2%
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.

(12) REVENUE

Bristol-Myers Squibb Company (BMS)

In May 2014, the Company entered into a clinical trial collaboration with BMS 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 the terms of this clinical trial collaboration, BMS made a one-time payment to the Company of $5.0 million and BMS and the Company amended the terms of the Company's existing license agreement with Medarex, which was acquired by BMS, related to the Company's CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from the Company to Medarex. In return, BMS was granted a time-limited right of first negotiation if the Company wishes to out-license varlilumab. The companies also agreed to work exclusively with each other to explore anti-PD-1 antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that the Company will be responsible for conducting the ongoing Phase 1/2 study.

The Company has determined that its performance obligations under the BMS agreement, which primarily include performing research and development, supplying varlilumab and participating in the joint development committee, should be accounted for as a single unit of accounting and estimated that its performance period under the BMS agreement would be 5 years. Accordingly, the $5.0 million up-front payment was initially recorded as deferred revenue and is being recognized as revenue on a straight-line basis over the estimated 5-year performance period using the Contingency Adjusted Performance Model ("CAPM"). The BMS agreement also provides for BMS to reimburse the Company for 50% of the external costs incurred by the Company in connection with the clinical trial. These BMS payments are being recognized as revenue using the CAPM. The Company recorded $2.1 million, $1.3 million and $0.7 million in revenue related to the BMS agreement during the year ended December 31, 2016, 2015 and 2014, respectively.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(12) REVENUE (Continued)

Rockefeller University (Rockefeller)

In September 2013, the Company entered into an agreement, as amended, with Rockefeller pursuant to which the Company performs research and development services for Rockefeller. The Company bills Rockefeller quarterly for actual time and direct costs incurred and records those amounts to revenue in the quarter the services are performed. The Company recorded $2.7 million, $3.4 million and $2.7 million in revenue related to the Rockefeller agreement during the years ended December 31, 2016, 2015 and 2014, 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 $1.6 million, $0.9 million and $3.2 million was recorded to research and development expense for the years ended December 31, 2016, 2015 and 2014, respectively.

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

The Company and Medarex have entered into an assignment and license agreement, as amended, that provides for the assignment of certain patent and other intellectual property rights and a license to certain Medarex technology related to the Company's APC Targeting Technology™ and an anti-mannose receptor product. Under the terms of the agreement, the Company may be required to pay royalties in the low-single digits on any net product sale of a Licensed Royalty-Bearing Product or Anti-Mannose Product to Medarex 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.

The Company and Medarex have also entered into a research and commercialization agreement, as amended, that provides that the Company may be required to pay Medarex milestones of up to $7.0 million upon obtaining first approval for commercial sale in a first indication of a product containing a licensed antibody and royalty payments in the low-to-mid single digits on any net product sales with respect to the development of any products containing such licensed antibodies 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. In September 2010, the Company exercised an option under the agreement, whereby it licensed from Medarex access to the UltiMab technology to develop and commercialize human antibodies to CD27, including varlilumab. In connection with the clinical trial collaboration, the Company entered into with BMS in May 2014, certain future milestone payments were waived and future royalty rates that the Company may have owed Medarex in connection with any CD27 program were reduced.

Rockefeller University (Rockefeller)

In November 2005, the Company and Rockefeller entered into a license agreement for the exclusive worldwide rights to human DEC-205 receptor, with the right to sublicense the technology.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(13) COLLABORATION AGREEMENTS (Continued)

The license grant is exclusive except that Rockefeller may use and permit other nonprofit organizations to use the human DEC-205 receptor patent rights for educational and research purposes. The Company may be required to pay Rockefeller milestones of up to $3.8 million upon obtaining first approval for commercial sale in a first indication of a product targeting the licensed receptor and royalty payments in the low-to-mid single digits on any net product sales with respect to development and commercialization of the human DEC-205 receptor.

University of Southampton, UK (Southampton)

In November 2008, the Company entered into a license agreement with Southampton 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)

In March 2009, the Company entered into a license agreement with Amgen to acquire the exclusive rights to CDX-301 and CD40 ligand (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 respect to development and commercialization of the technology licensed from Amgen, including CDX-301.

