# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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		FOR	RM 10-K	
(Mark one)				
×	ANNUAL REPORT PURSUAN EXCHANGE ACT OF 1934	NT TO SECTION 13 OR 15	(D) OF THE SECURITIES	
		For the fiscal year o	ended December 31, 2017	
			or	
	TRANSITION REPORT PURS	SUANT TO SECTION 13 O	R 15(D) OF THE SECURITIES	S EXCHANGE ACT OF 1934
			e Number 000-15006	
			ERAPEUTICS, INC. unt as specified in its charter)	
		<b>Delaware</b> (State or other jurisdiction o incorporation or organization)	f (I.R.S. Employer Identification No.)	
	Perryville		oad, Suite 220, Hampton, New executive offices) (Zip Code)	Jersey 08827
	Re	gistrant's telephone number,	including area code: (908) 200-	7500
		Securities registered pursu	nant to Section 12(b) of the Act:	
	т	Title of Class:	Name of Each Excha Register	
	Common St	ock, par value \$.001	NASDAQ Glob	pal Market
		Securities registered pursuan	t to Section 12(g) of the Act: No	ne
Indicate	by check mark if the registrant is	a well-known seasoned issue	r, as defined in Rule 405 of the S	Securities Act. Yes □ No 🗷
Indicate	by check mark if the registrant is	not required to file reports pu	rsuant to Section 13 or Section	15(d) of the Act. Yes □ No 区
during the pre		orter period that the registran		3 or 15(d) of the Securities Exchange Act of 193 s), and (2) has been subject to such filing
required to be		Rule 405 of Regulation S-T	(§232.405 of this chapter) during	Web site, if any, every Interactive Data File ng the preceding 12 months (or for such shorter
will not be co				405 of this Chapter) is not contained herein, and corporated by reference in Part III of this Form 10
emerging grov		of "large accelerated filer," "a		elerated filer, smaller reporting company, or an ing company" and "emerging growth company"
	Large accelerated filer □	Accelerated filer 🗷	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any

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, 2017 was \$313 million. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the actions of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.
The number of shares of common stock outstanding at February 28, 2018 was 141,073,668 shares.

new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

# CELLDEX THERAPEUTICS, INC. ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

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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;
- our ability to negotiate strategic partnerships, where appropriate, for our programs, which may include, glembatumumab vedotin;
- 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 realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently;
- 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 varillumab, 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 principle in a Phase 1 study with varlilumab, which supported the initiation of combination studies in various indications. CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3), is in Phase 2 development in combination with cetuximab for the treatment of head and neck squamous cell carcinoma. We also have a number of earlier stage drug candidates in clinical development, including CDX-014, an antibody-drug conjugate targeting renal and ovarian cancers; CDX-1140, a human monoclonal antibody targeted to CD40, a key activator of immune response; CDX-301, an immune cell mobilizing agent and dendritic cell growth factor; and CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APCs, for cancer indications. Our drug candidates address market opportunities for which we believe current 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 (single-agent, with varlilumab or CPI <sup>(1)</sup> or CDX-301)	Phase 2	Celldex
Varlilumab	Multiple solid tumors (with Opdivo®)	Phase 2	Celldex <sup>(2)</sup>
CDX-3379	Head and neck squamous cell cancer (with Erbitux®)	Phase 2	Celldex
CDX-014	Renal cell and ovarian carcinomas	Phase 1	Celldex
CDX-1140	Multiple solid tumors	Phase 1	Celldex

- checkpoint inhibitor;
- (2) 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 six 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	Malignant melanoma	Phase 2	NCI (CRADA)
CDX-1401/Tecentriq®/SGI-110	Ovarian cancer	Phase 1	NCI (CRADA)
Varlilumab/Opdivo®	B-cell malignancies	Phase 2	NCI (CRADA)

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**

#### Glembatumumah 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 U.S. 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:** Glembatumumab vedotin has been evaluated for the treatment of metastatic breast cancer (MBC) in multiple studies including a single-arm Phase 1/2 study (*Journal of Clinical Oncology*, September 2014); a randomized, controlled Phase 2b study compared to Investigator's Choice chemotherapy in patients with gpNMB-positive MBC called EMERGE (*Journal of Clinical Oncology*, April 2015); and the ongoing randomized, controlled Phase 2b study in patients with triple negative, gpNMB overexpressing breast cancer, called METRIC. We expect to report topline primary endpoint data from the METRIC study during the second quarter of 2018.

The most recent data presented for glembatumumab vedotin in breast cancer are from the EMERGE study, the randomized, multi-center Phase 2b study in 124 patients with heavily pre-treated, advanced, gpNMB-positive breast cancer. 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, progression-free survival (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. Adverse events prominent with the glembatumumab vedotin arm included rash and peripheral neuropathy, while hematologic toxicity was more frequent and severe in the Investigator's Choice arm.

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

	High gpNMB Expression		Triple Negative and gpNMB Over-Expression		
	Glembatumumab Vedotin	Investigator's Choice	Glembatumumab Vedotin	Investigator's Choice	
Response Rate	$\frac{(n=23)}{30\%}$	(n=11) 9%	$\frac{(n=10)}{40\%}$	(n=6) 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.	1.5	3.5 p=0.0	1.5 017	
Median OS (months)	10.0 p=0.	5.7	10.0 p=0.0	5.5	

In December 2013, we initiated METRIC, a randomized, controlled (2:1) Phase 2b study of glembatumumab vedotin versus Xeloda® in patients with triple negative breast cancer that over-expresses gpNMB. Clinical trial study sites were opened 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, defined as the time from randomization to the earlier of disease progression or death due to any cause. 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.

Enrollment (n=327) in METRIC was completed in August 2017. The study calls for 203 progression events for evaluation of the primary endpoint, which will be assessed based on an independent, central reading of patient scans. The sum of the data, including the secondary endpoints of response rate, OS, DOR and safety, will be important in assessing clinical benefit. Based on the current rate of progression events in the study, the Company projects that topline primary endpoint data should be available in the second quarter of 2018.

Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic are underway. While we have made and continue to make progress on these fronts, we have made the decision to stage some of the more costly work in these areas to begin after we have received results from the study. While this step will extend the timeline to complete our regulatory submissions, we believe this is the most prudent use of our funds as we seek to advance our pipeline overall. Assuming positive data, we plan to work with the FDA on a regulatory strategy that would support submitting a Biologics License Application (BLA) in the second half of 2019.

**Treatment of Metastatic Melanoma:** Glembatumumab vedotin has been evaluated for the treatment of unresectable stage III or IV metastatic melanoma in two studies including a single-arm Phase 1/2 open-label study and an ongoing multi-cohort Phase 2 study. Results from the Phase 1/2 study were published in the *Journal of Clinical Oncology* in September 2014.

The most recent data for glembatumumab vedotin in metastatic melanoma are from the ongoing Phase 2 study. This study currently includes four single arm cohorts: (1) a single-agent cohort (enrollment completed; data presented at ASCO 2017), (2) a combination cohort with varillumab (enrollment completed; data presented at SITC 2017), (3) a combination cohort with an approved checkpoint inhibitor (i.e., Opdivo® or Keytruda®) following progression on the checkpoint inhibitor alone (enrollment completed; follow-up continues), and (4) a combination cohort with CDX-301 (enrollment ongoing).

The primary endpoint for each cohort is ORR, except the fourth cohort which is assessing safety and tolerability in anticipation of additional combinations. Secondary endpoints include analyses of PFS, DOR, OS, retrospective investigation of whether the anticancer 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 mature data from the single-agent cohort in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2017. The cohort enrolled 62 evaluable patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor therapy, and almost all patients had received both ipilimumab (n=58; 94%) and anti-PD-1/anti-PD-L1 (n=58; 94%) therapy. Twelve patients presented with BRAF mutation, and fifteen had prior treatment with BRAF or BRAF/MEK targeted agents. Median OS for all patients was 9.0 months (95% CI: 6.1, 13.0). The primary endpoint of the cohort (threshold of 6 or more objective responses in 52 evaluable patients) was exceeded. 7 of 62 (11%) patients experienced a confirmed response. One patient experienced a complete response (CR), and six patients experienced partial responses (PR). An additional three patients also experienced single timepoint PRs. The median DOR 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. Consistent with previous studies in melanoma and breast cancer, early development of rash was associated with greater clinical benefit, including more prolonged PFS and OS. The safety profile was consistent with prior studies of glembatumumab vedotin with rash, neutropenia and neuropathy experienced as the most significant adverse events. Pre-treatment tumor tissue was available for 59 patients. All samples were gpNMB positive, and 78% of patients had tumors with 100% of their epithelial cells expressing gpNMB. Given both the high level of expression and the intensity of expression across this patient population, identifying a potential population for gpNMB

enrichment is not feasible; therefore, all patients with metastatic melanoma could be evaluated as potential candidates for treatment with glembatumumab vedotin in future studies.

Data from the second cohort, combining glembatumumab vedotin and varlilumab, were presented at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in November 2017. The cohort enrolled 34 patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor (CPI) therapy (median prior CPI therapies = 2; range 1-4). Almost all patients had received ipilimumab (n=26; 76%) and/or anti-PD-1/anti-PD-L1 (n=34; 100%) therapy. Nine patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents. Median PFS for all patients was 2.6 months (95% CI: 1.4, 2.8), and median OS for all patients was 6.4 months (95% CI: 3.2, 8.3). One of 31 patients eligible for response evaluation experienced a confirmed partial response (3%), and an additional two patients also experienced single timepoint partial responses. 52% of patients experienced stable disease (minimum of six or more weeks). A 19% disease control rate (patients without progression for greater than three months) was demonstrated. The safety profile was consistent with prior observations and did not appear to be impacted by the addition of an ADC. Modest clinical benefit in the combination could be due to multiple factors, including potential lack of sensitivity to immunotherapy in patients with checkpoint refractory disease, many of whom progressed so rapidly that they experienced a very short duration of varlilumab treatment (median 2 doses); a possible dearth of antigen presenting cells in tumors; and the potential for immune checkpoint molecules to remain unblocked without checkpoint inhibitor therapy. Future cohorts are designed to address some of these potential factors. No significant correlation between rash and outcome was observed but will continue to be monitored in future cohorts.

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 and is ongoing. 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 is designed to assess the safety and tolerability of glembatumumab vedotin at varying dose levels. 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 a Phase 2 study of glembatumumab vedotin in uveal melanoma. The study is a single-arm, open-label study in patients with locally recurrent or metastatic uveal melanoma. The study has a two-stage design with a pre-specified activity threshold necessary in the first stage to progress enrollment to the second stage. The primary outcome measure is ORR. Secondary outcome measures include change in gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. Data from this study were presented at the 9<sup>th</sup> World Congress of Melanoma in October 2017. Two (6%) objective responses were observed in 31 patients to date, and 35% of patients experienced stable disease greater than 100 days (median 5.5 months). The disease control rate (response rate + stable disease) for all patients on study was noteworthy at 61%. Median PFS was 3.2 months, and median OS was 11.8 months. For patients

who experienced either a partial response or stable disease, median PFS was 5.5 months, and median OS had not yet been reached. The NCI is conducting exploratory immune correlates to provide insight into target saturation, antigen release and potential combination strategies.

#### Varlilumab

Variilumab 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 variilumab 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 variilumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, variilumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *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. Variilumab 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 variilumab 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. Variilumab has also been explored in other combination studies, including with glembatumumab vedotin, and is being studied in ongoing and planned investigator-sponsored and collaborative studies.

Single-Agent Phase 1 Study: In an open-label Phase 1 study of variilumab in patients with selected malignant solid tumors or hematologic cancers, variilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients were dosed in the study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of a maximum tolerated dose (MTD). The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade have been observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anticancer therapy, including a complete response in a patient with Hodgkin lymphoma (ongoing at last follow-up at 2.8 years) and a partial response in a patient with renal cell carcinoma (ongoing at last follow-up at 3.7 years). In addition, a patient with renal cell carcinoma that experienced significant stable disease (4+ years) subsequently achieved a partial response maintained through last follow-up at 4.6+ years without additional anticancer therapy. Twelve patients experienced stable disease up to 14 months. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

Phase 1/2 Varlilumab/Opdivo® Combination Study: In 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb 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.

Data (n=36) from the Phase 1 dose-escalation portion of the study were presented in an oral presentation at the American Society of Clinical Oncology Annual Meeting in June 2017. The majority of patients had PD-L1 negative tumor at baseline and presented with stage IV, heavily pre-treated disease. 80% of patients enrolled presented with refractory or recurrent colorectal (n=21) or ovarian cancer (n=8), a population expected to have minimal response to checkpoint blockade. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination was well tolerated at all varillumab dose levels tested 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, was also noted. Notable disease control was also observed (stable disease or better for at least 3 months), considering the stage IV patient population contained mostly (80%) colorectal and ovarian cases: 0.1 mg/kg varlilumab + 240 mg Opdivo: 1/5 (20%), 1 mg/kg varlilumab + 240 mg Opdivo: 6/15 (40%).

Three partial responses (PR) were observed. A patient with PD-L1 negative, MMR proficient (MSI-low) colorectal cancer, typically unlikely to respond to checkpoint blockade monotherapy, achieved a confirmed PR (95% decrease in target lesions) and, following completion of combination treatment, continues to receive treatment with Opdivo monotherapy at 31+ months. A patient with low PD-L1 (5% expression) squamous cell head and neck cancer achieved a confirmed PR (59% shrinkage) and experienced PFS of 6.7 months. A patient with PD-L1 negative ovarian cancer experienced a single timepoint PR (49% shrinkage) but discontinued treatment to a dose-limiting toxicity (immune hepatitis, an event known to be associated with checkpoint inhibition therapy). A subgroup analysis was conducted in patients with ovarian cancer based on an observed increase of PD-L1 and tumor-infiltrating lymphocytes in this patient population. In patients with paired baseline and on-treatment biopsies (n=13), only 15% were PD-L1 positive ( $\square$  1% tumor cells) at baseline compared to 77% during treatment (p=0.015). Patients with increased tumor PD-L1 expression and tumor CD8 T cells correlated with better clinical outcome with treatment (stable disease or better).

The Phase 2 portion of the study opened to enrollment in April 2016 and completed enrollment in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is ORR, except glioblastoma, where the primary objective is the rate of 12-month OS. Secondary objectives include pharmacokinetic assessments, determining the immunogenicity of varillumab when given in combination with Opdivo, evaluating alternate dosing schedules of varillumab and further assessing the anti-tumor activity of combination treatment. We plan to work with Bristol-Myers Squibb to present data from the study at future medical meetings in 2018.

**Third-Party Sponsored Studies:** We have also entered into a CRADA with the NCI under which NCI is sponsoring a Phase 2 study of varillumab in combination with nivolumab in relapsed or refractory aggressive B-cell lymphomas. Patients receive either nivolumab alone or the combination. The primary outcome measure is ORR. Secondary outcome measures include DOR, safety, PFS and OS. The study opened to enrollment in January 2018 and is expected to enroll 106 patients.

#### CDX-3379

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

The most recent data for CDX-3379 were reported from a Phase 1a/1b study conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. 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=9) and Herceptin® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, In the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one durable complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar® and was considered refractory, as well as a single timepoint partial response in a patient with thyroid cancer. Initial data were presented at the American Society of Clinical Oncology Annual Meeting in June 2016.

We have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The primary objective of the study is objective response rate. Second objectives include assessments of clinical benefit response (CBR), DOR, PFS and OS, and safety and pharmacokinetics associated with the combination.

#### 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 cancers.

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. In January 2018, we amended the protocol, converting the study to Phase 1, expanding enrollment to include patients with ovarian clear cell carcinoma and enabling the evaluation of alternate dosing regimens. Enrollment is ongoing. The study includes a dose-escalation portion across three separate cohorts to determine the MTD followed by expansion cohorts of up to 15 patients each to assess the preliminary anti-tumor activity of CDX-014, as measured by objective response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

## CDX-1140

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

We initiated a Phase 1 study of CDX-1140 in November 2017. This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic solid tumors, is designed to determine the MTD during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

## 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.

CDX-301's potential activity is being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-301 in combination with CDX-1401 is being conducted in malignant 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 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.

CDX-301 is also being studied in a combination cohort with glembatumumab vedotin in a Phase 2 study in metastatic melanoma (opened to enrollment in January 2018) and is being studied in ongoing and planned investigator-sponsored and collaborative studies.

## 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. CDX-1401 is being developed for the treatment of malignant melanoma and a variety of solid tumors which express the cancer antigen NY-ESO-1. Preclinical studies have shown that CDX-1401 treatment results in activation of human T cell responses against NY-ESO-1.

We 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.

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 malignant melanoma by the 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. Enrollment is complete, and initial results were presented at the 2016 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.

In September 2017, a randomized, open-label Phase 1/2 study of CDX-1401 in combination with atezolizumab and SGI-110 opened to enrollment in recurrent ovarian, fallopian tube, or primary peritoneal cancer. This study is being conducted under a CRADA with the NCI Division of Cancer Treatment and Diagnosis and is designed to determine the activity of atezolizumab alone, atezolizumab plus SGI-110 and atezolizumab plus SGI-110 plus CDX-1401. The primary outcome of the Phase 1 dose-escalation study is safety and only evaluates atezolizumab alone and in combination with SGI-110.

The Phase 2 portion of the study is expected to add CDX-1401. The primary outcome of the Phase 2 portion of the study is a comparison of PFS between the three cohorts.

Other studies are ongoing and planned through investigator-sponsored and collaborative agreements.

Anti-KIT Program: CDX-0158 and CDX-0159

KIT activation is implicated in many disease processes including some cancers, neurofibromatosis, mast cell-related diseases and autoimmune diseases. We conducted a Phase 1 dose-escalation study of CDX-0158, a humanized monoclonal antibody that is a potent inhibitor of wildtype KIT, in 28 patients with advanced refractory GIST and other KIT positive tumors with doses up to 15 mg/kg. No evidence of myelosuppression, an effect commonly associated with KIT inhibition, was observed in this study. Approximately two-thirds of the patients on study had infusion reactions that were manageable with premedication and longer infusion times. The biomarker data showed evidence of dose-related KIT engagement, and two patients experienced partial metabolic responses on fluorodeoxyglucose (FDG)-PET scan; however, these PET responses were not associated with tumor shrinkage.

Given the infusion reactions, modifications have been introduced into the Fc portion of the CDX-0158 antibody to prevent these interactions, which should eliminate the potential for Fc receptor mediated agonist activity. This second-generation version, called CDX-0159, also includes modifications to increase the half-life of the antibody, giving it an additional advantage over CDX-0158. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development. We expect manufacturing and IND-enabling efforts for CDX-0159 will be completed in 2018.

## **Development Strategy**

Immunotherapy Platform:

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

Our intent is to leverage this knowledge 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 (BMS)

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<sup>TM</sup> 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.

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

Rockefeller University (Rockefeller)

Under a license agreement with Rockefeller, we acquired 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)

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

Amgen Inc. (Amgen)

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

Amgen Fremont

Under a license agreement with Amgen Fremont, we acquired rights to develop fully-human monoclonal antibody therapeutics. In May 2009, an amendment to the license agreement was entered into related to our exclusive rights to develop and commercialize glembatumumab vedotin, CDX-014 and antibodies to 10 other licensed antigens. Under the amendment, we and Amgen Fremont agreed to modify the terms of our existing cross-license of antigens whereby our amended license is fully paid-up and royalty-free.

Seattle Genetics, Inc. (Seattle Genetics)

Under a license agreement with Seattle Genetics, we acquired the rights to proprietary ADC technology, with the right to sublicense, for use with our proprietary antibodies for the potential treatment of cancer. Under the terms of the agreement, we have the responsibility to use 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 tenth 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.

Yale University (Yale)

Under a license agreement with Yale, we may be required to make a one-time payment to Yale of \$3.0 million with respect to each therapeutic or prophylactic receptor tyrosine kinase (RTK) royalty-bearing product, including CDX-3379, that achieves a specified commercial milestone. In addition, we

may be required to pay a low single-digit royalty on annual worldwide net sales of each RTK royalty-bearing product, including CDX-3379. Unless earlier terminated by us or Yale, the Yale license agreement is due to expire no later than May 2038 but may expire earlier on a country-by-country basis under specified circumstances.

MedImmune, LLC (MedImmune)

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

## Competition

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

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 Therapeutics, 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 are a research and development company and have limited experience in commercial manufacturing. Our ability to conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, depends on the ability of Contract Manufacturing Organizations (CMOs) to manufacture our drug candidates on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices (cGMP) and U.S. and foreign regulatory requirements, as applicable. We also rely on CMOs for 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 2017, we successfully transferred the monoclonal antibody (mAb) intermediate manufacturing process and manufactured a cGMP batch at Patheon Biologics in Brisbane, Australia. Piramal Healthcare UK Ltd. manufactures the antibody-drug conjugate with the vcMMAE linker-toxin. The drug substance is then filled and packaged at our drug product commercial manufacturer, 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 biologics license application (BLA) filing and, if regulatory approval is obtained, commercial launch of glembatumumab vedotin.

We operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA regulations, allowing us to distribute drug candidates to clinical sites in the U.S. for early-stage clinical

trials. We currently manufacture CDX-1140, CDX-301 and CDX-1401 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 ADC, is then manufactured by Lonza (Visp). We expect that our existing clinical supplies of CDX-3379 and varillumab will be sufficient to carry out our current planned clinical development. Additional manufacturing options are under review and may involve utilization of the Fall River facility and/or a CMO. All products are then filled and packaged at contract manufacturers. Any manufacturing failures or compliance issues at contract manufacturers could cause delays in our Phase 1 and Phase 2 clinical studies for these drug candidates.