Seattle Genetics, Inc. (Seattle Genetics)

In connection with the acquisition of CuraGen, the Company assumed the license agreement between CuraGen and Seattle Genetics whereby CuraGen acquired the rights to proprietary antibody-drug conjugate (ADC) technology for use with the Company's proprietary antibodies for the potential treatment of cancer. The Company may be required to pay Seattle Genetics milestones of up to $5.0 million and $8.5 million for glembatumumab vedotin and CDX-014, respectively, upon obtaining first approval for commercial sale in a first indication and royalty payments in the mid-single digits on any net product sales with respect to development and commercialization of these drug candidates.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) INCOME TAXES

The components of income tax expense attributable to continuing operations consist of the following:

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
Income tax benefit (provision):			
Federal	$ 45,518	$ 46,598	$ 43,536
State	7,268	10,642	7,328
Foreign	1,124	—	—
Expiration of Net Operating Losses and Research & Development Tax Credits	—	(155)	(2,302)
	53,910	57,085	48,562
Deferred tax valuation allowance	(53,910)	(57,085)	(48,562)
	$ —	$ —	$ —

A reconciliation between the amount of reported income tax and the amount computed using the U.S. Statutory rate of 34% follows:

	2016	2015	2014
		(In thousands)	
Pre-tax loss	$ (128,530)	$ (127,197)	$ (118,080)
Loss at Statutory Rates	(43,700)	(43,247)	(40,147)
Difference in Foreign Tax Rates	150	—	—
Research and Development Credits	(5,203)	(4,935)	(4,126)
State Taxes	(7,268)	(10,642)	(7,328)
Other	2,111	1,584	737
Expiration of Net Operating Losses and Research & Development Tax Credits	—	155	2,302
Change in Valuation Allowance	53,910	57,085	48,562
Income tax (benefit) provision	$ —	$ —	$ —

The Company incurred a foreign pre-tax loss of $3.7 million during the year ended December 31, 2016. 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. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) INCOME TAXES (Continued)

The principal components of the deferred tax assets and liabilities at December 31, 2016 and 2015, respectively, are as follows:

	December 31, 2016	December 31, 2015
	(In thousands)	
Gross Deferred Tax Assets		
Net Operating Loss Carryforwards	$ 174,555	$ 180,777
Foreign Net Operating Loss Carryforwards	1,124	—
Tax Credit Carryforwards	32,306	35,895
Deferred Research and Development Expenses	109,520	48,608
Stock-based Compensation	12,362	8,393
Fixed Assets	1,526	2,017
Deferred Revenue	1,418	1,703
Accrued Expenses and Other	894	219
	333,705	277,612
Gross Deferred Tax Liabilities		
Other Acquired Intangibles	(2,868)	(3,382)
IPR&D Intangibles	(28,054)	(4,661)
	(30,922)	(8,043)
Total Deferred Tax Assets and Liabilities	302,783	269,569
Deferred Tax Assets Valuation Allowance	(330,837)	(274,230)
Net Deferred Tax Asset (Liability)	$ (28,054)	$ (4,661)

The net deferred tax liability of $28.1 million and $4.7 million at December 31, 2016 and 2015, respectively relates to the temporary differences associated with the IPR&D intangible assets acquired in the Kolltan and CuraGen acquisitions, respectively, which are not deductible for tax purposes. Since the IPR&D intangible assets are indefinite-lived, the related deferred tax liability cannot be netted against definite-lived deferred tax assets to reduce the valuation allowance required.

As of December 31, 2016, the Company had the following federal net operating loss ("NOL") carryforwards:

- Prior to the merger of the Company and AVANT, $33.0 million was generated by the Company which expire at various dates starting in 2023 and going through 2028;
- Prior to the merger of the Company and AVANT, $101.2 million, net of expirations and utilization, was generated by AVANT which expire at various dates starting in 2018 and going through 2028;
- Following the merger of the Company and AVANT, $356.7 million was generated by the combined company which expire at various dates starting in 2028 and going through 2036; and
- Prior to its acquisition by the Company, $518.3 million was generated by CuraGen.
- Prior to its acquisition by the Company, $110.5 million was generated by Kolltan Pharmaceuticals, Inc.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) INCOME TAXES (Continued)

As of December 31, 2016, the Company had foreign net operating loss carryforwards of $3.7 million which can be carried forward indefinitely.