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 CDX-014 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 are the estimated expirations if all maintenance fees and annuities are paid when due, and do not include any possible additional terms for Patent Term Extensions (PTEs) or Supplementary Protection Certificates (SPCs), if these may be secured in due course):

- 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 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 an exclusive license to under our license agreement, which broadly supports varlilumab. The patent includes 18 claims covering various methods of treating cancer using agonistic anti-human CD27 antibodies and relates, among other things, directly to our CD27 antibody program and therapeutic uses of varlilumab. In September 2014, two European patent oppositions were filed against the University of Southampton European patent, and at a hearing on November 23, 2016 the European Patent Office (EPO) revoked the European patent on the ground of lack of inventive step. The University of Southampton has filed an appeal against this decision, and we intend to defend the European patent vigorously in cooperation with the University of Southampton. This EPO

decision does not affect the later filed Celldex patents and applications for varillumab. We also have an issued U.S. patent which covers varillumab 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 (including claims covering CDX-1401 as compositions of matter) 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, Australian and Canadian patents and a pending patent application in 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 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 patents and patent applications relating to particular ErbB3 inhibitors from MedImmune. These patents and patent applications include claims directed to particular anti-ErbB3 antibody compositions of matter, including CDX-3379 compositions of matter, and methods of using such antibodies. Patents have been issued in the U.S., Japan, Russia and New Zealand which have estimated patent expiry dates in 2032. Patent applications in this portfolio are pending in Europe, 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.
- We own a family of patents and patent applications directed to anti-KIT receptor antibody compositions of matter and methods of using such antibodies. U.S. patents have been issued, and foreign counterparts 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 (not including increases of term due to Patent Term Adjustment in the U.S.). We also have pending U.S. and European patent applications directed to use of anti-KIT receptor antibodies for treatment of particular eosinophil or mast cell related disorders, including neurofibromatosis. Any patents that issue based on the latter patent applications would have estimated patent expiry dates in at least 2035.
- We acquired rights to a portfolio of patents and patent applications related to the "TAM family" of RTKs (comprised of Tyro3, AXL and MerTK) receptors which are in-licensed from, or co-owned with, the Salk Institute for Biological Studies. For example, we have an exclusive license to two issued U.S. patents directed to TAM receptor inhibition to treat infections and to a U.S. patent application directed to methods for the modulation of the immune response via targeting TAM receptors. Foreign counterparts to these patents and this patent application are

pending in Europe and Canada. If and where issued the foregoing would have estimated patent expiry dates in at least 2028.

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 and/or a specified period from first commercial sale on a territory-by-territory basis. We have generally agreed to use reasonable efforts to develop and commercialize licensed products and to achieve specified milestones and pay license fees, milestone payments and royalties based on the net sales of the licensed products or to pay a percentage of sublicense income. If we breach our obligations, the licensor has the right to terminate the license, and, in some cases, convert the license to a non-exclusive license. Generally, we control and are responsible for the cost of defending the patent rights of the technologies that we license.

### Proprietary Rights

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

agreements will provide meaningful protection for our information in the event of unauthorized use or disclosure of such confidential information.

#### Government Regulation

Our activities and products are significantly regulated by a number of governmental entities, including the U.S. Food and Drug Administration, or FDA, in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of our products. We must obtain regulatory approval from the FDA and comparable authorities in other countries, as applicable, for our drug candidates before we can commercialize such drugs in the U.S. and foreign jurisdictions. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. Many drug candidates that initially appear promising ultimately do not reach the 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, disgogement 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 clinical trials in no way assures that the FDA will ultimately approve the product. Clinical trials are generally conducted in three sequential phases. In a Phase 1 trial, the product is given to a small number of patients to test for safety (adverse effects), determine a recommended Phase 2 dose(s) and evaluate any signals of efficacy. Phase 2 trials are conducted on a limited group of the target patient population; safety, optimal dosage and efficacy are studied. A Phase 3 trial is performed in a large patient population, generally over a wide geographic area to provide evidence for the safety and efficacy of the product. The FDA maintains and exercises oversight authority throughout the clinical trial process.

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

## Marketing Approval

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

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after receipt before accepting them for filing based on the agency's threshold determination that they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs and BLAs. Most such applications for non-priority products are reviewed within ten to twelve months after filing, and most applications for priority review products, that is, drugs and biologics that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months after filing. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or biological products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

After the FDA's evaluation of the NDA or BLA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, 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, many types of changes to the approved product, such as changes in indications, manufacturing changes and labeling, are subject to further testing requirements and FDA review and approval.

Special Regulatory Procedures

Fast track designation—The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product, concurrent with or after the filing of the IND for the drug candidate. A drug that receives fast track designation is eligible for some or all of the following:
(i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
(ii) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for accelerated approval and priority review, if relevant criteria are met; and (iv) Rolling Review, which means that a drug company can submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the NDA or BLA is completed before the entire application can be reviewed. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

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

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

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

Orphan drug designation—Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is generally

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

## 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, the Office of the Inspector General of Health and Human Services and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

## Biosimilars Law

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

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

## 21st Century Cures Act

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

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

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

Furthermore, even after PMA approval is obtained, numerous regulatory requirements apply to the manufacturer of the companion diagnostic. The FDA enforces these requirements by inspection and market surveillance. These requirements include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off label" uses, the medical device reporting regulation, and the reports of corrections and removals regulation. If the FDA finds a violation, it can

institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for PMA of new products; and withdrawing PMAs already granted.

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

In addition to FDA restrictions on marketing and promotion of pharmaceutical products, several other types of federal and state laws have been applied to restrict certain marketing business practices in the biopharmaceutical and medical device industries in recent years. These laws include, without limitation, state and federal anti-kickback statutes and false claims statutes and false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to health care providers. Applicable state law may be broader in scope than federal law and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to health care professionals.

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

## Foreign Regulation

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

Under the EU regulatory system, we will submit most of our marketing authorization applications under the centralized procedure. The centralized procedure is compulsory for medicines produced by biotechnology, or are for the treatment of cancer, or officially designated as 'orphan medicines.' The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. As in the United States, we may apply for designation of a drug candidate as an

orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. The EMA grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. Orphan drugs in Europe enjoy economic and marketing benefits, including a 10-year market exclusivity period for the approved indication, but not for the same product, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

## Other Regulatory Processes

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

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

## Third-Party Payor Coverage and Reimbursement

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

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

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

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

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, 2017, we employed 197 employees (192 full-time, 3 part-time and 2 interns), 38 of whom have Ph.D. and/or M.D. degrees. Of these employees, 167 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 \$96.2 million, \$102.7 million and \$100.2 million during the years ended December 31, 2017, 2016 and 2015, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2018 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, which was liquidated in June 2017. 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 \$812.5 million as of December 31, 2017. 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 \$121.5 million, \$132.9 million and \$129.5 million during 2017, 2016 and 2015, respectively, and expect to incur an operating loss in 2018 and beyond. We believe that operating losses will continue in 2018 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, 2017, 2016 and 2015, we incurred \$21.1 million, \$24.9 million and \$36.3 million in clinical trial expense and \$11.4 million, \$18.3 million and \$14.8 million in contract manufacturing expense. Our net losses have had and will continue to have an adverse effect on, among other things, our stockholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot predict when we will become profitable, if at all.

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

We expect to incur significant costs as we develop our drug candidates. In particular, the continuing development and commercialization of glembatumumab vedotin and our other drug candidates requires additional capital beyond our current resources. As of December 31, 2017, we had cash, cash equivalents and marketable securities of \$139.4 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 drug candidates 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.

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

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

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

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

certain income tax deductions. The estimated impact of the TCJA is based on our management's current knowledge and assumptions, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. We have revalued our net deferred tax assets and liabilities at the newly enacted U.S. federal rate, and we recognized a tax benefit of \$19.1 million during the year ended December 31, 2017 related to the TCJA. We continue to examine the impact this tax reform legislation may have on our business.

# Risks Related to Development and Regulatory Approval of Drug Candidates

Our long term success depends heavily on our ability to fund and complete the research and development activities and obtain regulatory approval for our program assets, 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 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 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 drug candidate's safety and effectiveness on laboratory animals. Preclinical tests can last years. If a product passes its preclinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. Phase 1 testing generally lasts between 6 and 24 months. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. Phase 2 testing generally lasts between 6 and 36 months. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Phase 3 studies generally last between 12 and 48 months. Once clinical testing is completed and a BLA or NDA is filed with the FDA, it may take more than a year to receive FDA approval.

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 drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

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

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

# 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 drug candidates but subject to delay or cancellation if we have difficulty enrolling patients.

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

- the nature of the clinical test;
- the size of the patient population;

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

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

## 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;
- drug candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- · competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

Any delay or failure to 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.

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

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

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

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 Therapeutics, 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 Therapeutics, 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. To the extent we enter into such strategic partnerships, co-promotion or other licensing arrangements. To the extent we enter into such strategic partnerships, co-promotion or other licensing arrangements on acceptable terms or at all, we 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 with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

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

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

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

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

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

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

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

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

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

We plan to seek approval for glembatumumab vedotin in Europe, 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. If any of these third parties is unable to perform in a quality and timely manner, and at a feasible cost, our clinical studies will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory standards, our testing could be delayed, cancelled or rendered ineffective.

We rely on contract manufacturers over whom we have limited control. Should the cost, delivery and quality of clinical 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 2017, we successfully transferred the mAb intermediate manufacturing process and manufactured a cGMP batch at Patheon Biologics in Brisbane, Australia. Piramal Healthcare UK Ltd. manufactures the antibody-drug conjugate (ADC) with the vcMMAE linker-toxin. The drug substance is then filled and packaged at our drug product commercial manufacturer, 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 operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA regulations, allowing us to distribute potential products to clinical sites in the U.S. for early-stage clinical trials. We currently manufacture CDX-1140, CDX-301 and CDX-1401 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 ADC, is then manufactured by Lonza (Visp). We expect that our existing clinical supplies of CDX-3379 and varillumab will be sufficient to carry out our current planned clinical development. Additional manufacturing options are under review and may involve utilization of the Fall River facility and/or a CMO. All products are then filled and packaged at contract manufacturers. Any manufacturing failures or compliance issues at contract manufacturers could cause delays in our Phase 1 and Phase 2 clinical studies for these drug candidates.

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

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

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

Because we rely on third parties to develop our drug candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs which may require us to share trade secrets 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 any of our executive officers could harm us. We entered into employment agreements with each of our executive officers, although an employment agreement as a practical matter does not guarantee retention of an employee. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for this type of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

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

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

# We may not operate efficiently or realize the anticipated benefits of our acquisition of Kolltan.

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable privacy laws, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could

result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and launched a Health Care Compliance program, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

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

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

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

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

# We 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 we may face the loss of our investment of financial resources and time in the integration process.

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

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

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

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

Our research and development activities involve the use of hazardous chemicals, biological materials and radioactive compounds. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, an injured party will likely sue us for any resulting damages with potentially significant liability. The ongoing cost of complying with environmental laws and regulations is significant and may increase in the future.

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

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

Insurance covering product liability claims becomes increasingly expensive as a drug candidate moves through the development pipeline to commercialization. Under our license agreements, we are required to maintain clinical trial liability insurance coverage up to \$15 million. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaborative agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader

product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and have a material adverse effect on our business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business and inhibit or prevent development of our drug candidates and, if approval is obtained, commercialization of our future drugs.

# Risks Related to Intellectual Property

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

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

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 varillumab. We also have an issued U.S. patent which covers varillumab 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 with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products, and our business may suffer.

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

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or
  paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable
  under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the

Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

• state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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 health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the EU, and this regulation will become more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) comes into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business,

including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

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

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

# 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 \$812.5 million as of December 31, 2017. 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 2017 through December 2017, the market price of our common stock has fluctuated from a high of \$4.02 per share in the first quarter of 2017, to a low of \$2.20 per share in the second quarter of 2017. 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 the provisions of the merger agreement. The number of shares of our common stock issuable in connection with a milestone payment, if any, will be determined based on the average closing price per share of our common stock for the five trading day period ending three calendar days prior to the achievement of such milestone. If we elect to issue additional shares of our common stock, in lieu of paying cash, for such milestone payments, our stockholders may experience significant dilution.

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

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

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

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

Refer to Note 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, 2017 our significant leased properties are described below.

	Approximate		
Property Location	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)

- (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.

# 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

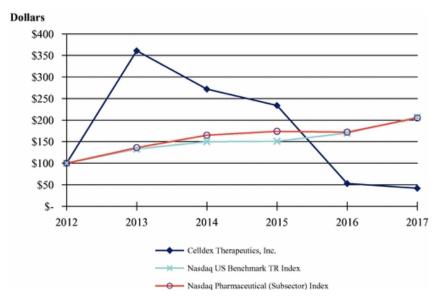
Our common stock currently trades on the Nasdaq Global Market (NASDAQ) under the symbol "CLDX." The following table sets forth for the periods indicated the high and low sale prices per share for our common stock, as reported by NASDAQ.

Fiscal Period	High	Low
Year Ended December 31, 2017		
First Quarter	\$ 4.02	\$ 3.05
Second Quarter	3.65	2.20
Third Quarter	3.14	2.27
Fourth Quarter	3.26	2.31
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

As of February 28, 2018, there were approximately 322 shareholders of record of our common stock. On February 28, 2018 the closing price of our common stock, as reported by NASDAQ, was \$2.25 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, 2012 through December 31, 2017, 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, 2012 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.



	2012	2013	2014	2015	2016	2017
Celldex Therapeutics, Inc.	\$ 100	\$ 361	\$ 272	\$ 234	\$ 53	\$ 42
NASDAQ U.S. Benchmark TR Index	\$ 100	\$ 133	\$ 150	\$ 151	\$ 170	\$ 207
NASDAQ Pharmaceutical (Subsector) Index	\$ 100	\$ 136	\$ 165	\$ 174	\$ 172	\$ 205

# Item 6. SELECTED FINANCIAL DATA

The following selected financial data are derived from our audited financial statements. The statement of operations data for the years ended December 31, 2017, 2016 and 2015 and the balance sheet data as of December 31, 2017 and 2016 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,									
		2017		2016		2015		2014		2013
REVENUE:										
Product Development and Licensing Agreements	\$	3,153	\$	2,174	\$	1,442	\$	838	\$	160
Contracts and Grants		9,590		4,612		4,038		2,748		1,617
Product Royalties										2,334
Total Revenue		12,743		6,786		5,480		3,586		4,111
OPERATING EXPENSE:								<u> </u>		
Research and Development		96,171		102,726		100,171		104,381		67,401
Royalty		_		_		_		_		2,334
Other Operating Expense		38,099		36,976		34,850		21,635		15,818
Total Operating Expense		134,270		139,702		135,021		126,016		85,553
Operating Loss		(121,527)		(132,916)		(129,541)		(122,430)		(81,442)
Investment and Other Income, Net		4,214		4,386		2,344		4,350		819
Interest Expense						<u> </u>				(927)
Net Loss Before Income Tax Benefit	\$	(117,313)	\$	(128,530)	\$	(127,197)	\$	(118,080)	\$	(81,550)
Income Tax Benefit		24,282				_				
Net Loss	\$	(93,031)	\$	(128,530)	\$	(127,197)	\$	(118,080)	\$	(81,550)
Basic and Diluted Net Loss Per Common Share	\$	(0.72)	\$	(1.27)	\$	(1.31)	\$	(1.32)	\$	(1.02)
Shares Used in Calculating Basic and Diluted Net Loss						-				
Per Common Share	_	128,543	_	101,529	_	97,051	_	89,399	_	79,777

# BALANCE SHEET DATA (In thousands)

	December 31,							
		2017		2016		2015	2014	2013
Working Capital*	\$	117,020	\$	160,346	\$	264,696	\$ 180,494	\$ 284,839
Total Assets		315,624		383,358		337,584	248,014	347,095
Long-Term Liabilities		51,519		82,704		17,239	11,863	6,950
Accumulated Deficit		(812,517)		(719,486)		(590,956)	(463,759)	(345,679)
Total Stockholders' Equity		236,369		265,431		290,105	211,660	319,795

<sup>\*</sup> 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 cancertargeting 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 principle in a Phase 1 study with varlilumab, which supported the initiation of combination studies in various indications. CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3), is in Phase 2 development in combination with cetuximab for the treatment of head and neck squamous cell carcinoma. We also have a number of earlier stage drug candidates in clinical development, including CDX-014, an antibody-drug conjugate targeting renal and ovarian cancers; CDX-1140, a human monoclonal antibody targeted to CD40, a key activator of immune response; CDX-301, an immune cell mobilizing agent and dendritic cell growth factor; and CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APCs, for cancer indications. Our drug candidates address market opportunities for which we believe current 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 (single-agent, with varlilumab or CPI <sup>(1)</sup> or CDX-301)	Phase 2	Celldex
Varlilumab	Multiple solid tumors (with Opdivo®)	Phase 2	Celldex <sup>(2)</sup>
CDX-3379	Head and neck squamous cell cancer (with Erbitux®)	Phase 2	Celldex
CDX-014	Renal cell and ovarian carcinomas	Phase 1	Celldex
CDX-1140	Multiple solid tumors	Phase 1	Celldex

(1) checkpoint inhibitor;

(2) 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 six 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	Malignant melanoma	Phase 2	NCI (CRADA)
CDX-1401/Tecentriq®/SGI-110	Ovarian cancer	Phase 1	NCI (CRADA)
Varlilumab/Opdivo®	B-cell malignancies	Phase 2	NCI (CRADA)

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:

	Estimated
	Completion
Clinical Phase	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 are safe and effective. Historically, the results from preclinical testing and early clinical trials (through Phase 2) have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

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

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into 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, 2017, we incurred an aggregate of \$470.9 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the years ended December 31, 2017, 2016 and 2015. 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.

	ar Ended ber 31, 2017	Year Ended December 31, 2016	Year Ended December 31, 2015
		(In thousands)	
Glembatumumab vedotin	\$ 36,873	\$ 30,156	\$ 19,124
Varlilumab	14,940	28,554	18,484
CDX-3379	4,167	416	_
CDX-014	2,534	3,623	5,724
CDX-1140	6,909	3,802	_
CDX-1401	836	4,323	3,385
CDX-301	1,294	4,053	2,206
Anti-KIT Program	4,156	279	_
TAM	5,512	438	_
Rintega	1,685	15,337	43,038
Other Programs	17,265	11,745	8,210
Total R&D Expense	\$ 96,171	\$ 102,726	\$ 100,171

# **Clinical Development Programs**

# 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 U.S. 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:** Glembatumumab vedotin has been evaluated for the treatment of metastatic breast cancer (MBC) in multiple studies including a single-arm Phase 1/2 study (*Journal of Clinical Oncology*, September 2014); a randomized, controlled Phase 2b study compared to Investigator's Choice chemotherapy in patients with gpNMB-positive MBC called EMERGE (*Journal of Clinical Oncology*, April 2015); and the ongoing randomized, controlled Phase 2b study in patients with triple negative, gpNMB overexpressing breast cancer, called METRIC. We expect to report topline primary endpoint data from the METRIC study during the second quarter of 2018.

The most recent data presented for glembatumumab vedotin in breast cancer are from the EMERGE study, the randomized, multi-center Phase 2b study in 124 patients with heavily pre-treated, advanced, gpNMB-positive breast cancer. 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, progression-free survival (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 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. Adverse events prominent with the glembatumumab vedotin arm included rash and peripheral neuropathy, while hematologic toxicity was more frequent and severe in the Investigator's Choice

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

			Triple Neg and gpNI	MB			
	High gpNMB Ex		Over-Expression				
	Glembatumumab	Investigator's	Glembatumumab	Investigator's			
	Vedotin	Choice	Vedotin	Choice			
	(n=23)	(n=11)	(n=10)	(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 No and gpl Over-Exp	NMB
	Glembatu mumab Vedotin	Investigator's Choice	Glembatumumab Vedotin	Investigator's Choice
Median PFS (months)	2.8 p=0	1.5	3.5 p=0.0	1.5
Median OS (months)	10.0 p=0.3	5.7	10.0 p=0.0	5.5

In December 2013, we initiated METRIC, a randomized, controlled (2:1) Phase 2b study of glembatumumab vedotin versus Xeloda® in patients with triple negative breast cancer that over-expresses gpNMB. Clinical trial study sites were opened 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, defined as the time from randomization to the earlier of disease progression or death due to any cause. 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.

Enrollment (n=327) in METRIC was completed in August 2017. The study calls for 203 progression events for evaluation of the primary endpoint, which will be assessed based on an independent, central reading of patient scans. The sum of the data, including the secondary endpoints of response rate, OS, DOR and safety, will be important in assessing clinical benefit. Based on the current rate of progression events in the study, the Company projects that topline primary endpoint data should be available in the second quarter of 2018.

Efforts to ensure delivery of manufactured drug that is ready for commercialization and a companion diagnostic are underway. While we have made and continue to make progress on these fronts, we have made the decision to stage some of the more costly work in these areas to begin after we have received results from the study. While this step will extend the timeline to complete our regulatory submissions, we believe this is the most prudent use of our funds as we seek to advance our pipeline overall. Assuming positive data, we plan to work with the FDA on a regulatory strategy that would support submitting a Biologics License Application (BLA) in the second half of 2019.

**Treatment of Metastatic Melanoma:** Glembatumumab vedotin has been evaluated for the treatment of unresectable stage III or IV metastatic melanoma in two studies including a single-arm Phase 1/2 open-label study and an ongoing multi-cohort Phase 2 study. Results from the Phase 1/2 study were published in the *Journal of Clinical Oncology* in September 2014.

The most recent data for glembatumumab vedotin in metastatic melanoma are from the ongoing Phase 2 study. This study currently includes four single arm cohorts: (1) a single-agent cohort (enrollment completed; data presented at ASCO 2017), (2) a combination cohort with varillumab (enrollment completed; data presented at SITC 2017), (3) a combination cohort with an approved

checkpoint inhibitor (i.e., Opdivo® or Keytruda®) following progression on the checkpoint inhibitor alone (enrollment completed; follow-up continues), and (4) a combination cohort with CDX-301 (enrollment ongoing).

The primary endpoint for each cohort is ORR, except the fourth cohort which is assessing safety and tolerability in anticipation of additional combinations. Secondary endpoints include analyses of PFS, DOR, OS, retrospective investigation of whether the anticancer 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 mature data from the single-agent cohort in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2017. The cohort enrolled 62 evaluable patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor therapy, and almost all patients had received both ipilimumab (n=58; 94%) and anti-PD-1/anti-PD-L1 (n=58; 94%) therapy. Twelve patients presented with BRAF mutation, and fifteen had prior treatment with BRAF or BRAF/MEK targeted agents. Median OS for all patients was 9.0 months (95% CI: 6.1, 13.0). The primary endpoint of the cohort (threshold of 6 or more objective responses in 52 evaluable patients) was exceeded. 7 of 62 (11%) patients experienced a confirmed response. One patient experienced a complete response (CR), and six patients experienced partial responses (PR). An additional three patients also experienced single timepoint PRs. The median DOR 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. Consistent with previous studies in melanoma and breast cancer, early development of rash was associated with greater clinical benefit, including more prolonged PFS and OS. The safety profile was consistent with prior studies of glembatumumab vedotin with rash, neutropenia and neuropathy experienced as the most significant adverse events. Pre-treatment tumor tissue was available for 59 patients. All samples were gpNMB positive, and 78% of patients had tumors with 100% of their epithelial cells expressing gpNMB. Given both the high level of expression and the intensity of expression across this patient population, identifying a potential population for gpNMB enrichment is not feasible; therefore, all patients with metastatic melanoma could be evaluated as potential candidates for treatment with glembatumumab vedotin in future s

Data from the second cohort, combining glembatumumab vedotin and varlilumab, were presented at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in November 2017. The cohort enrolled 34 patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies = 3; range 1-8) and had progressed during or after checkpoint inhibitor (CPI) therapy (median prior CPI therapies = 2; range 1-4). Almost all patients had received ipilimumab (n=26; 76%) and/or anti-PD-1/anti-PD-L1 (n=34; 100%) therapy. Nine patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents. Median PFS for all patients was 2.6 months (95% CI: 1.4, 2.8), and median OS for all patients was 6.4 months (95% CI: 3.2, 8.3). One of 31 patients eligible for response evaluation experienced a confirmed partial response (3%), and an additional two patients also experienced single timepoint partial responses. 52% of patients experienced stable disease (minimum of six or more weeks). A 19% disease control rate (patients without progression for greater than three months) was demonstrated. The safety profile was consistent with prior studies of glembatumumab vedotin, and there was no evidence of additive toxicity associated with the combination. Biological effects of varlilumab were consistent with prior observations and did not appear to be impacted by the addition of an ADC. Modest clinical benefit in the combination could be due to multiple factors, including potential lack of sensitivity to immunotherapy in patients with checkpoint refractory disease, many of whom progressed so rapidly that they experienced a very short duration of varlilumab treatment (median 2 doses); a possible dearth of antigen presenting cells in tumors; and the potential for immune checkpoint molecules to remain unblocked without checkpoint inhibitor therapy. Future cohorts are designed to

address some of these potential factors. No significant correlation between rash and outcome was observed but will continue to be monitored in future cohorts.

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 and is ongoing. 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 is designed to assess the safety and tolerability of glembatumumab vedotin at varying dose levels. 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 a Phase 2 study of glembatumumab vedotin in uveal melanoma. The study is a single-arm, open-label study in patients with locally recurrent or metastatic uveal melanoma. The study has a two-stage design with a pre-specified activity threshold necessary in the first stage to progress enrollment to the second stage. The primary outcome measure is ORR. Secondary outcome measures include change in gpNMB expression on tumor tissue via immunohistochemistry, safety, OS and PFS. Data from this study were presented at the 9<sup>th</sup> World Congress of Melanoma in October 2017. Two (6%) objective responses were observed in 31 patients to date, and 35% of patients experienced stable disease greater than 100 days (median 5.5 months). The disease control rate (response rate + stable disease) for all patients on study was noteworthy at 61%. Median PFS was 3.2 months, and median OS was 11.8 months. For patients who experienced either a partial response or stable disease, median PFS was 5.5 months, and median OS had not yet been reached. The NCI is conducting exploratory immune correlates to provide insight into target saturation, antigen release and potential combination strategies.

## Varlilumab

Varillumab 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 varillumab 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 varillumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, varillumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *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. Varillumab 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 varillumab 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. Varillumab has also been explored in other combination studies, including with glembatumumab vedotin, and is being studied in ongoing and planned investigator-sponsored and collaborative studies.

Single-Agent Phase 1 Study: In an open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers, varlilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients received varlilumab in the study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of a MTD. The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade have been observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anticancer therapy, including a complete response in a patient with Hodgkin lymphoma (ongoing at last follow-up at 2.8 years) and a partial response in a patient with renal cell carcinoma (ongoing at last follow-up at 3.7 years). In addition, a patient with renal cell carcinoma that experienced significant stable disease (4+ years) subsequently achieved a partial response maintained through last follow-up at 4.6+ years without additional anticancer therapy. Twelve patients experienced stable disease up to 14 months. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

Phase 1/2 Varlilumab/Opdivo® Combination Study: In 2014, we entered into a clinical trial collaboration with Bristol-Myers Squibb 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.

Data (n=36) from the Phase 1 dose-escalation portion of the study were presented in an oral presentation at the American Society of Clinical Oncology Annual Meeting in June 2017. The majority of patients had PD-L1 negative tumor at baseline and presented with stage IV, heavily pre-treated disease. 80% of patients enrolled presented with refractory or recurrent colorectal (n=21) or ovarian cancer (n=8), a population expected to have minimal response to checkpoint blockade. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination was well tolerated at all varlilumab dose levels tested 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, was also noted. Notable disease control was also observed (stable disease or better for at least 3 months), considering the stage IV patient population contained mostly (80%) colorectal and ovarian cases: 0.1 mg/kg varlilumab + 240 mg Opdivo: 1/5 (20%), 1 mg/kg varlilumab + 240 mg Opdivo: 6/15 (40%).

Three partial responses (PR) were observed. A patient with PD-L1 negative, MMR proficient (MSI-low) colorectal cancer, typically unlikely to respond to checkpoint blockade monotherapy, achieved a confirmed PR (95% decrease in target lesions) and following completion of combination treatment, continues to receive treatment with Opdivo monotherapy at 31+ months. A patient with low PD-L1 (5% expression) squamous cell head and neck cancer achieved a confirmed PR (59% shrinkage) and experienced PFS of 6.7 months. A patient with PD-L1 negative ovarian cancer experienced a single timepoint PR (49% shrinkage) but discontinued treatment to a dose-limiting toxicity (immune hepatitis, an event known to be associated with checkpoint inhibition therapy). A subgroup analysis was conducted in patients with ovarian cancer based on an observed increase of PD-L1 and tumor-infiltrating lymphocytes in this patient population. In patients with paired baseline and on-treatment biopsies (n=13), only 15% were PD-L1 positive ( $\Box$  1% tumor cells) at baseline compared to 77% during treatment (p=0.015). Patients with increased tumor PD-L1 expression and tumor CD8 T cells correlated with better clinical outcome with treatment (stable disease or better).

The Phase 2 portion of the study opened to enrollment in April 2016 and completed enrollment in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is ORR, except glioblastoma, where the primary objective is the rate of 12-month OS. Secondary objectives include pharmacokinetic assessments, determining the immunogenicity of varillumab when given in combination with Opdivo, evaluating alternate dosing schedules of varillumab and further assessing the anti-tumor activity of combination treatment. We plan to work with BMS to present data from the study at future medical meetings in 2018.

**Third-Party Sponsored Studies:** We have also entered into a CRADA with the NCI under which NCI is sponsoring a Phase 2 study of varillumab in combination with nivolumab in relapsed or refractory aggressive B-cell lymphomas. Patients receive either nivolumab alone or the combination. The primary outcome measure is ORR. Secondary outcome measures include DOR, safety, PFS and OS. The study opened to enrollment in January 2018 and is expected to enroll 106 patients.

## CDX-3379

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

The most recent data for CDX-3379 were reported from a Phase 1a/1b study conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. 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=9) and Herceptin® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one durable complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar® and was considered refractory, as well as a single timepoint partial response in a patient with thyroid cancer. Initial data were presented at the American Society of Clinical Oncology Annual Meeting in June 2016.

We have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux-resistant, advanced head and neck squamous cell carcinoma who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The primary objective of the study is objective response rate. Second objectives include assessments of clinical benefit response (CBR), DOR, PFS and OS, and safety and pharmacokinetics associated with the combination.

## 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 cancers.

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. In January 2018, we amended the protocol, converting the study to Phase 1, expanding enrollment to include patients with ovarian clear cell carcinoma and enabling the evaluation of alternate dosing regimens. Enrollment is ongoing. The study includes a dose-escalation portion across three separate cohorts to determine the MTD followed by expansion cohorts of up to 15 patients each to assess the preliminary anti-tumor activity of CDX-014, as measured by objective response rate. Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity.

## CDX-1140

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

We initiated a Phase 1 study of CDX-1140 in November 2017. This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic solid tumors, is designed to determine the MTD during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

#### 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.

CDX-301's potential activity is being explored in investigator sponsored and collaborative studies. A Phase 2 study of CDX-301 in combination with CDX-1401 is being conducted in malignant 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 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.

CDX-301 is also being studied in a combination cohort with glembatumumab vedotin in a Phase 2 study in metastatic melanoma (opened to enrollment in January 2018) and is being studied in ongoing and planned investigator-sponsored and collaborative studies.

# 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. CDX-1401 is being developed for the treatment of malignant melanoma and a variety of solid tumors which express the cancer antigen NY-ESO-1. Preclinical studies have shown that CDX-1401 treatment results in activation of human T cell responses against NY-ESO-1.

We 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.

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 malignant melanoma by the 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. Enrollment is complete, and initial results were presented at the 2016 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.

In September 2017, a randomized, open-label Phase 1/2 study of CDX-1401 in combination with atezolizumab and SGI-110 opened to enrollment in recurrent ovarian, fallopian tube, or primary peritoneal cancer. This study is being conducted under a CRADA with the NCI Division of Cancer Treatment and Diagnosis and is designed to determine the activity of atezolizumab alone, atezolizumab plus SGI-110 and atezolizumab plus SGI-110 plus CDX-1401. The primary outcome of the Phase 1 dose-escalation study is safety and only evaluates atezolizumab alone and in combination with SGI-110. The Phase 2 portion of the study is expected to add CDX-1401. The primary outcome of the Phase 2 portion of the study is a comparison of PFS between the three cohorts.

Other studies are ongoing and planned through investigator-sponsored and collaborative agreements.

Anti-KIT Program: CDX-0158 and CDX-0159

KIT activation is implicated in many disease processes including some cancers, neurofibromatosis, mast cell-related diseases and autoimmune diseases. We conducted a Phase 1 dose-escalation study of CDX-0158, a humanized monoclonal antibody that is a potent inhibitor of wildtype KIT, in 28 patients with advanced refractory GIST and other KIT positive tumors with doses up to 15 mg/kg. No evidence of myelosuppression, an effect commonly associated with KIT inhibition, was observed in this study. Approximately two-thirds of the patients on study had infusion reactions that were manageable with premedication and longer infusion times. The biomarker data showed evidence of dose-related KIT engagement, and two patients experienced partial metabolic responses on fluorodeoxyglucose (FDG)-PET scan; however, these PET responses were not associated with tumor shrinkage.

Given the infusion reactions, modifications have been introduced into the Fc portion of the CDX-0158 antibody to prevent these interactions, which should eliminate the potential for Fc receptor mediated agonist activity. This second-generation version, called CDX-0159, also includes modifications to increase the half-life of the antibody, giving it an additional advantage over CDX-0158. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development. We expect manufacturing and IND-enabling efforts for CDX-0159 will be completed in 2018.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could materially change our reported results. We believe the following accounting policies are the most critical to us in that they are important to the portrayal of 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, 2017 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 is 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. 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

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. During the third quarter of 2017, we recorded a partial impairment charge of \$13.0 million related to changes in projected development and regulatory timelines regarding the anti-KIT program. The remaining IPR&D assets were assessed for impairment during 2017 and were determined not to be impaired.

Intangible assets acquired in a business combination with a finite life are recorded at fair value and amortized over the greater of economic consumption or on a straight-line basis over their estimated useful life.

# Research and Development Expenses

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

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

# Stock-Based Compensation Expense

We record stock-based compensation expense for all stock-based awards made to employees and directors based on the estimated fair values of the stock-based awards expected to vest at the grant date and adjust, if necessary, to reflect actual forfeitures. Our estimates of employee stock option values rely on estimates of future uncertain events. Significant assumptions include the use of historical volatility to estimate the expected stock price volatility. We also estimate expected term based on historical exercise patterns. 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 remeasured over the vesting term resulting in periodic adjustments to stock-based compensation expense.

# RESULTS OF OPERATIONS

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

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

# Net Loss

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

#### Revenue

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

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 I	Ended				
Decem	ber 31,	In	Increase/ (Decrease)		
2017	2016		\$	%	
	(In thousands	)			
\$ 36,470	\$ 36,070	\$	400	1%	
4,514	3,697		817	22%	
8,617	6,314		2,303	36%	
677	1,614		(937)	(58)%	
36,711	46,852	(	(10,141)	(22)%	
	\$ 36,470 4,514 8,617 677	\$ 36,470 \$ 36,070 4,514 \$ 3,697 8,617 6,314 677 1,614	December 31,   In   2017   2016     (In thousands)	December 31,         Increase/ (December 31)           2017         2016         \$           (In thousands)         \$           \$ 36,470         \$ 36,070         \$ 400           4,514         3,697         817           8,617         6,314         2,303           677         1,614         (937)	

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$0.4 million increase in personnel expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to an increase in salaries expense and headcount related to the Kolltan acquisition partially offset by lower stock-based compensation expenses. We expect personnel expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.8 million increase in laboratory supply expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to higher laboratory materials and supplies purchases. We expect laboratory supplies expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance and other related expenses incurred at our facilities. The \$2.3 million increase in facility expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to the addition of our New Haven, CT facility that we acquired with the Kolltan acquisition and higher depreciation expense of \$1.3 million. In March 2017, we terminated our lease in Branford, CT and consolidated our Connecticut operations in our New Haven facility. 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 \$0.9 million decrease in license fee expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. 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 \$10.1 million decrease in product development expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to lower contract manufacturing and clinical trial costs of \$9.9 and \$7.6 million, respectively, related to varillumab and Rintega. These decreases were partially offset by increases in (i) glembatumumab vedotin contract manufacturing expenses of \$2.7 million and (ii) glembatumumab vedotin, anti-KIT and CDX-3379 clinical trial costs of \$3.6 million. The amount of product development expenses incurred over the next twelve months will

be impacted by our clinical data results from our METRIC clinical study and their impact on our pace of commercial manufacturing.

# General and Administrative Expense

The \$11.0 million decrease in general and administrative expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, was primarily due to lower commercial planning costs of \$4.5 million, lower stock-based compensation of \$1.9 million and lower severance expense related to the Kolltan acquisition of \$2.6 million. The amount of general and administrative expenses incurred over the next twelve months will be impacted by our clinical data results from our METRIC clinical study and their impact on the rate of expansion of our commercial operations.

## In-Process Research and Development Impairment

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

## Gain on Fair Value Remeasurement of Contingent Consideration

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

## Amortization Expense

Amortization expense for the year ended December 31, 2017 was relatively consistent with the year ended December 31, 2016. We expect amortization expense of acquired intangible assets to remain consistent over the next twelve months.

## Investment and Other Income, Net

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

### Income Tax Benefit

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

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

	Year Ended December 31,				Increase/ (Decrease)		Increase/ (Decrease)
		2016		2015	5 \$		%
				(In thous	sands	)	
Revenues:							
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 Expenses:							
Research and Development	1	02,726		100,171		2,555	3%
General and Administrative		35,979		33,837		2,142	6%
In-Process Research and Development Impairment		_		_		_	n/a
Gain on Fair Value Remeasurement of Contingent							
Consideration		_		_		_	n/a
Amortization of Acquired Intangible Assets		997		1,013		(16)	(2)%
Total Operating Expense	1	39,702		135,021		4,681	3%
Operating Loss	(1	32,916)		(129,541)		3,375	3%
Investment and Other Income, Net	,	4,386		2,344		2,042	87%
Net Loss Before Income Tax Benefit	(1	28,530)		(127,197)		1,333	1%
Income Tax Benefit				<u> </u>			n/a
Net Loss	\$ (1	28,530)	\$	(127,197)	\$	1,333	1%

# Net Loss

The \$1.3 million increase in net loss for the year ended December 31, 2016, as 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, as compared to the year ended December 31, 2015, was primarily related to our BMS agreement. The \$0.6 million increase in contracts and grants revenue for the year ended December 31, 2016, as 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 Ei Decembe	Increas (Decreas		
	2016	2015	\$	%
	(I	n 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)%

The \$6.3 million increase in personnel expenses for the year ended December 31, 2016, as 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.

The \$0.7 million decrease in laboratory supply expenses for the year ended December 31, 2016, as compared to the year ended December 31, 2015, was primarily due to lower manufacturing supply purchases.

The \$0.6 million increase in facility expenses for the year ended December 31, 2016, as compared to the year ended December 31, 2015, was primarily due to an increase in rent.

The \$0.7 million increase in license fee expenses for the year ended December 31, 2016, as 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.

The \$5.9 million decrease in product development expenses for the year ended December 31, 2016, as 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 varillumab program costs of \$4.6 million and \$9.6 million, respectively.

## General and Administrative Expense

The \$2.1 million increase in general and administrative expenses for the year ended December 31, 2016, as 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.

# Amortization Expense

Amortization expense for the year ended December 31, 2016 was consistent compared to the year ended December 31, 2015.

## Investment and Other Income, Net

The \$2.0 million increase in investment and other income, net for the year ended December 31, 2016, as 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.

### LIOUIDITY AND CAPITAL RESOURCES

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

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

At December 31, 2017, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$139.4 million. We have had recurring losses and incurred a loss of \$93.0 million for the year ended December 31, 2017. Net cash used in operations for the year ended December 31, 2017 was \$99.9 million. We believe that the cash, cash equivalents and marketable securities at December 31, 2017 combined with the (i) \$6.1 million in net proceeds from sales of our common stock under the Cantor agreement from January 1, 2018 through February 28, 2018 and (ii) anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2019. This could be impacted by our clinical data results from our METRIC clinical study and their impact on our pace of commercial manufacturing and the rate of expansion of our commercial operations. This could also be impacted if we elected to pay Kolltan contingent milestones, if any, in cash.

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

## Operating Activities

Net cash used in operating activities was \$99.9 million for the year ended December 31, 2017 compared to \$113.0 million for the year ended December 31, 2016. The decrease in net cash used in operating activities was primarily due to an increase in revenue and decreases in both general and administrative and research and development expenses. We expect that cash used in operating activities will decrease over the next twelve months, although there may be fluctuations on a quarterly basis.

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 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 \$46.5 million for the year ended December 31, 2017 compared to net cash provided by investing activities of \$68.9 million for the year ended December 31, 2016. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the year ended December 31, 2017 of \$48.3 million as compared to net sales and maturities of marketable securities of \$68.9 million for the year ended December 31, 2016. We expect that cash provided by investing activities will decrease over the next twelve months as we decrease cash used in operations which is funded mainly through the combination of net proceeds from the sales and maturities of marketable securities, cash provided by financing activities and/or new partnerships, although there may be significant fluctuations on a quarterly basis.

Net cash provided by investing activities was \$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.

# Financing Activities

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

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.

# 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 \$250.0 million. Such registration statement was declared effective on February 13, 2017.

In May 2016, we entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow us to issue and sell shares of our common stock having an aggregate offering price of up to \$60.0 million from time to time through Cantor, acting as agent. In November 2017, we filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional \$75.0 million under the agreement with Cantor. During the years ended December 31, 2017 and 2016, we issued 17,722,863 and 3,303,800 shares of common stock, respectively, under this controlled equity offering sales agreement with Cantor resulting in net proceeds of \$51.0 million and \$13.9 million, respectively, after deducting commission and offering expenses. At December 31, 2017, we had \$67.6 million remaining in aggregate gross offering price available under the Cantor agreement. From January 1, 2018 through February 28, 2018, we issued 2,401,847 shares of our common stock resulting in net proceeds of \$6.1 million.

During the year 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, 2017 such contingencies have not been recorded in our financial statements. We expect to incur approximately \$0.2 million of license and milestone payments in 2018.

The following table summarizes our contractual obligations (not including contingent royalty and milestone payments as described above) at December 31, 2017 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	2018	2019 - 2020	2021 - 2022	Thereafter
			(In thousands)		
Contractual obligations:					
Operating lease obligations(1)	\$ 11,561	\$ 4,591	\$ 6,970	\$ —	\$ —
Other contractual obligations(2)(3)	11,330	11,330	_	_	_
Total contractual obligations	\$ 22,891	\$ 15,921	\$ 6,970	<u>\$</u>	<u> </u>

- 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 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, 2017 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.

## Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Celldex Therapeutics, Inc. and its subsidiary as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 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, 2017 based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the COSO.