As of December 31, 2016, the Company has an additional $17.7 million of federal and state net operating losses not reflected above, that are attributable to stock option exercises which will be recorded as an increase in additional paid in capital on the balance sheet once they are "realized" in accordance with ASC 718.

As of December 31, 2016, the Company had federal and state net operating loss carryforwards of $458.5 million and $344.9 million, respectively, which may be available to offset certain future income tax liabilities and begin to expire in 2018 and 2028, respectively. As of December 31, 2016, the Company also had federal and state research and development tax credit carryforwards of $26.1 million and $9.4 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 due to ownership changes that have 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 in this paragraph 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 as a stand-alone company experienced a change in ownership in October 2007. As a result of the ownership changes in October 2007, utilization of the Company's NOLs prior to October 2007 is subject to an annual limitation of $4.5 million on $28.3 million of NOLs generated before that date. As a result of the ownership changes in June 2009 and December 2009, there is an annual limitation amount of $6.0 million on $67.7 million of NOLs generated before that date. As a result of the ownership change in December 2013, there is an annual limitation amount of $77.0 million on $178.7 million of NOLs generated before that date. 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 the Company's net assets are 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. However, the Company has not completed a 382 study to assess whether a change of control has occurred for the NOLs it has acquired in its various acquisitions, including most recently Kolltan, or whether there have been multiple changes of control since inception, particularly within the ownership of acquired entities prior to their acquisition by the Company, due to the significant complexity and cost associated with such a study. If the Company or its acquired entities have experienced additional changes of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards could be subject to additional annual limitations under Section 382, which are determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(14) INCOME TAXES (Continued)

additional adjustments, as required. Any additional limitations may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any additional limitations are known, no amounts are being presented as an uncertain tax positions.

The Company applies the authoritative guidance on account for and disclosure of uncertainty in income tax positions which requires the Company to determine whether an income tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. For income tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced to the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement with the relevant taxing authority. At December 31, 2016 and 2015, we had no unrecognized tax benefits. A full valuation allowance has been provided against our deferred tax assets and liabilities and, if an adjustment for unrecognized tax benefits is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required.

Massachusetts, New Jersey and Connecticut are the three states 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. For federal and state 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.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at December 31, 2016 against the Company's net deferred tax assets. The net increase in the valuation allowance during the year ended December 31, 2016 primarily related to an increase in deferred tax assets for research and development expenses which have been deferred for tax purposes.

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, 2016 do not include the exercise of renewal terms or early termination provisions (in thousands):

2017	$ 4,319
2018	4,782
2019	4,381
2020	2,348
2021	—
Thereafter	—
Total minimum lease payments	$ 15,830

The Company's total rent and CAM expense for all facility leases was $4.8 million, $2.9 million and $2.7 million for the years ended December 31, 2016, 2015 and 2014, 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, $0.4 million and $0.3 million for the years ended December 31, 2016, 2015 and 2014, respectively.

(17) KOLLTAN ACQUISITION

In connection with the Kolltan Acquisition, effective November 29, 2016, the Company issued 18,257,996 shares of common stock of the Company in exchange for all of the share and debt interests in Kolltan. Following closing, certain officers of Kolltan will receive an aggregate of 437,901 shares of Celldex's common stock in lieu of cash severance obligations, less tax withholdings. In December 2016, the Company issued 111,111 shares of Celldex's common stock as partial payment of this obligation. In addition, 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, Celldex will be required to pay Kolltan's stockholders milestone payments of up to $172.5 million, which milestone payments may be made, at Celldex's sole election, in cash, in shares of Celldex's common stock or a combination of both, subject to NASDAQ listing requirements and provisions of the Merger Agreement.