# Basis for Opinions

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

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

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

## Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts March 7, 2018

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

# CONSOLIDATED BALANCE SHEETS

# (In thousands, except share and per share amounts)

	December 31, 2017		December 31, 2016	
ASSETS				
Current Assets:				
Cash and Cash Equivalents	\$	40,288	\$	42,461
Marketable Securities		99,139		147,315
Accounts and Other Receivables		1,880		1,784
Prepaid and Other Current Assets		3,449		4,009
Total Current Assets		144,756		195,569
Property and Equipment, Net		10,372		13,192
Intangible Assets, Net		67,591		81,487
Other Assets		1,929		2,134
Goodwill		90,976		90,976
Total Assets	\$	315,624	\$	383,358
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts Payable	\$	1,715	\$	1,740
Accrued Expenses		19,455		28,657
Current Portion of Long-Term Liabilities		6,566		4,826
Total Current Liabilities		27,736		35,223
Other Long-Term Liabilities		51,519		82,704
Total Liabilities		79,255		117,927
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, 2017 and 2016		_		_
Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 138,520,404				
and 120,516,654 Shares Issued and Outstanding at December 31, 2017 and				
2016, Respectively		139		121
Additional Paid-In Capital		1,046,183		982,255
Accumulated Other Comprehensive Income		2,564		2,541
Accumulated Deficit		(812,517)		(719,486)
Total Stockholders' Equity		236,369		265,431
Total Liabilities and Stockholders' Equity	\$	315,624	\$	383,358

# STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

# (In thousands, except per share amounts)

	Consolidated Year Ended December 31, 2017		Consolidated Year Ended December 31, 2016		 ar Ended iber 31, 2015
REVENUES:					
Product Development and Licensing Agreements	\$	3,153	\$	2,174	\$ 1,442
Contracts and Grants		9,590		4,612	 4,038
Total Revenues		12,743		6,786	 5,480
OPERATING EXPENSES:					
Research and Development		96,171		102,726	100,171
General and Administrative		25,003		35,979	33,837
In-Process Research and Development Impairment		13,000		_	_
Gain on Fair Value Remeasurement of Contingent					
Consideration		(800)		_	_
Amortization of Acquired Intangible Assets		896		997	1,013
Total Operating Expenses		134,270		139,702	 135,021
Operating Loss		(121,527)	(	132,916)	(129,541)
Investment and Other Income, Net		4,214		4,386	 2,344
Net Loss Before Income Tax Benefit	\$	(117,313)	\$ (	128,530)	\$ (127,197)
Income Tax Benefit		24,282			<u> </u>
Net Loss	\$	(93,031)	\$ (	128,530)	\$ (127,197)
Basic and Diluted Net Loss Per Common Share	\$	(0.72)	\$	(1.27)	\$ (1.31)
Shares Used in Calculating Basic and Diluted Net Loss per					
Share		128,543		101,529	97,051
COMPREHENSIVE LOSS:					
Net Loss	\$	(93,031)	\$ (	128,530)	\$ (127,197)
Other Comprehensive Income (Loss):					
Foreign Currency Translation Adjustments		_		_	15
Unrealized Gain (Loss) on Marketable Securities		23		234	 (298)
Comprehensive Loss	\$	(93,008)	\$ (	128,296)	\$ (127,480)

# ${\bf CELLDEX\,THE RAPEUTICS, INC.}$

# 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, 2014	89,592,779	\$ 90	\$ 672,739	\$ 2,590	\$ (463,759)	\$ 211,660
Shares Issued under Stock Option	0,0,0,2,7,7	Ψ , υ	\$ 07 <b>2</b> ,709	<b>-,</b> c>0	ψ (100,703)	<b>211,000</b>
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	_	_	<u> </u>	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		_	<u> </u>		(128,530)	(128,530)
Consolidated Balance at						
December 31, 2016	120,516,654	121	982,255	2,541	(719,486)	265,431
Shares Issued under Stock Option						
and Employee Stock Purchase						
Plans	173,712	_	265	_	_	265
Shares Issued in Connection with						
Cantor Agreement	17,722,863	18	51,007	_	_	51,025
Shares Issued in Connection with						
Kolltan Severance	107,175	_	344	_	_	344
Share-Based Compensation	_	_	12,312			12,312
Unrealized Gains on Marketable						
Securities	_	_	<u> </u>	23	_	23
Net Loss					(93,031)	(93,031)
Consolidated Balance at						
December 31, 2017	138,520,404	<u>\$ 139</u>	\$ 1,046,183	\$ 2,564	<u>\$ (812,517)</u>	\$ 236,369

# STATEMENTS OF CASH FLOWS

# (In thousands)

	Consolidated Year Ended December 31, 2017		Consolidated Year Ended cember 31, 2016	Year En December 3	
Cash Flows From Operating Activities:					
Net Loss	\$ (93,03	(1) \$	(128,530)	\$ (1	27,197)
Adjustments to Reconcile Net Loss to Net Cash Used in					, ,
Operating Activities:					
Depreciation and Amortization	4,41	4	3,095		2,998
Amortization of Intangible Assets	89	6	997		1,013
Amortization and Premium of Marketable Securities, Net	(29	00)	926		350
Loss on Sale or Disposal of Assets		5	81		_
In-Process Research and Development Impairment	13,00	00	_		_
Gain on Fair Value Remeasurement of Contingent					
Consideration	(80	00)	_		_
Non-Cash Income Tax Benefit	(24,28	32)			_
Stock-Based Compensation Expense	12,31	2	15,317		12,774
Non-Cash Expense	-	_	1,638		288
Changes in Operating Assets and Liabilities:					
Accounts and Other Receivables	(9	96)	(814)		(543)
Prepaid and Other Current Assets	79	13	1,320		(653)
Other Assets	20	-	(89)		6
Accounts Payable and Accrued Expenses	(8,74		(4,970)		4,875
Other Liabilities	(4,36	<u>(33</u> )	(2,007)		7,202
Net Cash Used in Operating Activities	(99,93	(1)	(113,036)	(	(98,887)
Cash Flows From Investing Activities:					
Sales and Maturities of Marketable Securities	219,23	6	242,792	1	61,090
Purchases of Marketable Securities	(170,98	30)	(173,925)	(2	06,405)
Investment in Other	-	_	(1,801)		_
Cash Acquired in Kolltan Acquisition, Net	-	_	4,592		_
Acquisition of Property and Equipment	(1,78	(88)	(2,751)		(4,876)
Net Cash Provided by (Used in) Investing Activities	46,46	8	68,907	(	(50,191)
Cash Flows From Financing Activities:					
Net Proceeds from Stock Issuances	51,02	25	13,946	1	88,840
Proceeds from Issuance of Stock from Employee Benefit Plans	26	55	536		4,311
Net Cash Provided by Financing Activities	51,29	00	14,482	1	93,151
Effect of Exchange Rate Changes on Cash and Cash					
Equivalents	-	_	_		15
Net (Decrease) Increase in Cash and Cash Equivalents	(2,17	<sup>'3</sup> )	(29,647)		44,088
Cash and Cash Equivalents at Beginning of Period	42,40		72,108		28,020
Cash and Cash Equivalents at End of Period	\$ 40,28	88 \$	42,461	\$	72,108
Non-cash Investing Activities					
Accrued construction in progress	\$ 2	20 \$	159	S	75
Non-cash Supplemental Disclosure	•				
Shares issued to former Kolltan executive for settlement of					
severance	\$ 34	4 \$	426	\$	_
Shares issued in connection with Kolltan Acquisition		<b>-</b> \$	73,397	\$	_
1			,		

# NOTES TO FINANCIAL STATEMENTS

## (1) Nature of Business and Overview

Celldex Therapeutics, Inc. (the "Company" or "Celldex") is a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies and other cancer-targeting biologics. The Company currently has seven drug candidates in clinical development, including glembatumumab vedotin (also referred to as CDX-011), varlilumab (also referred to as CDX-1127), CDX-3379, CDX-014, CDX-1140, CDX-301 and CDX-1401.

At December 31, 2017, the Company had cash, cash equivalents and marketable securities of \$139.4 million. The Company has had recurring losses and incurred a loss of \$93.0 million for the year ended December 31, 2017. Net cash used in operations for the year ended December 31, 2017 was \$99.9 million. The Company believes that the cash, cash equivalents and marketable securities at March 7, 2018 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 resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financings may be dilutive to the Company's stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company's ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company's economic potential from products under development. The Company's ability to continue funding its planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or s

# (2) Summary of Significant Accounting Policies

Basis of Presentation

The balance sheets and statements of operations and comprehensive loss, stockholders' equity, and cash flows, are consolidated for the years ended December 31, 2017 and 2016. In February 2016, the Company formed a wholly-owned subsidiary, Celldex Therapeutics Europe GmbH, in Zug, Switzerland, which was liquidated in June 2017. In July 2016, the Company formed a wholly-owned subsidiary, Celldex Australia Pty Ltd, in Brisbane, Australia. These consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one segment, which is

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

the business of development, manufacturing and commercialization of novel therapeutics for human health care.

Use of Estimates

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

Cash and Cash Equivalents

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

## Marketable Securities

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

Concentration of Credit Risk and of Significant Customers and Suppliers

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

Combined revenue from International AIDS Vaccine Initiative, Frontier Biotechnologies, Inc. and BMS represented 73% of total Company revenue for the year ended December 31, 2017. Combined revenue from Rockefeller and BMS represented 71% and 86% of total Company revenue for the years ended December 31, 2016 and 2015, 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

## NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

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 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.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

Other Assets

Other assets include a \$1.8 million non-controlling investment in a privately-held company that is accounted for under the cost method of accounting as of December 31, 2017 and 2016. The Company periodically evaluates the carrying value of the investment if significant adverse events or circumstances indicate an impairment in value.

## **Business Combinations**

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

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

# Intangible Assets

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

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

Each IPR&D asset is assessed for impairment at least annually or when impairment indicators are present. During the year ended December 31, 2017, we recorded a partial impairment charge of \$13.0 million related to changes in projected development and regulatory timelines regarding the anti-KIT program. The remaining IPR&D assets were assessed for impairment during 2017 and were determined not to be impaired.

Intangible assets acquired in a business combination with a finite life are recorded at fair value and amortized over the greater of economic consumption or on a straight-line basis over their estimated useful life.

### Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis during the third quarter, or earlier if impairment indicators are present. The Company has the option to assess qualitative factors to determine if it is more likely than not that goodwill might be impaired and whether it is necessary to perform a quantitative single-step goodwill impairment test required under U.S. GAAP. As part of its annual impairment test of the goodwill asset as of July 1, 2017, the Company bypassed the optional qualitative assessment and performed a quantitative assessment under the single-step impairment assessment. 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

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

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

### Patent Costs

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

## Stock-Based Compensation

The Company records stock-based compensation expense for all stock-based awards made to employees 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

## NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

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 accumulated other comprehensive income. At December 31, 2017 and 2016, accumulated other comprehensive income includes a net unrealized gain related to foreign currency translation of \$2.6 million.

### Income Taxes

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

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

# Comprehensive Loss

Comprehensive loss is comprised of net loss and certain changes in stockholders' equity that are excluded from net loss. The Company includes foreign currency translation adjustments and unrealized 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, 2017, 2016 and 2015.

## 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

## NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

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,					
	2017	2016	2015			
Stock options	10,856,212	10,218,710	8,110,239			
Restricted stock	96,668	50,000	19,500			
	10,952,880	10,268,710	8,129,739			

## Newly-Adopted Accounting Pronouncements

On January 1, 2017, the Company adopted a new 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 Company elected to continue to estimate forfeitures expected to occur to determine stock-based compensation expense. Upon adoption, the Company's gross deferred tax assets and corresponding valuation allowance each increased by \$17.7 million related to tax deductions from the exercise of stock options that previously would have been credited to additional paid-in-capital when realized.

On January 1, 2017, the Company adopted a new accounting standard which simplifies how an entity tests goodwill for impairment. A goodwill impairment is now calculated under a single-step quantitative test which compares a reporting unit's carrying value to its fair value. A goodwill impairment is the amount by which the carrying value of the reporting unit exceeds its fair value, not to exceed the carrying amount of goodwill. Under this standard, the Company continues to have the option to perform a qualitative assessment to determine if the single-step quantitative test is necessary.

## Recent Accounting Pronouncements

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

In May 2014, the FASB issued a new accounting standard that updates guidance and disclosure requirements for recognizing revenue. The new revenue recognition standard provides a five-step model for recognizing revenue from contracts with customers. The core principle is that a company should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services.

The Company will adopt the new revenue standard as of January 1, 2018 using the modified retrospective application method. All material open contracts as of December 31, 2017 were identified by the Company and assessed under the updated revenue recognition guidance. As of December 31, 2017, the Company had finalized its assessment of the impact of this standard and expects to recognize an immaterial decrease to both accumulated deficit and deferred revenue on January 1, 2018. As a result of adopting this standard, the Company has implemented additional processes and controls, and plans to include additional disclosures in future filings to comply with this standard.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (2) Summary of Significant Accounting Policies (Continued)

In February 2016, the FASB issued a new 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 consolidated financial statements.

In August 2016, the FASB issued updated guidance which clarifies the classification of certain cash receipts and payments in the statement of cash flows. This standard is effective for the company on January 1, 2018. The adoption of this new guidance is not expected to have a material impact on the Company's consolidated financial statements.

# (3) Accumulated Other Comprehensive Income

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the year ended December 31, 2017 are summarized below:

	Unrealized		
	Gain (Loss) on		
	Marketable	Foreign	
	Securities	Currency Items	Total
		(In thousands)	
Balance at December 31, 2016	\$ (55)	\$ 2,596	\$ 2,541
Other comprehensive gain	23	_	23
Balance at December 31, 2017	\$ (32)	\$ 2,596	\$ 2,564

No amounts were reclassified out of accumulated other comprehensive income during the years ended December 31, 2017, 2016 and 2015.

# (4) Fair Value Measurements

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

		As of December 31, 2017	Level 1	Level 2	Level 3
	_		(In thousands)		
Assets:					
Money market funds and cash equivalents	\$	24,061	_	\$ 24,061	_
Marketable securities	_	99,139		99,139	
	<u>\$</u>	123,200		\$ 123,200	
Liabilities:	_				
Kolltan acquisition contingent consideration	\$	43,400	_	_	\$ 43,400
	\$	3 43,400			\$ 43,400
	_				

## NOTES TO FINANCIAL STATEMENTS (Continued)

# (4) Fair Value Measurements (Continued)

	Decem	As of nber 31, 2016	Level 1 (In thousan	Level 2	Level 3
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

The Company's financial assets consist mainly of cash and cash equivalents and marketable securities and are classified as Level 2 within the valuation hierarchy. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the year ended December 31, 2017 (in thousands):

	Othe	Other Liabilities:	
	Contingent		
	Cor	nsideration	
Balance at December 31, 2016	\$	44,200	
Fair value adjustments included in operating expenses		(800)	
Balance at December 31, 2017	\$	43,400	

The valuation technique used to measure fair value of the Company's Level 3 liabilities, which consist of contingent consideration related to the acquisition of Kolltan in 2016 (Note 17), was primarily an income approach. The Company may be required to pay future consideration of up to \$172.5 million that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The significant unobservable inputs used in the fair value measurement of the contingent consideration are estimates, including probability of success, discount rates and amount of time until the conditions of the milestone payments are met.

During the year ended December 31, 2017, the Company recorded a \$0.8 million gain on fair value remeasurement of contingent consideration, primarily due to a reduction in fair value attributed to the milestones related to the Company's anti-KIT and TAM programs and partially offset by losses related to changes in discount rates, passage of time and probabilities affecting remaining milestones. The Company's anti-KIT program includes CDX-0158 and CDX-0159, a variant of CDX-0158. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the years ended December 31, 2017 and 2016.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (5) Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains (In tho	Gross Unrealized Losses usands)	Fair Value
December 31, 2017				
Marketable securities				
U.S. government and municipal obligations				
Maturing in one year or less	\$ 26,164	\$ 3	\$ (9)	\$ 26,158
Maturing after one year through three years				
Total U.S. government and municipal obligations	\$ 26,164	\$ 3	\$ (9)	\$ 26,158
Corporate debt securities				
Maturing in one year or less	\$ 73,007	\$ 1	\$ (27)	\$ 72,981
Maturing after one year through three years				
Total corporate debt securities	\$ 73,007	\$ 1	\$ (27)	\$ 72,981
Total marketable securities	\$ 99,171	\$ 4	\$ (36)	\$ 99,139
December 31, 2016			<del></del>	<del></del>
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

The Company holds investment grade marketable securities, and none were considered to be other-than-temporarily impaired as of December 31, 2017. Marketable securities include \$0.3 million and \$0.6 million in accrued interest at December 31, 2017 and December 31, 2016, respectively.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# (6) Property and Equipment, Net

Property and Equipment, Net includes the following:

	r	December 31, 2017	December 31, 2016	
	· <u></u>	(In thousands)		
Laboratory Equipment	\$	7,770	\$	6,771
Manufacturing Equipment		4,354		4,312
Office Furniture and Equipment		3,764		3,677
Leasehold Improvements		17,164		17,115
Construction in Progress		932		1,283
Total Property and Equipment		33,984		33,158
Less: Accumulated Depreciation and Amortization		(23,612)		(19,966)
Property and Equipment, Net	\$	10,372	\$	13,192

Depreciation and amortization expense related to property and equipment was \$4.4 million, \$3.1 million and \$3.0 million for the years ended December 31, 2017, 2016 and 2015, respectively.

# (7) Intangible Assets and Goodwill

Intangible Assets, Net

The table below presents information for the Company's finite-lived intangible assets that are subject to amortization and indefinite-lived intangible assets:

		December 31, 2017			December 31, 2016		
	Estimated Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount (In tho	Gross Carrying Amount usands)	Accumulated Amortization	Net Carrying Amount
Finite-lived Intangible Assets:							
License Rights	16 years	\$ 14,500	\$ (7,399)	\$ 7,101	\$ 14,500	\$ (6,503)	\$ 7,997
Indefinite-lived Intangible Assets:							
IPR&D	Indefinite	60,490	_	60,490	73,490	_	73,490
Total Intangible Assets, Net		\$ 74,990	\$ (7,399)	\$ 67,591	\$ 87,990	\$ (6,503)	\$ 81,487

Indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of glembatumumab vedotin, CDX-3379, the anti-KIT program and the TAM program. As of December 31, 2017, no IPR&D asset had reached technological feasibility nor did any have alternative future uses.

The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired. During the year ended December 31, 2017, the Company recorded a non-cash partial impairment charge of \$13.0 million on the anti-KIT program IPR&D assets acquired from Kolltan. The Company determined that changes in projected development and regulatory timelines related to the anti-KIT program taken together constituted a triggering event that required the Company to evaluate the intangible asset for

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (7) Intangible Assets and Goodwill (Continued)

impairment. As part of this evaluation, the present value of probability adjusted estimated net future cash flows was used to determine the fair value of the program and compared to the carrying value of the program. As a result of this impairment assessment, the Company concluded that a non-cash partial impairment charge of \$13.0 million on the anti-KIT program IPR&D asset be recorded for the year ended December 31, 2017 for the amount the fair value of the anti-KIT program exceeded its carrying amount.

Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

Amortization expense for intangible assets was \$0.9 million for the year ended December 31, 2017 and \$1.0 million for both the years ended December 31, 2016 and 2015. The future amortization expense of intangible assets is estimated to be \$0.9 million for each of the years ending December 31, 2018, 2019, 2020, 2021 and 2022.

## Goodwill

There have been no changes to the carrying amount of goodwill during the year ended December 31, 2017. The Company performs an annual impairment test of goodwill as of July 1 each year. The Company tested goodwill for impairment as of July 1, 2017 and concluded that goodwill was not impaired.

## (8) Accrued Expenses

Accrued expenses include the following:

	Dec	ember 31, 2017	De	cember 31, 2016
	(In thousands)			
Accrued Payroll and Employee Benefits	\$	6,348	\$	7,132
Accrued Research and Development Contract Costs		11,399		17,742
Accrued Professional Fees		1,408		1,146
Other Accrued Expenses		300		2,637
	\$	19,455	\$	28,657

#### NOTES TO FINANCIAL STATEMENTS (Continued)

## (9) Other Long-Term Liabilities

Other long-term liabilities include the following:

		December 31, 2017		nber 31, 2016	
	·	(In thousands)			
Net Deferred Tax Liabilities Related to IPR&D (Note 14)	\$	3,772	\$	28,054	
Deferred Income From Sale of Tax Benefits		6,756		9,436	
Other		1,344		2,091	
Contingent Milestones (Note 4)	4	13,400		44,200	
Deferred Revenue		2,813		3,749	
Total	4	58,085		87,530	
Less Current Portion		(6,566)		(4,826)	
Long-Term Portion	\$ 5	51,519	\$	82,704	

In November 2015, December 2014, January 2014 and January 2013, 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 and \$0.8 million to an independent third party for \$9.2 million, \$1.8 million, \$1.0 million and \$0.8 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, 2017, 2016 and 2015, the Company recorded \$2.7 million, \$2.8 million and \$1.0 million to other income related to the sale of these tax benefits, respectively.

#### (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.

In May 2016, the Company entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to issue and sell shares of its common stock having an aggregate offering price of up to \$60.0 million from time to time through Cantor, acting as agent. In November 2017, the Company filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional \$75.0 million under the agreement with Cantor. During the years ended December 31, 2017 and 2016, the Company issued 17,722,863 and 3,303,800 shares of its common stock, respectively, under this controlled equity offering sales agreement with Cantor resulting in net proceeds to the Company of \$51.0 million and \$13.9 million, respectively, after deducting commission and offering expenses. At December 31, 2017, the Company had \$67.6 million remaining in aggregate gross offering price available under the Cantor agreement. From January 1, 2018 through February 28, 2018, the Company issued 2,401,847 shares of its common stock resulting in net proceeds to the Company of \$6.1 million.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (10) Stockholders' Equity (Continued)

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.

#### Convertible Preferred Stock

At December 31, 2017, the Company had authorized 3,000,000 shares of preferred stock all of which have been designated Class C Preferred Stock including 350,000 shares which have been designated Series C-1 Junior Participating Cumulative Preferred Stock (the "Series C-1 Preferred Stock"). No shares of Series C-1 Preferred Stock were outstanding at December 31, 2017 or 2016.

#### (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.

## Employee Stock Purchase Plan

At December 31, 2017, a total of 400,000 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, 2017, 2016 and 2015, the Company issued 80,379, 59,335 and 15,755 shares under the 2004 ESPP Plan, respectively. At December 31, 2017, 197,857 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, 2017, the 2008 Plan allowed for a maximum of 20,000,000 shares of common stock to be issued for grants of new awards until June 9, 2025 and grants of incentive stock options until April 16, 2025. The Company's board of directors determines the term of each option, option price, and number of shares for which each option is granted and the rate at which each option vests. Options generally vest over a period not to exceed four years. The term of each option cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of the Company), and the exercise price of stock options cannot be less than the fair market value of the common stock at the date of grant (110% of fair market value for incentive stock options granted to holders of more than 10% of the voting stock of the Company). Vesting of all employee and non-employee director stock option awards may accelerate upon a change in control as defined in the 2008 Plan.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (11) Stock-Based Compensation (Continued)

A summary of stock option activity for the year ended December 31, 2017 is as follows:

	Shares	Weighted Average Exercise Price Per Share		Weighted Average Remaining Contractual Term (In Years)
Options Outstanding at December 31, 2016	10,218,710	\$	11.14	6.5
Granted	2,427,200	\$	2.37	
Exercised	_	\$	_	
Canceled	(1,789,698)	\$	9.76	
Options Outstanding at December 31, 2017	10,856,212	\$	9.40	6.1
Options Vested and Expected to Vest at December 31, 2017	10,780,023	\$	9.43	6.1
Options Exercisable at December 31, 2017	6,846,254	\$	11.18	4.5
Shares Available for Grant Under the 2008 Plan	8,324,310			

The total intrinsic value of stock options exercised during the years ended December 31, 2017, 2016 and 2015 was \$0.0 million, \$0.1 million and \$14.4 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2017, 2016 and 2015 was \$1.58, \$3.18 and \$15.25, respectively. The total fair value of stock options vested during the years ended December 31, 2017, 2016 and 2015 was \$13.4 million, \$17.0 million and \$10.0 million, respectively.

The aggregate intrinsic value of stock options outstanding at December 31, 2017 was \$1.1 million. The aggregate intrinsic value of stock options vested and expected to vest at December 31, 2017 was \$1.1 million. As of December 31, 2017, total compensation cost related to non-vested employee and non-employee director stock options not yet recognized was approximately \$15.0 million, net of estimated forfeitures, which is expected to be recognized as expense over a weighted average period of 2.7 years.

## Restricted Stock

A summary of restricted stock activity under the 2008 Plan for the year ended December 31, 2017 is as follows:

			ighted erage
		Grant Date	
	Shares		Value share)
Outstanding and unvested at December 31, 2016	50,000	\$	4.72
Granted	70,000	\$	2.32
Vested	(16,665)	\$	4.72
Canceled	(6,667)	\$	4.72
Outstanding and unvested at December 31, 2017	96,668	\$	2.98

#### NOTES TO FINANCIAL STATEMENTS (Continued)

# (11) Stock-Based Compensation (Continued)

Valuation and Expenses Information

Stock-based compensation expense for the years ended December 31, 2017, 2016 and 2015 was recorded as follows:

	2017		2016			2015
			(In	thousands)	, _	
Research and development	\$	6,693	\$	7,821	\$	6,186
General and administrative		5,619		7,496		6,588
Total stock-based compensation expense	\$	12,312	\$	15,317	\$	12,774

The fair values of employee and director stock options granted during the years ended December 31, 2017, 2016 and 2015 were valued using the Black-Scholes option pricing model with the following assumptions:

	2017	2016	2015
Expected stock price volatility	75 - 77%	70 - 77%	67 - 69%
Expected option term	6.0 Years	6.0 Years	6.0 Years
Risk-free interest rate	2.0 - 2.3%	1.4 - 2.3%	1.8 - 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

Rockefeller University (Rockefeller)

In 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 \$2.2 million, \$2.7 million and \$3.4 million in revenue related to the Rockefeller agreement during the years ended December 31, 2017, 2016 and 2015, respectively.

Bristol-Myers Squibb Company (BMS)

In 2014, the Company entered into a clinical trial collaboration with BMS to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo®, BMS' PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. 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

#### NOTES TO FINANCIAL STATEMENTS (Continued)

## (12) Revenue (Continued)

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 varillumab. 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 variliumab 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 five 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 five 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 \$2.8 million, \$2.1 million and \$1.3 million in revenue related to the BMS agreement during the years ended December 31, 2017, 2016 and 2015, respectively.

International AIDS Vaccine Initiative (IAVI)

In 2017, the Company entered into an agreement with IAVI pursuant to which the Company performs research and development and manufacturing services for IAVI outlined under subsequently negotiated task orders. Revenue is recognized as services are performed under the negotiated task orders. The Company recorded \$4.9 million in revenue related to the IAVI agreement during the year ended December 31, 2017.

Frontier Biotechnologies, Inc. (Frontier)

In 2017, the Company entered into an agreement with Frontier pursuant to which the Company performs research and development and manufacturing services for Frontier outlined under subsequently negotiated task orders. Revenue is recognized as services are performed under the negotiated task orders. The Company recorded \$1.7 million in revenue related to the Frontier agreement during the year ended December 31, 2017.

## (13) Collaboration Agreements

The Company has entered into license agreements whereby the Company has received licenses or options to license technology, specified patents or patent applications. The Company's licensing and development collaboration agreements generally provide for royalty payments equal to specified percentages of product sales, annual license maintenance fees, continuing patent prosecution costs and potential future milestone payments to third parties upon the achievement of certain developmental, regulatory and/or commercial milestones. Nonrefundable license fee expense of \$0.7 million, \$1.6 million and \$0.9 million was recorded to research and development expense for the years ended December 31, 2017, 2016 and 2015, respectively.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### (13) Collaboration Agreements (Continued)

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.

Under a license agreement with Medarex, as amended, the Company acquired access to the UltiMab technology to develop and commercialize human antibodies to CD27, including varillumab. The Company may be required to pay Medarex royalty payments in the low-to-mid single digits on any net product sales with respect to the development and commercialization of varillumab 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.

Rockefeller University (Rockefeller)

Under a license agreement with Rockefeller, the Company acquired 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. 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)

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

Amgen Inc. (Amgen)

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

#### NOTES TO FINANCIAL STATEMENTS (Continued)

## (13) Collaboration Agreements (Continued)

Seattle Genetics, Inc. (Seattle Genetics)

Under a license agreement with Seattle Genetics, the Company acquired the rights to proprietary ADC technology, with the right to sublicense, 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.

Yale University (Yale)

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

MedImmune, LLC (MedImmune)

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

# NOTES TO FINANCIAL STATEMENTS (Continued)

## (14) Income Taxes

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

	Year Ended December 31,				
	2017	2016	2015		
		In thousands)			
Income Tax Benefit (Provision):					
Federal	\$ 57,547	\$ 45,518	\$ 46,598		
State	(2,479)	7,268	10,642		
Foreign	2,448	1,124	_		
Income Tax Rate Change	(99,528)	_	_		
Expiration of Net Operating Losses and Research & Development Tax Credits			(155)		
	(42,012)	53,910	57,085		
Deferred Tax Valuation Allowance	66,294	(53,910)	(57,085)		
	\$ 24,282	\$ —	<u>\$</u>		

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

	2017	2016	2015
		(In thousands)	
Pre-Tax Loss	\$ (117,313)	\$ (128,530)	\$ (127,197)
Loss at Statutory Rates	(39,887)	(43,700)	(43,247)
Difference in Foreign Tax Rates	326	150	_
Research and Development Credits	(2,847)	(5,203)	(4,935)
State Taxes	(6,283)	(7,268)	(10,642)
Income Tax Rate Change	99,528	_	
Other	(321)	2,111	1,584
Recognition of APIC NOLs	(5,729)	_	_
Impact of Pass-through Entities	(2,775)	_	_
Expiration of Net Operating Losses and Research & Development Tax Credits	_	_	155
Change in Valuation Allowance	(66,294)	53,910	57,085
Income Tax (Benefit) Provision	\$ (24,282)	<u> </u>	\$

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

#### NOTES TO FINANCIAL STATEMENTS (Continued)

## (14) Income Taxes (Continued)

principal components of the deferred tax assets and liabilities at December 31, 2017 and 2016, respectively, are as follows:

	December 31, 2017			ecember 31, 2016
	(In thousands)			
Gross Deferred Tax Assets				
Net Operating Loss Carryforwards	\$	146,228	\$	174,555
Foreign Net Operating Loss Carryforwards		3,572		1,124
Tax Credit Carryforwards		36,458		32,306
Deferred Research and Development Expenses		79,272		109,520
Stock-based Compensation		10,718		12,362
Fixed Assets		1,305		1,526
Deferred Revenue		686		1,418
Accrued Expenses and Other		316		894
•		278,555		333,705
Gross Deferred Tax Liabilities				
Other Acquired Intangibles		(1,792)		(2,868)
IPR&D Intangibles		(15,992)		(28,054)
Total Deferred Tax Assets and Liabilities		260,771		302,783
Valuation Allowance		(264,543)		(330,837)
Net Deferred Tax Liability	\$	(3,772)	\$	(28,054)

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

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

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted, leading to significant changes to U.S. tax law. Among other provisions, the TCJA lowered the U.S. federal corporate income tax rate from 35% to 21%, limited the deduction for net operating losses to 80% of taxable income while providing that net operating loss carryovers for years after 2017 will not expire, imposed a mandatory one-time transition tax on previously deferred foreign earnings and eliminated or reduced certain income tax deductions. Also on December 22, 2017, the SEC staff issued SAB 118, allowing companies to record the effects of the TCJA on a provisional basis during a measurement period not to extend beyond one year of the enactment date.

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

#### NOTES TO FINANCIAL STATEMENTS (Continued)

## (14) Income Taxes (Continued)

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

In accordance with SAB 118, the Company considers the aforementioned adjustments related to the TCJA to be provisional amounts based on the Company's best estimates at December 31, 2017. Updated guidance, interpretations or assumptions could lead the Company to make further adjustments to income tax benefit (provision) in the future. The Company expects its accounting for the tax effects of the TCJA to be completed in 2018.

The net deferred tax liability of \$3.8 million and \$28.1 million at December 31, 2017 and 2016, respectively, relates to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and are not deductible for tax purposes. The Company recorded an income tax benefit of \$5.2 million during the year ended December 31, 2017 due to a decrease in deferred tax liabilities resulting from the partial impairment of the anti-KIT program.

As of December 31, 2017, the Company had federal and state net operating loss carryforwards of \$561.8 million and \$435.9 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, 2017, the Company also had federal and state research and development tax credit carryforwards of \$29.0 million and \$9.5 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2018 and 2017, respectively.

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

The Company incurred a foreign pre-tax loss of \$8.2 million and \$3.7 million during the years ended December 31, 2017 and 2016, respectively. Beginning with the 2016 tax returns, the Company elected to classify the Australian entity as a disregarded entity for income tax purposes. The foreign pre-tax losses have been included with the Federal net operating loss carryforwards.

As of December 31, 2017 and 2016, the Company did not have any unrecognized tax benefits.

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

#### 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, 2017 do not include the exercise of renewal terms or early termination provisions (in thousands):

2018	\$ 4,591
2019	4,472
2020	2,498
2021	_
2022	_
Thereafter	_
Total minimum lease payments	\$ 11,561

The Company's total rent and CAM expense for all facility leases was \$4.1 million, \$4.8 million and \$2.9 million for the years ended December 31, 2017, 2016 and 2015, 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 \$0.5 million for the year ended December 31, 2017 and \$0.4 million for each of the years ended December 31, 2016 and 2015.

#### (17) Kolltan Acquisition

On November 29, 2016, the Company acquired all of the share and debt interests of Kolltan Pharmaceuticals, Inc. ("Kolltan"), a clinical-stage biopharmaceutical company, in exchange for 18,257,996 shares of the Company's common stock plus contingent consideration in the form of development and approval milestones up to a maximum of \$172.5 million. The Company completed this acquisition in order to gain access to Kolltan's antibody-based drug development programs targeting receptor tyrosine kinases (RTKs) for the treatment of cancer and other diseases with significant unmet needs.

## Purchase Price

The purchase price for Kolltan was calculated based on the closing price of the Company's common stock of \$4.02 per share on November 29, 2016. The Company also recorded a liability of \$44.2 million which represented the initial fair value of the contingent consideration. This fair value measurement used significant unobservable inputs representing a Level 3 measurement more fully described in Note 4, Fair Value Measurements to these consolidated financial statements. Subsequent changes to the fair value of the contingent consideration will be recognized as adjustments to operating earnings. The acquisition was accounted for using the acquisition method of accounting which requires all assets acquired and liabilities assumed recognized at their acquisition-date fair values.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (17) Kolltan Acquisition (Continued)

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

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

#### Allocations of Assets and Liabilities

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

Cash and cash equivalents	\$	8,160
Other current and long-term assets		799
Property and equipment, net		2,072
In-process research and development (IPR&D)		61,690
Goodwill		82,011
Deferred tax liabilities, net		(23,393)
Other assumed liabilities		(9,974)
Total	\$ 1	121,365

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

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

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

## Acquisition-Related Expenses, Including Severance

The Company incurred \$0.7 million in acquisition-related expenses in the consolidated statements of operations for the year ended December 31, 2016. From the acquisition date through December 31, 2016, the consolidated statements of operations also include \$2.4 and \$0.7 million in Kolltan related

## NOTES TO FINANCIAL STATEMENTS (Continued)

## (17) Kolltan Acquisition (Continued)

severance expense within general and administrative and research and development expenses, respectively.

#### Pro Forma Financial Information

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

	Una	udited
	Years	Ended
	Decen	iber 31,
	2016	2015
	(In the	ousands)
Revenue	\$ 6,786	\$ 5,480
Net loss	\$ (146,905)	\$ (157,690)
Basic and diluted net loss per common share	\$ (1.24)	) \$ (1.37)

## (18) Selected Quarterly Financial Data (Unaudited)

<u>2017</u>	Q1 2017	Q2 2017	Q3 2017	Q4 2017
	(In the	ousands, except p	per share amour	its)
Total revenue	\$ 1,534	\$ 3,829	\$ 3,924	\$ 3,456
Net loss	(34,261)	(28,566)	(26,363)	(3,841)
Basic and diluted net loss per common share	(0.28)	(0.23)	(0.20)	(0.03)

2016	 Q1 2016		Q2 2016		Q3 2016		Q4 2016
	 (In the	hou	sands, excep	t pe	r share amou	ınts	5)
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, 2017, 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, 2017. 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, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017 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, 2017 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 2018 Annual Meeting of Stockholders, or the 2018 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 2018 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 2018 Proxy Statement under "Executive Compensation," and "Compensation Committee Interlocks and Insider Participation," and is incorporated herein by reference. If the 2018 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 2018 Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference. If the 2018 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 2018 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 2018 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 2018 Proxy Statement under "Independent Registered Public Accounting Firm" and is incorporated herein by reference. If the 2018 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		to	
No.	- Description	Form and SEC File No.	Exhibit No.	SEC Filing Date	
Plan of 2.1	Acquisition, Reorganization, Arrangement, Liquidation or Succession 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 3.1	of Incorporation and By-Laws  Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98	
3.2	Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.1	7/16/98	
3.3	Second Certificate of Amendment of Third Restated Certificate of Incorporation	S-4 (333-59215)	3.2	7/16/98	
3.4	Third Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.1	5/10/02	
3.5	Fourth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.1	3/11/08	
3.6	Fifth Certificate of Amendment of Third Restated Certificate of Incorporation	8-K (000-15006)	3.2	3/11/08	
3.7	Sixth Certificate of Amendment of Third Restated Certificate of Incorporation	10-Q (000-15006)	3.7	11/10/08	
3.8	Amended and Restated By-Laws, dated April 7, 2014	8-K (000-15006)	3.1	4/8/14	
Instrume 4.1	ents Defining the Rights of Security Holders Specimen of Common Stock Certificate	10-Q (000-15006)	4.1	8/8/17	
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		Incorporated	by Reference	to
No.	Description	Form and SEC File No.	Exhibit No.	SEC Filing Date
4.2	Certificate of Designations, Preferences and Rights of a Series of Preferred Stock classifying and designating the Series C-1 Junior Participating Cumulative Preferred Stock	8-A (000-15006)	3.1	11/8/04
Materia 10.1	l Contracts—Leases Commercial Lease Agreement of May 1, 1996 between the Company and Fourth Avenue Ventures Limited Partnership	10-Q/A (000-15006)	10.11	8/23/96
10.2	Extension of Lease Agreement of May 1, 1997 between the Company and DIV Needham 53 LLC (successor in interest to Fourth Avenue Ventures Limited Partnership) dated as of August 23, 2001	10-K (000-15006)	10.9	3/27/02
10.3	First Amendment to Lease by and between the Company and DIV Needham 115 LLC (successor in interest to Fourth Avenue Ventures Limited Partnership) dated November 29, 2005	10-K (000-15006)	10.40	3/16/06
10.4	Second Amendment to Lease by and between the Company and DIV Needham 115 LLC dated as of August 1, 2015	10-K/A (000-15006)	10.4	2/25/16
*10.5	Lease Agreement, by and between the Company and the Massachusetts Development Finance Agency, dated as of December 22, 2003	10-Q (000-15006)	10.1	4/30/04
10.6	First Amendment to Lease between Massachusetts Development Finance Agency and the Company dated March 17, 2005	10-K/A (000-15006)	10.6	12/23/10
10.7	Second Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of November 4, 2005	10-K (000-15006)	10.41	3/16/06
10.8	Third Amendment to Lease between Massachusetts Development Finance Agency and the Company dated December 20, 2006	10-K/A (000-15006)	10.7	12/23/10
10.9	Fifth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated October 3, 2008	10-K/A (000-15006)	10.8	12/23/10
10.10	Sixth Amendment to Lease between Massachusetts Development Finance Agency and the Company dated August 20, 2009	10-K/A (000-15006)	10.9	12/23/10
10.11	Seventh Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of June 22, 2010	10-Q (000-15006)	10.1	8/5/10
10.12	Eighth Amendment to Lease by and between the Company and the Massachusetts Development Finance Agency dated as of November 1, 2015	10-K/A (000-15006)	10.12	2/25/16

		Incorporated by Reference to		to	
No.	Description	Form and SEC File No.	Exhibit No.	SEC Filing Date	
10.13	Lease Agreement dated as of May 1, 2013 by and between Crown Perryville, LLC and the Company.	10-Q (000-15006)	10.1	5/03/13	
10.14	First Amendment to Lease between Company and Crown Perryville, LLC dated as of June 17, 2015	10-Q (000-15006)	10.2	8/10/15	
	l Contracts—License, Collaboration, Supply and Distribution Agreements 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 the Company	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 the Company	10-K (000-15006)	10.28	3/12/10	
10.22	Amgen Letter Agreement, by and between the Company and Amgen Fremont, Inc. dated May 2, 2009	10-K (000-15006)	10.29	3/12/10	
*10.23	<u>License Agreement between Medarex and Company dated</u> <u>September 17, 2010</u>	10-Q/A (000-15006)	10.3	12/23/10	
*10.24	License and Option Agreement by and between MedImmune, LLC and the Company, dated July 24, 2013, as amended by the Amendment, dated October 27, 2015	Filed herewith			
*10.25	Third Amended and Restated License Agreement by and between Yale University and the Company, dated March 14, 2013, as amended by the Amendments, dated March 21, 2014 and December 1, 2014	Filed herewith			
Materia 10.26	l Contracts—Stock Purchase, Financing and Credit Agreements 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	

		Incorporated b	y Reference	to
No.	Description	Form and SEC File No.	Exhibit No.	SEC Filing Date
	Contracts—Management Contracts and Compensatory Plans 2008 Stock Option and Incentive Plan, as amended and restated	Filed herewith		
†10.28	2004 Employee Stock Purchase Plan, as amended and restated	Filed herewith		
†10.29	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Anthony S. Marucci	8-K (000-15006)	10.1	12/29/17
†10.30	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Sam Martin	8-K (000-15006)	10.2	12/29/17
†10.31	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Tibor Keler, Ph.D.	8-K (000-15006)	10.3	12/29/17
†10.32	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Ronald Pepin, Ph.D.	8-K (000-15006)	10.4	12/29/17
†10.33	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Sarah Cavanaugh	8-K (000-15006)	10.5	12/29/17
†10.34	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Margo Heath-Chiozzi, M.D.	8-K (000-15006)	10.6	12/29/17
†10.35	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Elizabeth Crowley	8-K (000-15006)	10.7	12/29/17
†10.36	Amended and Restated Employment Agreement, dated as of January 1, 2018, by and between Celldex Therapeutics, Inc. and Richard Wright, Ph.D.	8-K (000-15006)	10.8	12/29/17
†10.37	Form of Stock Option Agreement	8-K (000-15006)	10.1	1/25/10
†10.38	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		

		Incorporated 1	by Reference	to
No.	Description	Form and SEC File No.	Exhibit No.	SEC Filing Date
101	XBRL Instance Document	Filed herewith		
101	1 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	ith	
101	XBRL Taxonomy Extension Label Linkbase Document	bel 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.

# Item 16. FORM 10-K SUMMARY

None.

<sup>†</sup> Indicates a management contract or compensation plan, contract or arrangement.

## **SIGNATURES**

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

# CELLDEX THERAPEUTICS, INC.

	By:	/s/ ANTHONY S. MARUCCI	
Date March 7, 2018		Anthony S. Marucci President and Chief Executive Officer	

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

Signature	Signature <u>Title</u>	
/s/ ANTHONY S. MARUCCI	President, Chief Executive Officer, and Director	
Anthony S. Marucci	(Principal Executive Officer)	March 7, 2018
/s/ SAM MARTIN	Senior Vice President, Chief Financial Officer and Treasurer	March 7, 2018
Sam Martin	(Principal Financial and Accounting Officer)	Match 7, 2016
/s/ LARRY ELLBERGER	Discotor Chairman afaba Danad af Discotor	March 7, 2019
Larry Ellberger	- Director, Chairman of the Board of Directors	March 7, 2018
/s/ KEITH L. BROWNLIE	- Director	March 7, 2018
Keith L. Brownlie	Bilector	Wiaicii 7, 2016
/s/ HERBERT J. CONRAD	- Director	March 7, 2018
Herbert J. Conrad	- Director	March 7, 2018
/s/ JAMES J. MARINO	- Director	Manah 7, 2019
James J. Marino	- Director	March 7, 2018
/s/ GERALD MCMAHON	Pin to	March 7, 2019
Gerald McMahon, Ph.D.	- Director	March 7, 2018
/s/ HARRY H. PENNER, JR.	Disease	March 7, 2019
Harry H. Penner, Jr.	- Director	March 7, 2018
/s/ KAREN L. SHOOS	Disease	Manah 7, 2019
Karen L. Shoos	- Director	March 7, 2018
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## **Execution Version**

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

LICENSE AND OPTION AGREEMENT

BY AND BETWEEN

MEDIMMUNE, LLC

AND

BULLDOG PHARMACEUTICALS, INC.

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## LICENSE AND OPTION AGREEMENT

This License and Option Agreement (this "Agreement") is entered into and made effective as of the 24th day of July, 2013 (the "Effective Date"), by and between MedImmune, LLC, a limited liability company organized and existing under the laws of Delaware, having a principal office located at One MedImmune Way, Gaithersburg, MD 20878 ("MedImmune"), and Bulldog Pharmaceuticals, Inc., a company organized and existing under the laws of the British Virgin Islands, having a registered office located at Midocean Chambers, Road Town, Tortola, British Virgin Islands ("Kolltan"). MedImmune and Kolltan are each referred to herein by name or as a "Party" or, collectively, as "Parties."

#### RECITALS

WHEREAS, Kolltan is a wholly-owned subsidiary of Kolltan Pharmaceuticals, Inc.;

WHEREAS, Kolltan possesses expertise in the Research, Development, Manufacture and Commercialization (each as defined below) of pharmaceutical products;

WHEREAS, MedImmune controls certain intellectual property and regulatory materials and biological materials related to the Licensed Antibody (as defined below);

WHEREAS, Kolltan is interested in receiving certain licenses and other rights under which it may Research, Develop, Manufacture and Commercialize the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products (each as defined below), in each case in the Field in the Territory (each as defined below), and MedImmune is willing to grant Kolltan such licenses and other rights on the terms and conditions set forth in this Agreement; and

WHEREAS, the Parties desire to set forth herein the terms and conditions of the licenses and other rights to enable Kolltan to Research, Develop, Manufacture and Commercialize the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

# ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth in this ARTICLE 1:

1.1 "Accounting Standards" means generally accepted accounting principles (GAAP) as practiced in the United States; provided, however, that from and after such time (if any) as Kolltan elects to maintain its books in accordance with International Financial Reporting Standards ("IFRS"), Accounting Standards shall mean IFRS.

- 1.2 "Affiliate" means, as to a Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with said first Person, regardless of whether such Affiliate is an Affiliate on the Effective Date or becomes an Affiliate after the Effective Date. For purposes of this definition, a Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the general management and policies of the Person.
- 1.3 "Annual Net Sales" means, for any Licensed Product or Follow-On Product, as the case may be, in any Calendar Year, aggregate Net Sales of such Licensed Product or Follow-On Product, as applicable, in such Calendar Year, but excluding any Net Sales of such Licensed Product or Follow-On Product, as applicable, in any country if the applicable sale is made after the expiration of the Royalty Term for such Licensed Product or Follow-On Product, as applicable, in such country.
- 1.4 "Antibody" means any antibody, or any antigen-binding fragment thereof, with a unique amino acid sequence. Two antibodies that have different amino acid sequences (even if differing by only a single amino acid) shall be deemed to be different Antibodies.
- 1.5 "Applicable Law" or "Applicable Laws" means all laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision that may be in effect from time to time and applicable to the activities contemplated by this Agreement.
- 1.6 "BLA" means a Biologics License Application and any amendments or supplements thereto filed with the FDA pursuant to 21 C.F.R. Part 601 or any other application that is required for the purpose of marketing and selling a biological product and is filed with a Regulatory Authority outside the United States, including, with respect to the EU, a Product License Application, Marketing Authorization Application and/or manufacturing and importation license.
  - 1.7 "Business Day" means a day on which banking institutions in New York, NY are open for business, excluding any Saturday or Sunday.
  - 1.8 "Calendar Quarter" means a period of three (3) consecutive months ending on the last day of March, June, September, or December.
  - 1.9 "Calendar Year" means a period of time commencing on January 1 and ending on the following December 31.
- 1.10 "Clinical Trial(s)" means individually and collectively a Phase 1 Clinical Trial, a Phase 1 b/2a Clinical Trial, a Phase 2 Clinical Trial, a Phase 3 Clinical Trial, a Phase 4 Study and a Post Approval Study.