The Company acquired Kolltan to gain access to Kolltan's programs including: (i) CLDX-0158 (formerly KTN0158) which is currently in a Phase 1 dose escalation study in patient with refractory gastrointestinal stromal tumors (GIST); (ii) CLDX-3379 (formerly KTN3379) which recently completed a Phase 1b study with combination cohorts where meaningful responses and stable disease were observed in cetuximab (Erbitux®) refractory patients in patients with head and neck squamous cell carcinoma and in BRAF-mutant non-small cell lung cancer (NSCLC); and (iii) a multi-faceted TAM

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(17) KOLLTAN ACQUISITION (Continued)

program, a broad antibody discovery effort underway to generate antibodies that modulate the TAM family of RTKs, comprised of Tyro3, AXL and MerTK, which are expressed on tumor-infiltrating macrophages, dendritic cells and some tumors.

The transaction is being accounted for as a business combination with Celldex treated as the accounting acquirer. All of the assets acquired and liabilities assumed in the transaction are recognized at their acquisition-date fair values, while transaction costs associated with the transaction are expensed as incurred.

Purchase Price

The purchase price for Kolltan is based on the acquisition-date fair value of the consideration transferred, which was calculated based on the closing price of the Company's common stock of $4.02 per share on November 29, 2016. The acquisition-date fair value of the 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

The contingent consideration relates to the achievement of certain regulatory and sales milestones as described in the agreement. The estimate of fair value of contingent consideration was $44.2 million at the acquisition date and at December 31, 2016, which was recorded as a noncurrent liability. The Company determined the fair value of these obligations to pay additional milestone payments using various estimates, including probabilities of success, discount rates and amount of time until the conditions of the milestone payments are met. This fair value measurement is based on significant inputs not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a cost of debt rate ranging from 10-11% for the milestones. The range of estimated milestone payments is from zero, if no milestones are achieved, to $172.5 million if all milestones are met.

In the future, if the estimate of the fair value of the contingent consideration changes, the changes in fair value will be recognized in operating earnings. Changes in fair values reflect new information about the probability and timing of meeting the conditions of the milestone payments. In the absence of new information, changes in fair value will only reflect the interest component of contingent consideration related to the passage of time as development work progresses towards the achievement of the milestones.

Allocations of Assets and Liabilities

The Company has allocated the consideration transferred for Kolltan to net tangible assets, intangible assets, and goodwill. The difference between the aggregate consideration transferred and the fair value of assets acquired and liabilities assumed was allocated to goodwill. This goodwill relates to the potential synergies from the Kolltan Acquisition 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.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(17) KOLLTAN ACQUISITION (Continued)

The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date (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

The purchase price allocation has been prepared on a preliminary basis and is subject to change as additional information becomes available concerning the fair value and tax basis of the acquired assets and liabilities. Any adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the acquisition date.

The estimated fair value attributed to IPR&D intangible assets represents an estimate of the fair value of purchased in-process technology for Kolltan's research programs that, as of November 29, 2016, had not reached technological feasibility and have no alternative future use. Only those research programs that had advanced to a stage of development where the Company believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed were included in the estimated fair value. Accordingly, the IPR&D programs primarily represent the estimated fair value of $40.0 million, $3.5 million and $18.0 million for the CDX-0158, CDX-3379 and TAM programs, respectively. The estimated fair value of the IPR&D programs was determined based on estimates of expected future net cash flows. These expected future net cash flows included estimates for revenue and associated costs for the IPR&D programs based on (i) relevant industry factors, (ii) current and expected trends in the product development life cycle, (iii) the ability to engage a strategic partner, (iv) the ability to obtain regulatory approval, and (v) the ability to manufacture and commercialize the products. The probability-adjusted future net cash flows which reflect the different stages of development of each program are then present valued utilizing an estimate of the appropriate discount rate which is consistent with the uncertainties of the cash flows utilized.

The expected future net cash flows for the CDX-0158, 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. The Company expects the commercial launch as promptly as commercially practicable after necessary regulatory approvals are received. The estimated development costs included in the expected future net cash flows was approximately $132 million. These assumptions require various levels of in-house and external testing, clinical trials and approvals from the FDA or comparable foreign regulatory authorities before the CDX-0158, CDX-3379 and TAM programs could be commercialized in the U.S. or other territories. Drug development involves a high degree of risk and most products that make it into clinical development do not receive marketing approval. Numerous risks and uncertainties can delay or stop clinical development of a pharmaceutical product prior to the receipt of marketing approval, including, but not limited to, results from clinical trials that do not support continuing development, issues related to manufacturing or intellectual property protection, and other events or circumstances that cause

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(17) KOLLTAN ACQUISITION (Continued)

unanticipated delays, technical problems or other difficulties. Given these risks and uncertainties, there can be no assurance that the development of the CDX-0158, CDX-3379 and TAM programs will be successfully completed. If the development of the CDX-0158, CDX-3379 and TAM programs are not successful, in whole or in part, or completed in a timely manner, the Company may not realize the expected financial benefits from the development of the CDX-0158, CDX-3379 and TAM programs or the transaction as a whole.

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.

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. These costs include fees for legal, accounting, due diligence, tax, valuation, printing and other various services necessary to complete the transaction. In addition, the Company recorded $2.4 million and $0.7 million in Kolltan severance expenses to general and administrative and research and development, respectively, in the consolidated statements of operations for the year ended December 31, 2016 since the severance was determined to be for the benefit of the Company.

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	2015
	(In thousands)	
Revenue	$ 6,786	$ 5,480
Net loss	$ (146,905)	$ (157,690)
Basic and Diluted Net Loss Per Common Share	$ (1.24)	$ (1.37)

(18) RESTRUCTURING EXPENSE

In December 2016, the Company decided not to occupy the 11,500 square feet of expansion space ("Needham Expansion") at its Needham, Massachusetts facility. The Company agreed to lease the Needham Expansion in August 2015 and the term of the lease expires in July 2020. The Company is actively trying to sublease the lease obligation. The Company recorded restructuring expenses of $1.2 million to general and administrative expense for the twelve months ended December 31, 2016.

CELLDEX THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(18) RESTRUCTURING EXPENSE (Continued)

The activity related to restructuring for the twelve months ended December 31, 2016, is presented below (in thousands):

	Charge for the Twelve Months Ended December 31, 2016	Cash Payments in 2016	Accrual as of December 31, 2016
		(In thousands)	
Needham Expansion	$ 1,154	$ —	$ 1,154
Short-term portion of lease accrual			378
Long-term portion of lease accrual			$ 776

In accordance with U.S. GAAP, the Company recorded an initial estimate, at fair value, in the fourth quarter of 2016. The Company will review its assumptions and estimates quarterly and updates the liability as changes in circumstances require. The liability recorded with respect to the potential lease restructuring was calculated using probability weighted discounted cash flows based on the Company's assumptions and estimates regarding the possible outcomes of the potential time to sublease the space and sublease rental rates. The Company used a credit-adjusted risk-free rate of approximately 10% to discount the estimated cash flows.

The expense and liability related to the potential lease restructuring requires the Company to make significant estimates and assumptions. The Company will review the estimates and assumptions on at least a quarterly basis, until the outcome is finalized, and make whatever modifications management believes to be necessary, based on the Company's best judgment, to reflect any changed circumstances. It is possible that such estimates could change in the future resulting in additional adjustments. Because the Company's estimate of the liability related to the potential lease restructuring includes the application of a discount rate to reflect the time value of money, the estimate of the liability will change as a result of time passing. Any such changes to the Company's estimate of the liability are recorded as additional restructuring and other expense.

(19) SELECTED QUARTERLY FINANCIAL DATA (Unaudited)

2015	Q1 2015	Q2 2015	Q3 2015	Q4 2015
	(In thousands, except per share amounts)			
Total revenue	$ 486	$ 2,178	$ 1,026	$ 1,790
Net loss	(30,174)	(32,359)	(31,980)	(32,684)
Basic and diluted net loss per common share	(0.33)	(0.33)	(0.32)	(0.33)

2016	Q1 2016	Q2 2016	Q3 2016	Q4 2016
	(In thousands, except per share amounts)			
Total revenue	$ 1,303	$ 1,389	$ 2,220	$ 1,874
Net loss	(34,673)	(31,952)	(29,598)	(32,307)
Basic and diluted net loss per common share	(0.35)	(0.32)	(0.29)	(0.30)

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, 2016, 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, 2016. 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, 2016.