- 1.11 "Combination Product" means a Licensed Product or Follow-On Product, as the case may be, that (a) includes the Licensed Antibody or a Follow-On Antibody, as applicable, as an active pharmaceutical ingredient, together with one or more other active ingredients, and (b) is sold either as a fixed dose or with separate doses in a single package.
- 1.12 "Commercialization" or "Commercialize" means any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product, including post-Regulatory Approval promotional activities conducted at scientific conferences or similar events.
- 1.13 "Commercially Reasonable Efforts" means, with respect to a Party, such level of efforts required to carry out an obligation in a sustained manner consistent with the efforts normally used by pharmaceutical or biopharmaceutical companies, as applicable, of comparable size and resources to such Party, for a similar activity with respect to the Research, Development, Manufacture or Commercialization of products that (a) are at a similar stage in their product life as the relevant Licensed Product or Follow-On Product, as applicable, and (b) that have commercial and market potential similar to the relevant Licensed Product or Follow-On Product, as applicable, taking into account issues of intellectual property scope, subject matter and coverage, safety and efficacy, product profile, competitiveness with respect to Third Party products in the marketplace, and profitability (including pricing and reimbursement status achieved or likely to be achieved).
- 1.14 "Competing Product" means any pharmaceutical product that (a) comprises or incorporates an Antibody as an active pharmaceutical ingredient alone or in combination with one or more other active agents and (b) operates by targeting HER-3.
- 1.15 "Control," "Controls," "Controlled" or "Controlling" means, with respect to any Know-How, Patent, Regulatory Documentation or other intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party of the right to assign or grant access to, or grant a license or sublicense under, such Know-How, Patent, Regulatory Documentation or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to make such assignment or grant such access, license or sublicense; provided, however, that any Know-How, Patent, Regulatory Documentation or other intellectual property right that is licensed or acquired by a Party from a Third Party after the Effective Date (other than rights arising from the In-License Agreements) that would otherwise be considered to be under the Control of such Party shall not be deemed to be under the Control of such Party if the application of such definition in the context of any licenses or sublicenses granted to the other Party under this Agreement would require the granting Party to make additional payments or royalties to such Third Party, unless the other Party agrees to pay such additional payments or royalties to the Third Party.
- 1.16 "Cover" or "Covered" means, for any product, technology, process or method and any Valid Claim, that the composition, manufacture, use, offer for sale, sale or importation of such product or the practice of such technology, process or method would, absent ownership of a

Patent that includes such Valid Claim or a license or sublicense under such Valid Claim, infringe such Valid Claim (assuming, in the case of a Valid Claim that has not yet issued, that such Valid Claim had issued). A product, technology, process or method shall be deemed Covered by a Patent if it is Covered by at least one Valid Claim included in such Patent.

- 1.17 "<u>Data Package Delivery Date</u>" means the date on which Kolltan completes delivery to MedImmune of (a) the full data set of clinical trial data (including validated data for primary and secondary endpoints) in the clinical trial database for a Phase 1b/2a Clinical Trial of the Licensed Antibody or a Licensed Product for each of two (2) indications as provided in Section 5.1.1, and (b) the clinical data and non-clinical and/or Development data and information required to be delivered under Sections 5.1.2 and 5.1.3 together with the full data set described in clause (a) above.
- 1.18 "Develop" or "Development" means development activities relating to the development of compounds, biologics, or processes, and submission of information to a Regulatory Authority for the purpose of obtaining Regulatory Approval of a product. Development includes non-clinical activities, pharmacology studies, toxicology studies, manufacturing process development activities, analytical method development activities, formulation development activities, chemical analysis, bioanalytical analysis, material performance studies (including measurements of stability, physical form, dissolution, and visual and spectroscopic analysis), pharmacokinetic studies, clinical studies, biomarker and companion diagnostic discovery and development, regulatory affairs activities, and all other activities relating to seeking, obtaining or maintaining any Regulatory Approvals from the FDA or any other applicable Regulatory Authority.
  - 1.19 "Dollars" or "\\$" means the legal tender of the United States.
- 1.20 "Dyax Agreement" means that certain Amended and Restated License Agreement, dated July 26, 2012 between MedImmune Limited and Dyax Corp.
  - 1.21 "EMA" means the European Medicines Agency, or any successor entity thereto.
- 1.22 "EU" means all of the member countries of the European Union as of the applicable time during the Term. For clarity, the member countries of the European Union as of the Effective Date are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.
- 1.23 "Executive Officers" means (a) with respect to Kolltan, the Chief Executive Officer of Kolltan, and (b) with respect to MedImmune, the Executive Vice President, Research and Development of MedImmune.
- 1.24 "Existing IND" means application number 116023 for the treatment of advanced solid tumors, filed with the FDA and effective as of January 11, 2013.
- 1.25 "Existing Proceeding" means any post-grant proceeding that is being prosecuted by MedImmune or its Affiliates as of the Effective Date and that relates to a Patent that (a) could

# Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

be relevant to the exercise by Kolltan of the rights, licenses and sublicenses granted to Kolltan by MedImmune under this Agreement (including the making, using, selling, offering for sale or import of the Licensed Antibody or any Licensed Product, Follow-On Antibody or Follow-On Product) or (b) could otherwise affect the Research, Development, Manufacture, or Commercialization of the Licensed Antibody or any Licensed Product, Follow-On Antibody or Follow-On Product. For the avoidance of doubt, Existing Proceeding includes the opposition proceeding set forth in Exhibit 9.2.6.

- 1.26 "FDA" means the U.S. Food and Drug Administration, or any successor entity thereto.
- 1.27 "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended.
- 1.28 "Field" means any use in humans, including diagnosis, prophylaxis and treatment of human disease.
- 1.29 "First Commercial Sale" means, for any Licensed Product or Follow-On Product, as the case may be, in any country, the first sale or other transfer for consideration of such Licensed Product or Follow-On Product, as applicable, in such country by or on behalf of Kolltan, its Affiliates or its Sublicensees for use or consumption pursuant to a Regulatory Approval (or as otherwise permitted by the applicable Governmental Authority) in such country, including any sales or other transfers for consideration to distributors (subject to the next sentence), that results in the recognition of revenue. Sale or other transfer for consideration of a Licensed Product or Follow-On Product, as the case may be, in a country by Kolltan to an Affiliate or Sublicensee of Kolltan shall not constitute a First Commercial Sale in such country where such Affiliate or such Sublicensee (a) is not the end user of such Licensed Product or Follow-On Product, as applicable, and has purchased or received such Licensed Product or Follow-On Product, as applicable, for purposes of re-selling, transferring, distributing or otherwise commercially disposing of such Licensed Product or Follow-On Product, as applicable, for the purposes set forth in subsections (a)-(c) of Section 1.98. In no event shall any sales in any country for sampling be deemed a First Commercial Sale in such country.
- 1.30 "Follow-On Antibody" means any Antibody, other than the Licensed Antibody, that is Covered by a claim of a national stage application of or claiming priority to Intl. Appl. No. [\*\*]. For avoidance of doubt, Follow-On Antibody includes any antibody or antigen-binding fragment thereof fused or conjugated to a molecule, which antibody is Covered by a claim of a national stage application of or claiming priority to Intl. Appl. No. [\*\*].
- 1.31 "Follow-On Product" means any pharmaceutical product (including all forms, presentations, doses and formulations) that comprises or incorporates any Follow-On Antibody as an active pharmaceutical ingredient alone or in combination with one or more other active agents.
- 1.32 "Follow-On Product Transaction" means any sale by Kolltan of, or any grant of any license or sublicense by Kolltan under, Kolltan's rights to Commercialize any Follow-On

Product; provided, however, that any Kolltan Sale or Financing, or any assignment or deemed assignment of this Agreement by Kolltan in connection with a Kolltan Sale or Financing, shall not be deemed a Follow-On Product Transaction.

- 1.33 "Follow-On Program" means the Parties' rights and obligations under this Agreement with respect to Follow-On Antibodies and Follow-On Products.
- 1.34 "GCP" means the then-current standards, practices and procedures (a) promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA; (b) set forth in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and Commission Directive 2005//28/EC of 8 April 2005; (c) set forth in ICH Guideline for Good Clinical Practice E6; (d) set forth in analogous Applicable Laws of an applicable Regulatory Authority; and (e) set forth in any Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.
- 1.35 "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, as such regulations may be amended from time to time, and analogous Applicable Laws of an applicable Regulatory Authority.
- 1.36 "GMP" means then-current standards for the manufacture of pharmaceutical products, pursuant to (a) the FD&C Act (21 U.S.C. 321 et seq.); (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) European Community Directives 2003/94 and 91/356/EC; (d) the European Community Guide to Good Manufacturing Practice for Medicinal Intermediate Products; (e) ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (f) analogous Applicable Laws of an applicable Regulatory Authority at the time of Manufacture; and (g) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.
- 1.37 "Governmental Authority" means any United States federal, state or local or any non-United States government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or governmental arbitrat body.
- 1.38 "HER-3" means the protein that (a) is also known as ErbB3 or EGFR3; (b) is an alias of V-erb-b2 erythroblastic leukemia viral oncogene homolog 3; (c) is a member of the ErbB family of receptor tyrosine kinases; and (d) has its DNA sequence located on human chromosome 12q13.
- 1.39 "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

- 1.40 "IND" means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application (CTA).
- 1.41 "In-License Agreement" means each agreement pursuant to which MedImmune is granted a license or sublicense under the In-Licensed IP. As of the Effective Date, the In-License Agreements are the agreements set forth on Exhibit 1.41.
  - 1.42 "In-Licensed IP" means the Patents and Know-How set forth on Exhibit 1.42.
- 1.43 "Insolvency Event" means, as to a Party, (a) the entry of an order for relief with respect to such Party under the Bankruptcy Code or any other bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect; (b) the commencement of an involuntary proceeding against such Party under the Bankruptcy Code or any other bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect, if not dismissed, bonded or stayed within ninety (90) days after such commencement; (c) the making by such Party of a general assignment for the benefit of creditors; or (d) the appointment of or taking possession by a receiver, liquidator, assignee, custodian, or trustee of all or substantially all of the business or property of such Party.
- 1.44 "<u>Joint Information and Inventions</u>" means Know-How that is first made or discovered jointly by (a) one or more employees, consultants or agents of MedImmune or its Affiliates and (b) one or more employees, consultants or agents of Kolltan or its Affiliates, in the course of Research, Development, Manufacture or Commercialization of the Licensed Antibody and Licensed Products.
  - 1.45 "Joint IP" means the Joint Know-How and the Joint Patents.
  - 1.46 "Joint Know-How" means all Joint Information and Inventions except to the extent disclosed by published Joint Patents.
  - 1.47 "Joint Patents" means Patents that Cover Joint Information and Inventions.
- 1.48 "Know-How" means all tangible and intangible (a) information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, strategies, skill, experience, data, results (including pharmacological, toxicological and non-clinical and clinical test data and results, and Research or Development data, reports and batch records), analytical and quality control data, analytical methods (including applicable reference standards), full batch documentation for all product forms, packaging records, release, stability, storage and shelf-life data, Manufacturing process information, results and descriptions, and software and algorithms (but excluding any Regulatory Documentation) and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material (including reagents and antibodies).
- 1.49 "Kolltan Development Costs" means the sum of (a) all Out-of-Pocket Costs incurred by Kolltan or its Affiliates under this Agreement as of a specified time that are specifically identifiable to (i) the Research or Development of the Licensed Antibody or Licensed Products or (ii) the Manufacture of the Licensed Antibody or Licensed Products in

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

support of such Research or Development, including the validation, qualification and subsequent audit of Manufacturing facilities, and (b) an amount equal to the lesser of (x) the number of Kolltan employee hours attributable to Kolltan's activities set forth in the foregoing subsections (i) and (ii) of clause (a) above multiplied by [\*\*] Dollars (\$[\*\*]) and (y) [\*\*] percent ([\*\*]%) of the amount described in clause (a) above. For avoidance of doubt, the Upfront Fee shall not be included in the Kolltan Development Costs.

- 1.50 "Kolltan Indemnitees" means Kolltan and its Affiliates and Sublicensees and the directors, officers, employees and consultants of Kolltan and its Affiliates and Sublicenses.
- 1.51 "Kolltan Information and Inventions" means Know-How that (a) is Controlled by Kolltan or its Affiliates during the Term and (b) relates to the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product, or the Manufacture of the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product; provided, however, that Kolltan Information and Inventions excludes any Joint Information and Inventions.
  - 1.52 "Kolltan IP" means the Kolltan Know-How and the Kolltan Patents.
  - 1.53 "Kolltan Know-How" means all Kolltan Information and Inventions except to the extent disclosed by published Kolltan Patents.
- 1.54 "Kolltan Patents" means Patents Controlled by Kolltan or its Affiliates during the Term that Cover Kolltan Information and Inventions; provided, however, that Kolltan Patents excludes any Joint Patents.
- 1.55 "Kolltan Sale or Financing" means (a) any transaction or series of related transactions that results in the sale or other disposition of all or substantially all of Kolltan's assets; (b) any merger, consolidation or similar business combination involving Kolltan; or (c) any issuance, sale or exchange of any securities of Kolltan, whether in a public or private offering.
- 1.56 "<u>Licensed Antibody</u>" means MedImmune's proprietary Antibody known as MEDI3379 (anti-HER3), with respect to which the Existing IND has been filed, and/or its parent Antibody 2C2 (anti-HER3), or any isotype thereof.
- 1.57 "<u>Licensed Product</u>" means any pharmaceutical product (including all forms, presentations, doses and formulations) that comprises or incorporates the Licensed Antibody as an active pharmaceutical ingredient alone or in combination with one or more other active agents.
  - 1.58 "<u>Licensed Program</u>" means the Parties' rights and obligations under this Agreement with respect to the Licensed Antibody and Licensed

Products.

1.59 "Lonza Agreement" means that certain Licenses and Services Agreement made effective as of January 21, 2005 by and between AstraZeneca AB and Lonza Biologics PLC, as (a) novated by that certain Novation Agreement effective January 1, 2007 by and among Lonza

# Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

Biologics PLC, Lonza Sales AG and AstraZeneca AB and (b) amended by Amendment No. 1 made effective as of March 20, 2009.

- 1.60 "Major Indication" means any indication with a market potential of at least [\*\*] Dollars (\$[\*\*]) in peak year sales in the Territory, as determined by Kolltan, in consultation with MedImmune, by reference to standard industry sources.
- 1.61 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of a product in all of its forms, including test method development, formulation development, process development, process and product characterization (including upstream and downstream processing), manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, storage, quality assurance/quality control development, quality control testing (including in-process, release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing.
- 1.62 "MedImmune Additional Information and Inventions" means Know-How (a) that is Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term; (b) that relates to the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product; and (c) the practice of which is reasonably useful in order to Research, Develop or Commercialize the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product in the Field in the Territory; provided, however, that MedImmune Additional Information and Inventions excludes any MedImmune Information and Inventions, any MedImmune Manufacturing Information and Inventions and any Joint Information and Inventions.
  - 1.63 "MedImmune Additional IP" means the MedImmune Additional Know-How and the MedImmune Additional Patents.
- 1.64 "<u>MedImmune Additional Know-How</u>" means all MedImmune Additional Information and Inventions except to the extent disclosed by published MedImmune Additional Patents.
- 1.65 "MedImmune Additional Patents" means Patents Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term that Cover MedImmune Additional Information and Inventions; provided, however, that MedImmune Additional Patents excludes any MedImmune Patents and any Joint Patents.
- 1.66 "MedImmune Indemnitees" means MedImmune, its Affiliates and the directors, officers, employees and consultants of MedImmune and its Affiliates.
- 1.67 "MedImmune Information and Inventions" means Know-How (a) that is Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term; (b) that relates to the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product; and (c) the practice of which is necessary to Research, Develop or Commercialize the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product in the Field in the Territory; provided, however, that MedImmune

Information and Inventions excludes any MedImmune Manufacturing Information and Inventions and any Joint Information and Inventions.

- 1.68 "MedImmune IP" means the MedImmune Know-How and the MedImmune Patents.
- 1.69 "MedImmune Know-How" means all MedImmune Information and Inventions except to the extent disclosed by published MedImmune Patents.
- 1.70 "MedImmune Manufacturing Information and Inventions" means Know-How (a) that is Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term and (b) either (i) the practice of which is necessary in order to Manufacture the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product in the Field in the Territory or (ii) is expressly disclosed in the Existing IND; provided, however, that MedImmune Manufacturing Information and Inventions excludes any Joint Information and Inventions. For avoidance of doubt, MedImmune Manufacturing Information and Inventions shall not include any Know-How related to MedImmune proprietary cell culture media and nutrient feeds used in the Manufacturing process.
- 1.71 "MedImmune Manufacturing Know-How" means all MedImmune Manufacturing Information and Inventions except to the extent disclosed by published MedImmune Manufacturing Patents.
- 1.72 "MedImmune Manufacturing Patents" means Patents Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term that Cover MedImmune Manufacturing Information and Inventions; provided, however, that MedImmune Manufacturing Patents excludes any Joint Patents; and provided, further, that any Patents that qualify as both (a) MedImmune Manufacturing Patents and (b) either MedImmune Patents or MedImmune Additional Patents, as applicable.
- 1.73 "MedImmune Patents" means Patents Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term that Cover MedImmune Information and Inventions; provided, however, that MedImmune Patents excludes any Joint Patents.
- 1.74 "MRC Agreement" means that certain Agreement, dated January 7, 1997, between Medical Research Council, Cambridge Antibody Technology Limited and Cambridge Antibody Technology Group plc, as may be amended from time to time.
- 1.75 "Net Sales" means, with respect to Licensed Products or Follow-On Products, as the case may be, the gross amounts billed or invoiced by or on behalf of Kolltan, its Affiliates or its Sublicensees to Third Parties that are not Sublicensees for the sale or other transfer for consideration of Licensed Products or Follow-On Product, as applicable, less the following deductions, determined in each case in accordance with the Accounting Standards:
  - (a) normal and customary trade, quantity or prompt settlement discounts allowed and taken;

	(b)	refunds, chargebacks and any other allowances given and taken which effectively reduce the gross amounts billed o
invoiced:		

- (c) product returns, credits, allowances and bad debt write-offs;
- (d) rebates, reimbursements, fees, taxes or similar payments to (i) wholesalers and other distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, governmental entities, or other institutions or health care organizations to the extent actually paid or credited; or (ii) patients and other Third Parties arising in connection with any program that provides low income, uninsured or other patients the opportunity to obtain discounted Licensed Products or Follow-On Product, as applicable:
- (e) discounts mandated by, or granted to meet the requirements of, Applicable Law, including required chargebacks and retroactive price reductions;
- (f) transportation, freight, postage charges and other charges such as insurance, relating thereto, in each case included as a specific line item on a bill or an invoice to such Third Parties; and
- (g) taxes, excises or other governmental charges upon or measured by the production, sale, transportation, delivery or use of goods, in each case included as a specific line item on a bill or an invoice to such Third Parties.

Sales or other transfers for consideration of Licensed Products or Follow-On Products, as the case may be, (1) between Kolltan and its Affiliates and/or its Sublicensees (except to the extent that such Affiliates or Sublicensees are end users of such Licensed Products or Follow-On Products, as applicable) or (2) provided to Third Parties without charge, in connection with research and development, Clinical Trials, compassionate use, humanitarian and charitable donations, or indigent programs or for use, in reasonable and customary quantities, as samples, shall in each case ((1) and (2)) be excluded from the computation of Net Sales, and no payments will be payable on such sales or such other transfers for consideration.

If a Licensed Product or Follow-On Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Licensed Product or Follow-On Product in arm's length transactions in the relevant country.

Notwithstanding the foregoing, to the extent a Licensed Product or Follow-On Product, as the case may be, is sold as a Combination Product:

(i) if, on a country-by-country basis, each of such Licensed Product or Follow-On Product, as applicable, and the other active ingredient(s) in such Combination Product are sold separately in a country, Net Sales with respect to such

Combination Product in such country for the purpose of determining milestones and royalties due hereunder shall be calculated by multiplying the actual Net Sales of the Combination Product in such country by the fraction A/(A+B), where "A" is the total weighted (by sales volume) average Net Sales price of such Licensed Product or Follow-On Product, as applicable, as sold separately in such country and "B" is the total weighted (by sales volume) average net sales (calculated in a manner analogous to the manner in which Net Sales are calculated as set forth above) price of such other active ingredient(s) as sold separately in such country;

- (ii) if, on a country-by-country basis, such Licensed Product or Follow-On Product, as applicable, is sold separately in a country but the other active ingredient(s) in such Combination Product are not sold separately in such country, Net Sales with respect to such Combination Product in such country for the purpose of determining milestones and royalties due hereunder shall be calculated by multiplying the actual Net Sales of the Combination Product in such country by the fraction A/C, where "A" is the total weighted (by sales volume) average Net Sales price of the Licensed Product or Follow-On Product, as applicable, as sold separately in such country and "C" is the total weighted (by sales volume) average Net Sales price of the Combination Product in such country;
- (iii) if, on a country-by-country basis, such Licensed Product or Follow-On Product, as applicable, is not sold separately in a country, but each of such Licensed Product or Follow-On Product, as applicable, and the other active ingredient(s) in such Combination Product are sold separately in at least one country, Net Sales with respect to such Combination Product in such first country for the purpose of determining milestones and royalties due hereunder shall be calculated by multiplying the actual Net Sales of such Combination Product in such first country by the fraction D/(D+E), where "D" is the worldwide average Net Sales price of the Licensed Product or Follow-On Product, as applicable, as sold separately, and "E" is the worldwide average net sales (calculated in a manner analogous to the manner in which Net Sales are calculated as set forth above) price of the other active ingredients included in the Combination Product as sold separately; and
- (iv) if, on a country-by-country basis, none of clauses (i) through (iii) above is applicable with respect to a country, Net Sales with respect to such Combination Product in such country for the purpose of determining milestones and royalties due hereunder shall be determined by the Parties in good faith based on the fair market value of the contribution of the Licensed Product or Follow-On Product, as applicable, to the total fair market value of the Combination Product, using, to the extent practicable, the principles outlined in clauses (i) through (iii) above.
- 1.76 "Out-of-Pocket Costs" means amounts actually paid by a Party or its Affiliates to a Third Party that are identifiable to the applicable activities under this Agreement, which amounts or commitments are not cancelable by such Party without penalty or otherwise reasonably capable of recovery from such Third Party.
- 1.77 "Patent" means (a) all patents and patent applications in any country or supranational jurisdiction, and (b) any substitutions, divisionals, continuations, continuations, repeating the provisional applications, reissues, renewals, registrations, confirmations, re-examinations,

extensions, supplementary protection certificates and the like of any such patents or patent applications.

- 1.78 "Patent Matter" means any Dispute that relates to the inventorship, infringement, enforceability or validity of any Patent.
- 1.79 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
- 1.80 "Phase 1 Clinical Trial" means a human clinical trial that is intended to initially evaluate the safety and/or pharmacological effect of a product or that would otherwise satisfy the requirements of 21 C.F.R. 312.21(a) or an equivalent clinical trial in a country other than the United States.
- 1.81 "Phase 1b/2a Clinical Trial" means a human clinical trial of a product as a single agent or in combination for any indication that (a) is intended for dose exploration, examination of pharmacological or clinical activity (including dose response, dose escalation, duration of effect or kinetic/dynamic relationship assessments) and preliminary determination of efficacy and safety in the target patient population, and (b) contains a sufficient number of well characterized and clinically uniform subjects for the applicable indication using a pre-specified and uniform dose, or, if in combination, a fixed combination regimen, to assess the response rate and safety of the investigational agent. As used herein, "response rate" in the case of a Phase 1b/2a Clinical Trial of the Licensed Antibody or Licensed Product must be sufficiently robust, and demonstrate clinical benefit compared to standard of care (historical controls can be used), up to a maximum obligation of 40 subjects in the uniform dose cohort.
- 1.82 "Phase 2 Clinical Trial" means a human clinical trial for which the primary endpoints include a determination of dose ranges or an indication of efficacy of a product in patients being studied as described in 21 C.F.R. §312.21(b), or an equivalent clinical trial in a country other than the United States.
- 1.83 "Phase 3 Clinical Trial" means a human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in the indication being investigated in a manner sufficient to obtain Regulatory Approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. §312.21(c), or an equivalent clinical trial in a country other than the United States.
- 1.84 "Phase 4 Study" means (a) a human clinical trial for a product for an indication that is required by a Regulatory Authority as a condition of (but is not completed before) obtaining the initial Regulatory Approval for such product for such indication and (b) any trial, test or study that is required or requested by a Regulatory Authority as a condition of maintaining the initial Regulatory Approval for a product for an indication, excluding any Post Approval Study.
- 1.85 "Post Approval Study" means any human clinical study or other test or study with respect to a product for an indication that is not required in order to obtain or maintain Regulatory Approval for such product for such indication. For clarity, any human clinical study

that is intended to expand the product labeling for such product shall be deemed not to be a Post Approval Study. Subject to the foregoing, Post Approval Study may include epidemiological studies, modeling and pharmacoeconomic studies, post-marketing surveillance studies, investigator or company sponsored or initiated studies and health economics studies.

- 1.86 "Product Acquisition Price" means the greater of (a) the applicable Product FMV and (b) the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which the applicable payment is made in accordance with this Agreement.
- 1.87 "Product FMV" means the fair market value of the Product Rights based on a calculation of risk adjusted net present value and, if deemed necessary by the Panel, using one or more additional standard methodologies generally accepted in the valuation industry (including review of comparable programs).
- 1.88 "Product Rights" means, as of the applicable time under this Agreement, (a) all right, title and interest of Kolltan or its Affiliates in and to the Licensed Antibody and any Licensed Products, including the rights, licenses and sublicenses granted by MedImmune hereunder, (b) to the extent not included in clause (a) above, the assignments to be made by Kolltan pursuant to Section 11.7.2(f), and (c) to the extent not included in clause (a) above, the licenses to be granted by Kolltan pursuant to Section 11.7.2(g), in each of the foregoing cases by reference to then-existing and future plans for Development of the Licensed Antibody and Licensed Products as reflected in any ongoing schedule of activities or otherwise in any Development plans to which Kolltan has committed, including for the specific indications included in any completed or in-progress Phase 1b/2a Clinical Trials with respect to the Licensed Antibody and Licensed Products, including the estimated costs for Development.
  - 1.89 "Program" means each of the Follow-On Program and the Licensed Program.
- 1.90 "Qualified Bidder" means any Third Party bidder participating in the auction conducted by Kolltan pursuant to Section 5.4.3(e)(i) that is generally regarded within the biopharmaceutical industry as an entity that does not (a) inappropriately disclose or misuse the confidential information of its customers and licensors or (b) infringe the patent rights or misappropriate the trade secrets of its customers and licensors.
- 1.91 "Qualified Contract Manufacturer" means any Third Party contract manufacturer that is generally regarded within the biopharmaceutical industry as an entity that does not (a) inappropriately disclose or misuse the confidential information of its customers and licensors or (b) infringe the patent rights or misappropriate the trade secrets of its customers and licensors.
- 1.92 "Regulatory Approval" means all approvals, licenses, registrations or authorizations of any applicable Regulatory Authority necessary for the Commercialization (excluding pricing and/or reimbursement approvals) of a biological product for a particular indication in a country.
- 1.93 "Regulatory Authority" means the FDA in the United States or any health authority in another country that is a counterpart to the FDA and holds responsibility for

regulating development of and/or granting Regulatory Approval for a biological product in such country, including the EMA, and any successor(s) thereto.

- 1.94 "Regulatory Documentation" means all INDs (and/or clinical trial applications), BLAs (and/or marketing applications), and other regulatory applications submitted to any Regulatory Authority, copies of Regulatory Approvals, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. §314.420 and any non-United States equivalents), and any other reports, records, regulatory correspondence, meeting minutes, telephone logs, and other materials relating to Regulatory Approval, including any underlying safety and effectiveness data whether or not submitted to any Regulatory Authority, and any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, methods, processes and reports, executed batch records, safety and efficacy, and any safety database required to be maintained for Regulatory Authorities, in each case related to, or required to Develop, Manufacture or Commercialize, a biological product.
- 1.95 "Research" means the use, discovery, identification, research, characterization, modification, derivatization and optimization of Antibodies and other biological products.
  - 1.96 "Research Program" means each of the internal MedImmune Research programs listed on Exhibit 1.96.
- 1.97 "Royalty Term" means (a) with respect to the relevant Licensed Product, for any country, the period (i) commencing on the First Commercial Sale of the first Licensed Product in such country and (ii) expiring on the later of (x) the tenth (10th) anniversary of such First Commercial Sale and (y) the expiration of the last to expire Valid Claim of an issued MedImmune Patent in such country that Covers the sale of the relevant Licensed Product in such country, and (b) with respect to the relevant Follow-On Product, for any country, the period (i) commencing on the First Commercial Sale of the first Follow-On Product in such country and (ii) expiring on the later of (x) the tenth (10th) anniversary of such First Commercial Sale and (y) the expiration of the last to expire Valid Claim of an issued MedImmune Patent in such country that Covers the sale of the relevant Follow-On Product in such country.
- 1.98 "Sublicensee" means a Third Party to whom Kolltan, as permitted under this Agreement, grants a license or sublicense, as the case may be, under the MedImmune IP, MedImmune Additional IP or Joint IP to Research, Develop, Manufacture, Commercialize or otherwise use the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product, or otherwise grants rights to distribute, promote or sell Licensed Products or Follow-On Products; provided, however, Sublicensee does not include any Third Party who purchases a Licensed Product or Follow-On Product under a limited license or sublicense, as the case may be, as required to enable such Third Party (a) to perform final packaging for such Licensed Product or Follow-On Product for local distribution, (b) to conduct a confirmatory Clinical Trial of such Licensed Product or Follow-On Product to support a filing for Regulatory Approval of such Licensed Product or Follow-On Product in such Third Party's distribution territory or (c) to prepare and make a filing for a Regulatory Approval of such Licensed Product or Follow-On Product in such Third Party's distribution territory.

- 1.99 "Term" means the period commencing on the Effective Date and ending on the expiration or earlier termination of this Agreement.
- 1.100 "Territory" means the entire world.
- 1.101 "Third Party" means any Person other than MedImmune or Kolltan that is not an Affiliate of MedImmune or of Kolltan.
- 1.102 "United States" or "U.S." means the United States of America and all of its territories and possessions.
- 1.103 "<u>Unredacted Provision</u>" means any provision of any In-License Agreement that was attached to an email sent by Christian Dinneen-Long to W. Bradford Middlekauff on July 25, 2013 at 4:30pm, 4:31pm, 4:32pm or 4:33pm Eastern Standard Time, which provision was included in such attachment in unredacted form; provided, however, that Unredacted Provisions excludes any provision that is partially redacted or incorporates any term the definition of which is redacted or partially redacted (including by incorporating any other term the definition of which is redacted or partially redacted).
- 1.104 "<u>UT Agreement</u>" means that certain Exclusive Patent License Agreement, effective November 1, 2005, between the Board of Regents of the University of Texas System on behalf of the University of Texas Southwestern Medical Center at Dallas and MedImmune, Inc., as amended by Amendment #1 to Exclusive License Agreement, effective December 13, 2011.
- 1.105 "Valid Claim" means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) or (b) a claim within a patent application which application has not been pending for more than five (5) years from the date of its first filing and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.
  - 1.106 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

Definition:	Section:
Actual Kolltan Development Costs	5.4.4
Auction License Agreement	5.4.3(e)(ii)
Audited Party	6.9.1
Auditing Party	6.9.1
Bankruptcy Code	2.4
Buyout Amount	5.4.1(b)
Clinical and Research Supply Agreement	3.6.3(a)
Co-Development and Co-Commercialization Agreement	5.4.1(c)
Co-Development and Co-Commercialization Agreement Terms	5.4.1(c)

Definition:	Section:
Commercial Supply Agreement	3.6.4(a)
Confidential Information	8.1
Court	12.2
Disclosing Party	8.1
Dispute	12.1
Effective Date	Preamble
Election Notice	5.4.1
Estimated Kolltan Development Costs	5.4.4
Exercise Notice	5.3.1(a)
Existing Confidentiality Agreement	8.4
Expert	5.2.2(a)
Final Kolltan Development Costs	5.4.4
Follow-On Product Transaction	2.5
Kolltan	Preamble
Kolltan ROFN Notice	2.5
Indemnified Party	10.3
Indemnifying Party	10.3
Indirect Taxes	6.9.3
Information Delivery Period	5.2.2(a)
Inventory	3.6.1
Losses	10.1
Materials	3.6.1
MedImmune	Preamble
MedImmune ROFN Notice	2.5
Non-Paying Party	6.9.2
Option Period	5.3.1(a)
Option Termination Date	3.5.2(a)
Panel	5.2.2(a)
Party or Parties	Preamble
Paying Party	6.9.1
Paying Party Withholding Tax Action	6.9.1
Product Acquisition Price Notice	5.2.2(b)
Receiving Party	8.1
Resolution Period	12.1
Same or Later Stage Clinical Trial	12.4.2(a)(i)
Selection Period	5.2.2(a)
Sublicensed Rights	11.7.6
Third Party Transaction	5.5
Triggering Sale	12.4.2(a)(i)
Trigger Period	5.2.1(a)
Trigger Notice	5.2.1(a)
Upfront Fee	6.1

### ARTICLE 2 GRANT OF RIGHTS

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## 2.1 <u>License Grants to Kolltan</u>.

- 2.1.1 <u>Licensed Antibody and Licensed Products.</u> Subject to the terms of this Agreement, MedImmune hereby grants Kolltan (a) an exclusive, royalty-bearing (to the extent provided in Section 6.4), non-transferable (except in accordance with Section 12.4) license or sublicense, as applicable, with the right to sublicense (subject to Sections 2.2 and 5.5), under MedImmune's and its Affiliates' interests in MedImmune IP, MedImmune Additional IP and Joint IP, to Research, Develop, Manufacture and Commercialize the Licensed Antibody and Licensed Products in the Field in the Territory; and (b) an exclusive, royalty-bearing (to the extent provided in Section 6.4), non-transferable (except in accordance with Section 12.4) license or sublicense, as applicable, with the right to sublicense (subject to Sections 2.2 and 5.5), under MedImmune's and its Affiliates' interests in MedImmune Manufacturing Know-How and MedImmune Manufacturing Patents, to Manufacture the Licensed Antibody and Licensed Products for use in Kolltan's Research, Development and Commercialization activities hereunder.
- 2.1.2 Follow-On Antibodies and Follow-On Products. Subject to the terms of this Agreement, MedImmune hereby grants Kolltan (a) an exclusive, royalty-bearing (to the extent provided in Section 6.4), non-transferable (except in accordance with Section 12.4) license or sublicense, as applicable, with the right to sublicense (subject to Section 2.2), under MedImmune's and its Affiliates' interests in MedImmune IP, MedImmune Additional IP and Joint IP, to Research, Develop, Manufacture and Commercialize Follow-On Antibodies and Follow-On Products in the Field in the Territory; and (b) an exclusive, royalty-bearing (to the extent provided in Section 6.4), non-transferable (except in accordance with Section 12.4) license or sublicense, as applicable, with the right to sublicense (subject to Section 2.2), under MedImmune's and its Affiliates' interests in MedImmune Manufacturing Know-How and MedImmune Manufacturing Patents, to Manufacture Follow-On Antibodies and Follow-On Products for use in Kolltan's Research, Development and Commercialization activities hereunder.
- 2.2 <u>Sublicenses.</u> Subject to Section 5.5 and in accordance with the requirements as set forth on <u>Exhibit 9.2.9(b)</u>, Kolltan shall have the right to grant sublicenses within the scope of the licenses and sublicenses under Section 2.1 to its Affiliates and to Third Parties; provided, however, that any such

sublicense granted to a Third Party shall be pursuant to a written agreement that subjects the sublicensee to all relevant restrictions and limitations set forth in this Agreement, including the confidentiality provisions of ARTICLE 8.

2.3 Rights Retained by MedImmune. Any rights of MedImmune not expressly granted to Kolltan pursuant to this Agreement shall be retained by MedImmune. Notwithstanding the exclusive licenses and sublicenses granted to Kolltan under Section 2.1, but subject to Section 7.9 and ARTICLE 8, MedImmune and its Affiliates retain the right (a) to practice under the MedImmune IP, MedImmune Additional IP and Joint IP solely (except as set forth under clause (b) below with respect to Joint IP) as necessary to (i) exercise their rights and perform their obligations hereunder, (ii) complete any activities under any Research Program

that are ongoing as of the Effective Date and (iii) conduct (or permit Third Parties to conduct) Research, Development or Commercialization activities other than Research, Development or Commercialization of the Licensed Antibody, Licensed Products, Follow-On Antibodies or Follow-On Products; and (b) to practice under the Joint IP, MedImmune Manufacturing Know-How and MedImmune Manufacturing Patents solely (except as set forth under clause (a) above with respect to Joint IP) as necessary to (i) exercise their rights and perform their obligations under this Agreement, the Clinical and Research Supply Agreement (if any) and the Commercial Supply Agreement (if any) and (ii) conduct (or permit Third Parties to conduct) Manufacturing activities other than Manufacture of the Licensed Antibody, Licensed Products, Follow-On Antibodies or Follow-On Products.

- 2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "Bankruptcy Code") or any analogous provision of Applicable Law outside the United States, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code or any analogous provision of Applicable Law outside the United States. Each Party shall retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code or any analogous provision of Applicable Law outside the United States. In the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or any analogous provision of Applicable Law outside the United States, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property subject to any rights or licenses granted to such other Party under or pursuant to this Agreement and to all embodiments thereof, which, if not already in such other Party's possession, shall be promptly delivered to (or otherwise made available to, as appropriate) such other Party upon such other Party's written request. Any agreements supplemental hereto shall be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code or any analogous provision of Applicable Law outside the United States.
- 2.5 Right of First Negotiation for a Follow-On Product Transaction. If Kolltan desires to enter into a Follow-On Product Transaction (as defined below) with respect to any Follow-On Product, Kolltan shall provide written notice thereof to MedImmune, including a reasonably detailed description of such Follow-On Product and any completed or ongoing Development activities (including a summary of any relevant clinical and non-clinical data) with respect thereto ("Kolltan ROFN Notice"). MedImmune shall have the right, exercisable by written notice delivered to Kolltan within [\*\*] days after delivery of the Kolltan ROFN Notice (the "MedImmune ROFN Notice"), to trigger its right of first negotiation under this Section 2.5 with respect to such Follow-On Product. If MedImmune delivers a MedImmune ROFN Notice within such [\*\*] day period, then (a) the Parties shall negotiate in good faith regarding a definitive agreement for a Follow-On Product Transaction with respect to such Follow-On Product until such time (if any) as MedImmune shall discontinue such negotiations, but in no event for longer than [\*\*] days unless the Parties otherwise mutually agree. During such period, Kolltan shall not negotiate or enter into any agreement with any Third Party for a Follow-On Product Transaction with respect to such Follow-On Product. If MedImmune does not deliver a MedImmune ROFN Notice within such [\*\*] day period, or if MedImmune delivers a MedImmune ROFN Notice within such [\*\*] day period but the Parties fail to enter into a definitive agreement for a Follow-On Product Transaction with respect to such Follow-On

Product within the applicable negotiation period, then (subject to any restrictions set forth in any provision of this Agreement other than this Section 2.5) Kolltan shall be free to negotiate and enter into an agreement with any Third Party for a Follow-On Product Transaction with respect to such Follow-On Product and (notwithstanding anything the contrary in this Section 2.5) Kolltan shall have no further obligations and MedImmune shall have no further rights under this Section 2.5 with respect to such Follow-On Product. For clarity, subject to the preceding sentence, in no event shall any Follow-On Product Transaction between Kolltan and a Third Party reduce or otherwise adversely affect any rights of MedImmune or obligations of Kolltan under this Agreement, including Kolltan's payment obligations pursuant to ARTICLE 6.

# ARTICLE 3 DEVELOPMENT AND REGULATORY

- 3.1 <u>Development.</u> Subject to the terms and conditions of this Agreement, as between the Parties, Kolltan shall be solely responsible for all costs, activities and decision-making related to the Development of the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products in the Field in the Territory.
- 3.2 Regulatory. Subject to the terms and conditions of this Agreement, as between the Parties, Kolltan shall be solely responsible for all submissions to and all communications and interactions with Regulatory Authorities with respect to the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products. MedImmune shall not make any submissions to or otherwise communicate or interact with any Regulatory Authority with respect to the Licensed Antibody or any Licensed Product, Follow-On Antibody or Follow-On Product unless Applicable Law requires such action, in which case MedImmune shall, unless prohibited by Applicable Law, (a) as promptly as practicable provide Kolltan with a draft of any proposed submission or communication and (b) consider in good faith any reasonable comments provided in a timely manner by Kolltan with respect to such proposed submission or communication. MedImmune shall promptly forward to Kolltan (i) any communication received by MedImmune from any Regulatory Authority with respect to the Licensed Antibody, Licensed Products, Follow-On Antibodies or Follow-On Products.
- 3.3 <u>Diligence</u>. Kolltan shall, at its own expense, (a) conduct (i) a Phase 1 Clinical Trial of the Licensed Antibody or a Licensed Product and (ii) a Phase 1b/2a Clinical Trial of the Licensed Antibody or a Licensed Product for at least two indications, and (b) use Commercially Reasonable Efforts to complete any additional clinical trials required for Kolltan to submit a BLA (or ex-US equivalent) to a Regulatory Authority(ies) to obtain Regulatory Approval for at least one Licensed Product in the United States, France, Germany, Italy, Spain and the United Kingdom. Kolltan shall use Commercially Reasonable Efforts with respect to the Research, Development, Manufacture or Commercialization of any Follow-On Antibody or Follow-On Product; provided, however, that such Commercially Reasonable Efforts shall not operate to impair or adversely affect Kolltan's obligation to use Commercially Reasonable Efforts in the foregoing subsection (b).

### 3.4 <u>Transfer of Know-How and Regulatory Documentation.</u>

- 3.4.1 Know-How. Promptly after the Effective Date, MedImmune shall (a) transfer to Kolltan all MedImmune Know-How and MedImmune Additional Know-How described in clause (b) of Section 1.48, including the MedImmune Know-How and MedImmune Additional Know-How described in Exhibit 3.4.1, including any data or study reports generated since the filing of the Existing IND (provided, however, that MedImmune shall not have any obligation under this Section 3.4.1 to prepare or finalize any study reports), and (b) disclose to Kolltan all MedImmune Know-How and MedImmune Additional Know-How other than MedImmune Know-How and MedImmune Additional Know-How transferred pursuant to clause (a) above. Such transfers and disclosures shall be made (x) in any manner or form reasonably requested by Kolltan (provided, however, that any data generated since the filing of the Existing IND shall be transferred in the form in which such data exists as of the Effective Date) and (y) at MedImmune's expense.
- 3.4.2 <u>Research Programs.</u> Without limiting Section 3.4.1, upon the completion or other termination of any Research Program, MedImmune shall, at its own expense, transfer and/or disclose to Kolltan all Know-How developed under such Research Program that is Controlled by MedImmune. Such transfers and disclosures shall be made (a) in any manner or form reasonably requested by Kolltan (provided, however, that any data included in such Know-How shall be transferred in the form in which MedImmune has collected or maintained such data prior to such transfer) and (b) at MedImmune's expense.
- Regulatory Documentation relating to the Licensed Antibody or Licensed Products Controlled by MedImmune as of the Effective Date, including the Existing IND. Promptly after the Effective Date, MedImmune shall (a) transfer and/or disclose to Kolltan all such Regulatory Documentation and (b) provide Kolltan with an executed copy of a letter notifying the FDA of the assignment of the Existing IND to Kolltan. MedImmune shall submit such assignment letter to the FDA as soon as reasonably possible following the Effective Date and shall promptly notify Kolltan of MedImmune's correspondence with the FDA with respect to such assignment. Promptly (but in no event more than five (5) Business Days) thereafter, Kolltan shall submit to the FDA its acceptance of such transfer and provide MedImmune with written notice of such acceptance. The transfers and disclosures described in clause (a) above shall be made (x) in any manner or form reasonably requested by Kolltan and (y) at MedImmune's expense; provided, however, if at Kolltan's request any such transfer or disclosure is made in any manner or form that is not reasonably standard in the biopharmaceutical industry for transfers or disclosures of a similar kind, such transfer or disclosure shall be made at Kolltan's expense.