The effectiveness of our internal control over financial reporting as of December 31, 2016 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, 2016 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 2017 Annual Meeting of Stockholders, or the 2017 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 2017 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 2017 Proxy Statement under "Executive Compensation," and "Compensation Committee Interlocks and Insider Participation," and is incorporated herein by reference. If the 2017 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 2017 Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference. If the 2017 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 2017 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 2017 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 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in the 2017 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference. If the 2017 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.

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 October 19, 2007, by and among AVANT, Celldex Merger Corporation, and Celldex Therapeutics, Inc.	8-K (000-15006)	2.1	10/22/07
2.2	Agreement and Plan of Merger, dated as of May 28, 2009, by and among Celldex Therapeutics, Inc., CuraGen Corporation and Cottrell Merger Sub, Inc.	8-K (000-15006)	2.1	5/29/09
2.3	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

No.	Description	Incorporated by Reference to		
		Form and SEC File No.	Exhibit No.	SEC Filing Date
3.8	Amended and Restated By-Laws, dated April 7, 2014	8-K (000-15006)	3.1	4/8/14
Instruments Defining the Rights of Security Holders				
4.1	Specimen of Common Stock Certificate	10-K (000-15006)	4.1	2/24/15
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

No.	Description	Incorporated by Reference to		
		Form and SEC File No.	Exhibit No.	SEC Filing Date
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
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	License Agreement dated as of November 1, 2005 by and between The Rockefeller University and the Company	S-4 (333-148291)	10.2	1/18/08
*10.16	Assignment and License Agreement, as amended, dated April 6, 2004 by and among Medarex, Inc., GenPharm International, Inc. and the Company	S-4 (333-148291)	10.4	1/18/08
*10.17	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
*10.18	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
*10.19	License and Assignment Agreement, between Amgen Inc. and the Company dated March 16, 2009	10-K/A (000-15006)	10.1	12/23/10
*10.20	Collaboration Agreement dated June 18, 2004 between Seattle Genetics and CuraGen	10-K (000-15006)	10.27	3/12/10
*10.21	Second Restated Collaboration Agreement dated April 12, 2004 and amended October 19, 2004 between Abgenix Inc. and CuraGen	10-K (000-15006)	10.28	3/12/10
10.22	Amgen Letter Agreement, by and between CuraGen and Amgen Fremont, Inc. dated May 2, 2009	10-K (000-15006)	10.29	3/12/10
*10.23	Transfer and Termination Agreement, dated as of April 21, 2008 by and between TopoTarget A/S and CuraGen	10-K (000-15006)	10.30	3/12/10
*10.24	License Agreement between Medarex and Company dated September 17, 2010	10-Q/A (000-15006)	10.3	12/23/10

No.	Description	Incorporated by Reference to		
		Form and SEC File No.	Exhibit No.	SEC Filing Date
10.25	Master Services Agreement dated March 29, 2010 by and between the Company and Prologue Research International, Inc. (Prologue)	10-Q (000-15006)	10.2	11/3/11
10.26	Amendment to Master Services Agreement dated July 6, 2011 by and between the Company and Novella Clinical Inc. (formerly known as Prologue)	10-Q (000-15006)	10.3	11/3/11
10.27	Master Services Agreement dated May 6, 2013 by and between the Company and PPD Development, LLC	10-Q (000-15006)	10.3	8/6/13
*10.28	Third Amended and Restated Supply Agreement dated October 15, 2014 between the Company and Biosyn Corporation	10-Q (000-15006)	10.1	11/5/14
10.29	Subscription Agreement dated as of October 15, 2014 by and between the Company and Biosyn Corporation	8-K (000-15006)	10.1	10/20/14
Material Contracts—Stock Purchase, Financing and Credit Agreements				
10.30	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				
†10.31	2008 Stock Option and Incentive Plan, as amended and restated	8-K (000-15006)	10.1	6/11/15
†10.32	2004 Employee Stock Purchase Plan, as amended and restated	8-K (000-15006)	10.1	6/13/13
†10.33	Employment Agreement, dated as of January 1, 2013, by and between the Company and Anthony S. Marucci	8-K (000-15006)	10.1	12/21/12
†10.34	Employment Agreement, dated as of January 1, 2013, by and between the Company and Avery W. Catlin	8-K (000-15006)	10.2	12/21/12
†10.35	Employment Agreement, dated as of January 1, 2013, by and between the Company and Thomas Davis, MD	8-K (000-15006)	10.3	12/21/12
†10.36	Employment Agreement, dated as of January 1, 2013, by and between the Company and Tibor Keler, Ph.D.	8-K (000-15006)	10.4	12/21/12
†10.37	Employment Agreement, dated as of January 1, 2013, by and between the Company and Ronald A. Pepin, Ph.D.	8-K (000-15006)	10.5	12/21/12
†10.38	Employment Agreement, dated as of July 1, 2015, by and between the Company and Richard Wright, Ph.D.	10-Q (000-15006)	10.3	8/10/15
†10.39	Amended and Restated Employment Agreement, dated August 10, 2016, by and between the Company and Elizabeth Crowley	8-K (000-15006)	10.1	8/11/16

No.	Description	Incorporated by Reference to		
		Form and SEC File No.	Exhibit No.	SEC Filing Date
†10.40	Employment Agreement, dated November 29, 2016, by and between the Company and Theresa LaVallee, Ph.D.	8-K (000-15006)	10.1	12/5/16
†10.41	Form of Stock Option Agreement	8-K (000-15006)	10.1	1/25/10
†10.42	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.

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

Anthony S. Marucci
President and Chief Executive Officer

Date
March 14, 2017

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 14, 2017
/s/ AVERY W. CATLIN Avery W. Catlin	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 14, 2017
/s/ LARRY ELLBERGER Larry Ellberger	Director, Chairman of the Board of Directors	March 14, 2017
/s/ HERBERT J. CONRAD Herbert J. Conrad	Director	March 14, 2017
/s/ GEORGE O. ELSTON George O. Elston	Director	March 14, 2017
/s/ JAMES J. MARINO James J. Marino	Director	March 14, 2017
/s/ GERALD MCMAHON Gerald McMahon, Ph.D.	Director	March 14, 2017
/s/ HARRY H. PENNER, JR. Harry H. Penner, Jr.	Director	March 14, 2017
/s/ KAREN L. SHOOS Karen L. Shoos	Director	March 14, 2017

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Exhibit 21.1

SUBSIDIARIES OF CELLDEX THERAPEUTICS, INC.

Name	Jurisdiction of Organization	Ownership Percentage
Abigail Pharmaceuticals, Inc.	British Virgin Islands	100%
Bulldog Pharmaceuticals, Inc.	British Virgin Islands	100%
Celldex Australia PTY LTD	Australia	100%
Celldex Therapeutics Europe GmbH	Switzerland	100%
Eltam Pharmaceuticals, Inc.	British Virgin Islands	100%

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-205694, 333-189336, 333-151728 and 333-117602) and on Form S-3 (Nos. 333-214882 and 333-215747) of Celldex Therapeutics, Inc. of our report dated March 14, 2017 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 14, 2017

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Exhibit 31.1

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this annual report on Form 10-K of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2017

By: /s/ ANTHONY S. MARUCCI

Name: Anthony S. Marucci
Title: *President and Chief Executive Officer*

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Exhibit 31.2

CERTIFICATION

I, Avery W. Catlin, certify that:

1. I have reviewed this annual report on Form 10-K of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2017

By: /s/ AVERY W. CATLIN

Name: Avery W. Catlin
Title: *Senior Vice President and Chief Financial Officer*

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Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Celldex Therapeutics, Inc. (the "Company"), that, to his knowledge, the Annual Report of the Company on Form 10-K for the period ended December 31, 2016 (the "Form 10-K"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §78m or 78o(d)) and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to the Form 10-K. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 14, 2017

By: /s/ ANTHONY S. MARUCCI

Name: Anthony S. Marucci
Title: *President and Chief Executive Officer*

Date: March 14, 2017

By: /s/ AVERY W. CATLIN

Name: Avery W. Catlin
Title: *Senior Vice President and Chief Financial Officer*

This certification shall be not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.

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