### 3.5 <u>Cooperation</u>.

3.5.1 Assistance. Without limiting any other obligations of MedImmune under this Agreement, MedImmune shall, at its own expense, for a period of three (3) months following the completion of the transfers, disclosures and assignments described in Section 3.4, use reasonable efforts to provide Kolltan with information or assistance reasonably requested by Kolltan in relation to the Know-How and Regulatory Documentation transferred, disclosed or assigned pursuant to Section 3.4 to ensure an expeditious transition of the applicable Research and Development activities. Such information and assistance shall not exceed (a) during the first (1st) such month, an aggregate of seventy (70) hours, (b) during the second (2nd) such month, an aggregate of fifty (50) hours, and (c) during the third (3rd) such month, an aggregate of thirty (30) hours. Following such three (3) month period, if requested by Kolltan, the Parties shall discuss in good faith the possibility of entering into a consulting agreement pursuant to which MedImmune would provide additional information and assistance to Kolltan at Kolltan's expense.

### 3.5.2 <u>Information</u>.

(a) Every six (6) months or otherwise upon reasonable request of MedImmune from time to time, Kolltan shall provide a reasonably detailed written update to MedImmune regarding Kolltan's Development activities hereunder with respect to the Licensed Antibody and Licensed Products; provided, however, that (i) Kolltan shall not be required to provide more than two (2) such written updates in any Calendar Year, and (ii) from and after the date on which the provisions of Sections 5.3 and 5.4 are of no further force or effect in

accordance with Section 5.2.1(b), or MedImmune has no further rights under ARTICLE 5 in accordance with Section 5.4.3(b) (the "Option Termination Date"), Kolltan shall not be required to provide more than one (1) such written update in any Calendar Year.

(b) Every six (6) months or otherwise upon reasonable request of MedImmune from time to time, Kolltan shall provide a reasonably detailed written update to MedImmune regarding Kolltan's Development activities hereunder with respect to Follow-On Antibodies and Follow-On Products; provided, however, that (i) Kolltan shall not be required to provide more than two (2) such written updates in any Calendar Year, and (ii) for any Follow-On Product, from and after the date on which MedImmune has no further rights under Section 2.5 with respect to such Follow-On Product, Kolltan shall not be required to provide more than one (1) such written update with respect to such Follow-On Product in any Calendar Year.

### 3.6 <u>Inventory; Supply</u>.

3.6.1 <u>Assignment of Inventory.</u> MedImmune hereby assigns to Kolltan all of MedImmune's right, title, interest and risk of loss in and to all quantities in the possession or under the control of MedImmune as of the Effective Date of the Licensed Antibody and Licensed Product ("<u>Inventory</u>") and the materials used in the production of the Licensed Antibody and Licensed Product ("<u>Materials</u>"), which quantities of Inventory and Materials are (except in the case of certain types of Materials) set forth in <u>Exhibit 3.6.1</u>. The foregoing sentence notwithstanding, MedImmune may retain reference samples of Inventory and Materials.

#### 3.6.2 Storage, Filling and Delivery of Inventory.

- (a) MedImmune shall store, formulate, fill and deliver Inventory and Materials as described in Exhibit 3.6.2(a) and shall:
- (i) store the Inventory and Materials in accordance with Applicable Law and the applicable specifications set forth in Exhibit 3.6.2(a)(i) and use at least the same level of care in storing the Inventory and Materials as MedImmune uses in storing its own inventory of similar products, but no less than industry standard level of care;
  - (ii) conduct stability testing of the Inventory in accordance with Applicable Law;

(iii) upon the written request of Kolltan from time to time, (x) fill, finish and prepare for shipment, in accordance with
Applicable Law and the specifications set forth in Exhibit 3.6.2(a), specified quantities of the Inventory, (y) prepare for shipment, in accordance with
Applicable Law and the specifications set forth in Exhibit 3.6.2(a), specified quantities of the Materials, and (z) deliver such quantities of Inventory and
Materials to Kolltan or any Third Party designated by Kolltan FCA MedImmune's facility (Incoterms 2010), in each case ((x), (y) and (z)) in accordance with
reasonable written instructions provided by Kolltan, including as to timing and manner of delivery; provided, however, that (1) with respect to any quantity
of Inventory that is, as of the date of Kolltan's request, in vialed form, MedImmune shall not be required to deliver such quantity to Kolltan or its designee in
less than [**] months from the date of such request, and (2) with respect to any quantity of Inventory that is, as of the date of Kolltan's request, not in vialed
form, MedImmune shall not be required to deliver such quantity to Kolltan or its designee in less than [**] months from the date of such request; and
(iv) maintain appropriate property insurance coverage for losses arising from MedImmune's failure to exercise due

- (iv) maintain appropriate property insurance coverage for losses arising from MedImmune's failure to exercise due care over the Inventory and Materials, for as long as, and to the extent that, the Inventory and Materials remain at MedImmune's facility; provided, however, that MedImmune's obligation under this clause (iv) shall terminate with respect to any quantity of the Inventory or Materials upon delivery of such quantity to the shipping carrier designated by Kolltan in accordance with clause (iii) above.
- (b) MedImmune shall notify Kolltan promptly after (i) discovering that any quantity of Inventory or Materials has not been Manufactured, stored or maintained in accordance with Applicable Law or any applicable specifications or is otherwise not in a condition reasonably suitable for use by Kolltan in conducting its Research and Development activities hereunder or (ii) determining that it is unable, or reasonably expects to be unable, to comply with any of its obligations under Section 3.6.2(a). MedImmune shall not transfer or otherwise dispose of any quantity of Licensed Antibody or Licensed Product from the Inventory except in accordance with Applicable Law, MedImmune's standard practices and policies (to the extent previously disclosed to Kolltan) and Kolltan's reasonable written instructions.
  - (c) MedImmune hereby represents and warrants that:
- (i) the Inventory was Manufactured in accordance with Applicable Law and the applicable product specifications set forth in Exhibit 3.6.2(c)(i), which Exhibit includes specifications for drug product and unformulated drug substance, as well as the justification of specifications for drug product (which in turn references a Guideline for Release Specifications for Monoclonal Antibodies (DEV000 GB 0049 ED 002), a copy of which was provided to Kolltan);
- (ii) as of the date on which any quantity of the Inventory or Materials is delivered to Kolltan or its designee hereunder, such quantity will have been stored and maintained in accordance with Applicable Law and the applicable storage specifications set forth in Exhibit 3.6.2(a)(i); and
  - (iii) as of the Effective Date, stability testing of the Inventory has been conducted in accordance with Applicable

Law;

(iv) as of the date of the last stability testing of the Inventory conducted prior to the Effective Date, the Inventory conformed to the applicable product specifications set forth in Exhibit 3.6.2(e)(i).

Except as expressly set forth in this Agreement, MedImmune makes no, and hereby disclaims all, other representations and warranties whatsoever concerning the Inventory and Materials, including any and all implied warranties of merchantability, fitness for a particular purpose and against infringement.

## 3.6.3 Clinical and Research Supply of Licensed Antibody and Licensed Products.

- (a) Within thirty (30) days after the Effective Date, the Parties shall commence good faith negotiations regarding a supply agreement pursuant to which MedImmune would supply to Kolltan, and Kolltan would purchase from MedImmune at rates not materially different from those charged by Third Party contract manufacturers, additional quantities of the Licensed Antibody and Licensed Products for use by Kolltan in conducting Research and Development activities with respect to the Licensed Program and the Follow-On Program, all in accordance with the principles set forth in Exhibit 3.6.3(a) (the "Clinical and Research Supply Agreement").
- If (i) the Parties fail to enter into the Clinical and Research Supply Agreement within sixty (60) days after the commencement of negotiations pursuant to Section 3.6.3(a) (or such longer period as may be agreed by the Parties), or (ii) the Clinical and Research Supply Agreement is entered into by the Parties but is terminated for any reason other than breach by Kolltan, then upon Kolltan's written request and subject to MedImmune's good faith consent as described below, MedImmune shall (x) transfer and/or disclose to Kolltan or any Qualified Contract Manufacturer designated in good faith by Kolltan such MedImmune Manufacturing Know-How and (y) provide to Kolltan or such Qualified Contract Manufacturer such technical assistance, in each case ((x) and (y)) as reasonably required for Kolltan or such Qualified Contract Manufacture to Manufacture the Licensed Antibody and Licensed Products for use in Kolltan's Research and Development activities hereunder. The foregoing sentence notwithstanding, except as set forth in Section 3.6.5 below, MedImmune has no obligation to disclose to Kolltan or any Qualified Contract Manufacturer the MedImmune Manufacturing Know How related to MedImmune proprietary cell culture media and nutrient feeds used in the Manufacturing process. Kolltan acknowledges and agrees that any transfer and/or disclosure by Kolltan of any MedImmune Manufacturing Know-How described in the immediately preceding sentence to a Third Party shall require the prior written consent of MedImmune; provided, however, that (A) MedImmune shall not unreasonably withhold such consent and (B) MedImmune's determination as to whether to provide such consent shall be made in good faith. The transfers and disclosures described in clause (x) above shall be made (1) in any manner or form reasonably requested by Kolltan and (2) at MedImmune's expense; provided, however, if at Kolltan's request any such transfer or disclosure is made in any manner or form that is not reasonably standard in the biopharmaceutical industry for transfers or disclosures of a similar kind, such transfer or disclosure shall be made at Kolltan's expense. The assistance described in clause (y) above shall be provided at MedImmune's expense, provided, however, that the scope

of such assistance will be limited to reasonable and customary assistance related to technology transfer under similar circumstances in the biologics industry.

- 3.6.4 <u>Commercial Supply</u>. After the Option Termination Date:
- (a) if requested by Kolltan, the Parties shall undertake good faith negotiations regarding a commercial supply agreement pursuant to which MedImmune would supply to Kolltan, and Kolltan would purchase from MedImmune, quantities of the Licensed Antibody or Licensed Product, in any of its forms, for use by Kolltan, for commercial sale ("Commercial Supply Agreement"); and
- if (i) for any reason the Parties have not entered into the Commercial Supply Agreement (including if Kolltan has not requested that the Parties undertake negotiations with respect to thereto pursuant to Section 3.6.4(a)) or (ii) the Commercial Supply Agreement is entered into by the Parties but expires or is terminated for any reason other than breach by Kolltan, without limitation of any other rights that may be available to Kolltan, upon Kolltan's written request and subject to MedImmune's good faith consent as described below, MedImmune shall (x) transfer and/or disclose to Kolltan or any Qualified Contract Manufacturer designated in good faith by Kolltan such MedImmune Manufacturing Know-How and (y) provide to Kolltan or such Qualified Contract Manufacturer such technical assistance, in each case ((x) and (y)) as reasonably required for Kolltan or such Qualified Contract Manufacturer to Manufacture the Licensed Antibody and Licensed Products for use in Kolltan's Commercialization activities hereunder. The foregoing sentence notwithstanding, except as set forth in Section 3.6.5 below, MedImmune has no obligation to disclose to Kolltan or any Qualified Contract Manufacturer the MedImmune Manufacturing Know How related to MedImmune proprietary cell culture media and nutrient feeds used in the Manufacturing process. Kolltan acknowledges and agrees that any transfer and/or disclosure by Kolltan of any MedImmune Manufacturing Know-How described in the immediately preceding sentence to a Third Party shall require the prior written consent of MedImmune; provided, however, that (A) MedImmune shall not unreasonably withhold such consent and (B) MedImmune's determination as to whether to provide such consent shall be made in good faith. The transfers and disclosures described in clause (x) above shall be made (1) in any manner or form reasonably requested by Kolltan and (2) at MedImmune's expense: provided, however, if at Kolltan's request any such transfer or disclosure is made in any manner or form that is not reasonably standard in the biopharmaceutical industry for transfers or disclosures of a similar kind, such transfer or disclosure shall be made at Kolltan's expense. The assistance described in clause (y) above shall be provided at MedImmune's expense, provided, however, that the scope of such assistance will be limited to reasonable and customary assistance related to technology transfer under similar circumstances in the biologics industry.
- 3.6.5 Supply of Media. In each instance where MedImmune transfers MedImmune Manufacturing Know-How to Kolltan or a Qualified Contract Manufacturer pursuant to this Section 3.6, for a period of [\*\*] months after the completion of such transfer, MedImmune shall sell to Kolltan, at MedImmune's standard cost, such quantities of MedImmune's proprietary cell culture media and nutrient feeds used in the Manufacture of the Licensed Antibody as may be reasonably requested by Kolltan in connection with the Manufacture by Kolltan or such Qualified Contract Manufacturer of the Licensed Antibody or

Licensed Products. Kolltan shall not reverse engineer, or have a third party reverse engineer, MedImmune's proprietary cell culture media and nutrient feeds.

# ARTICLE 4 COMMERCIALIZATION

- 4.1 <u>In General.</u> Subject to the terms and conditions of this Agreement, as between the Parties, Kolltan shall be solely responsible for all costs, activities and decision-making related to the Commercialization of Licensed Products and Follow-On Products in the Field in the Territory.
- 4.2 <u>Trademarks</u>. Kolltan, its Affiliates and Sublicensees shall select the trademarks under which to market Licensed Products and Follow-On Products, which trademarks shall not contain the word "MedImmune" or be identical to or likely to cause confusion with the MEDIMMUNE trademark or any trademark for any pharmaceutical product of MedImmune or any of its Affiliates.
- 4.3 <u>Standards of Conduct.</u> Kolltan shall in all respects comply with all Applicable Law and applicable guidelines concerning the advertising, sales and marketing of prescription drug products in Commercializing Licensed Products and Follow-On Products under this Agreement.

# ARTICLE 5 OPTION RIGHTS

## 5.1 <u>Delivery of Data</u>.

- 5.1.1 Upon receipt and review by Kolltan of a validated data set (including the full data set) from the clinical trial database for any Phase 1b/2a Clinical Trial of the Licensed Antibody or a Licensed Product, which data set comprises the clinical trial data for a cohort of not less than [\*\*] patients (or, if less, the number of remaining enrolled patients in such Phase 1b/2a Clinical Trial), and which data Kolltan has not previously delivered to MedImmune, Kolltan shall promptly deliver such data to MedImmune.
- 5.1.2 Together with its delivery of any data set pursuant to Section 5.1.1, Kolltan shall (to the extent it has not already done so) deliver to MedImmune all data in Kolltan's possession as of the date of such delivery that is contained in the clinical trial database for any Phase 1 Clinical Trial of the Licensed Antibody or a Licensed Product.
- 5.1.3 Together with its delivery of any data set pursuant to Section 5.1.1 and the data pursuant to Section 5.1.2, Kolltan shall (to the extent it has not already done so) deliver to MedImmune all non-clinical and/or Development data and information in Kolltan's possession as of the date of such delivery that (a) was generated by Kolltan's Research, Development or Manufacturing activities with respect to the Licensed Antibody or Licensed Products hereunder and (b) is likely to be useful to MedImmune's determination to deliver a Trigger Notice pursuant to Section 5.2.1 or Exercise Notice pursuant to Section 5.3.1, including any such pharmacokinetic data, pharmacodynamics data, biomarker data and genetic or epigenetic characterization of patients.

5.1.4 After the Data Package Delivery Date, if Kolltan comes into possession of any data or information that Kolltan would have been required to deliver to MedImmune under Section 5.1.2 or 5.1.3 if such data or information had been in Kolltan's possession as of the Data Package Delivery Date, or if MedImmune reasonably requests any other information related to the data and information described in Section 5.1.1, 5.1.2 or 5.1.3 or the foregoing clause of this Section 5.1.4, Kolltan shall promptly deliver such data or information to MedImmune.

## 5.2 <u>Trigger Period; Determination of Product Acquisition Price</u>.

### 5.2.1 <u>Trigger Period</u>.

- (a) From time to time between (i) the date on which Kolltan delivers the first data summary to MedImmune pursuant to Section 5.1.1 and (ii) the earlier of (x) ten (10) Business Days after the Data Package Delivery Date and (y) December 31, 2017 (the "Trigger Period"), MedImmune shall have the right, exercisable by written notice to Kolltan (a "Trigger Notice"), to trigger a determination of the Product Acquisition Price in accordance with Section 5.2.2. For clarity, MedImmune shall have the right to deliver multiple Trigger Notices during the Trigger Period; provided, however, that subject to Section 5.3.2, after MedImmune has delivered any Trigger Notice, it shall not deliver a subsequent Trigger Notice unless and until MedImmune revokes such earlier Trigger Notice in writing (provided, however, that MedImmune shall not be entitled to revoke any Trigger Notice after the Parties have received notice of the applicable Product FMV pursuant to Section 5.2.2(a)) or the Option Period with respect to such earlier Trigger Notice expires without MedImmune's having delivered an Exercise Notice.
- (b) If (i) MedImmune does not deliver a Trigger Notice to Kolltan prior to the expiration of the Trigger Period, (ii) as of the expiration of the Trigger Period, the Option Period with respect to any Trigger Notices previously delivered by MedImmune has expired without MedImmune's having delivered an Exercise Notice, or (iii) any Option Period that has not expired as of the expiration of the Trigger Period expires without MedImmune's having delivered an Exercise Notice, then the provisions of Sections 5.3 and 5.4 shall be of no further force or effect. If MedImmune provides written notice to Kolltan during the Trigger Period that MedImmune declines to deliver any further Trigger Notices, then the provisions of Sections 5.3, 5.4 and 5.5 shall be of no further force or effect.

### 5.2.2 <u>Determination of Product Acquisition Price</u>.

(a) In the event MedImmune delivers a Trigger Notice to Kolltan prior to the expiration of the Trigger Period, the Parties shall obtain a determination of the Product FMV as of the date on which such Trigger Notice was delivered, in accordance with this Section 5.2.2(a). Within eight (8) Business Days after MedImmune's delivery of any Trigger Notice (the "Selection Period"), each Party shall select an independent expert suitably qualified to determine the applicable Product FMV, who, at a minimum, shall have expertise in the valuation of development-stage biological oncology products (each, an "Expert"), and the two Experts thereby selected shall, as promptly as practicable, select a third Expert (such three Experts, collectively, the "Panel"). As soon as practicable after the selection of the Panel, the Parties shall meet with the Panel in order to agree upon a process for delivering to the Panel such information in the Parties' possession as the Panel may request in connection with the determination of the applicable Product FMV, which delivery shall be completed no later than five (5) Business Days after such initial meeting with the Panel (the "Information Delivery Period"). The Parties shall use reasonable efforts to cause the Panel to determine the applicable Product FMV and provide written notice to the Parties thereof within seven (7) Business Days after expiration of the Information Delivery Period (or, if the Panel is unable to comply with such timing, as promptly thereafter as practicable). The Panel's determination of applicable Product FMV shall be based on the agreement of a majority of the Panel members. Subject to Section 5.3.2, the determination of the Panel shall be binding on the Parties. Each Party shall bear its own costs and expenses with respect to the determination of the applicable Product FMV. Subject to Section 5.3.2, the reasonable costs and expenses of the Panel shall be bome by MedImmune.

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

(b) Within five (5) Business Days after the Parties receive notice of the applicable Product FMV pursuant to Section 5.2.2(a), Kolltan shall provide written notice to MedImmune of (i) Kolltan's good faith estimate of the Kolltan Development Costs as of the end of the calendar month immediately preceding the date of the applicable Trigger Notice, (ii) Kolltan's good faith estimate of the Kolltan Development Costs for the [\*\*] month period immediately following the period covered by estimate described in clause (i) above, and (iii) the Product Acquisition Price, on the assumption that the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which the applicable payment is made in accordance with this Agreement will be equal to the sum of the estimates described in clauses (i) and (ii) above (the "Product Acquisition Price Notice"), and shall include reasonable supporting documentation.

## 5.3 Option Period; New Determination of Product Acquisition Price.

### 5.3.1 Option Period.

- (a) If, within three (3) Business Days after delivery of any Product Acquisition Price Notice, MedImmune reasonably requests any additional supporting documentation relating to Kolltan's estimates of the Kolltan Development Costs included therein, Kolltan shall provide such additional supporting documentation to MedImmune within five (5) Business Days after the date of such request. For a period of five (5) Business Days after the expiration of the three (3) Business Day period described in the preceding sentence (or, if applicable, the date on which Kolltan satisfies its obligation under the preceding sentence to provide additional supporting documentation), (i) the Parties shall engage in informal, nonbinding discussions regarding their respective interests with respect to their rights and obligations under this Section 5.3 and Section 5.4 with respect to such Product Acquisition Price Notice and (ii) within twelve (12) Business Days after the conclusion of such five (5) Business Day period (each, an "Option Period"), MedImmune shall have the option, exercisable by written notice to Kolltan (each, an "Exercise Notice"), to trigger the rights and obligations of the Parties under Section 5.4 with respect to such Product Acquisition Price Notice.
- (b) If MedImmune does not deliver an Exercise Notice to Kolltan prior to the expiration of an Option Period, then the Parties shall have no further rights or obligations under Section 5.4 with respect to the applicable Product Acquisition Price Notice. If MedImmune provides written notice to Kolltan during an Option Period that MedImmune

declines to provide an Exercise Notice during such Option Period, then such Option Period shall be deemed expired and the Parties shall have no further rights or obligations under Section 5.4 with respect to the applicable Product Acquisition Price Notice.

5.3.2 New Determination of Product Acquisition Price. Notwithstanding anything to the contrary in Section 5.2, if at any time after the delivery by the Parties of information to the Panel pursuant to Section 5.2.2(a) and prior to the expiration of the applicable Option Period or, if MedImmune delivers an Exercise Notice to Kolltan prior to the expiration of the applicable Option Period, during any period for any election or rejection by a Party under Section 5.4.1 or 5.4.2, Kolltan receives additional data from (i) any Phase 1 Clinical Trial of the Licensed Antibody or any Licensed Product, (ii) any Phase 1b/2a Clinical Trial of the Licensed Antibody or a Licensed Product or (iii) any non-clinical studies or Development activities with respect to the Licensed Antibody or Licensed Products that would, in the case of any of (i), (ii) or (iii), likely have materially affected the determination of the Product FMV, (a) Kolltan shall promptly deliver such data to MedImmune (regardless of whether Kolltan would otherwise be required to deliver such data to MedImmune pursuant to Section 5.1) and (b) for a period of eight (8) Business Days after the date of such delivery, either Party shall have the right, exercisable by written notice to the other Party, to trigger a new determination of the Product Acquisition Price, factoring in such new information. If either Party exercises its right under clause (b) above, unless otherwise agreed by the Parties, (w) ongoing activities (if any) to determine the Product Acquisition Price shall terminate, (x) the current Option Period (if any) shall be deemed expired without MedImmune's having delivered an Exercise Notice, (y) the Parties shall have no further rights or obligations under Section 5.4 with respect to any Product Acquisition Price Notice delivered prior such Party's exercise of its right under clause (b) above, and (z) a new determination of the Product FMV and the Product Acquisition Price shall be made in accordance with the provisions of Section 5.2.2 (which shall aga

#### 5.4 Kolltan Election; MedImmune Rights.

- 5.4.1 <u>Kolltan Election</u>. In the event MedImmune delivers an Exercise Notice in accordance with Section 5.3.1(a) with respect to any Product Acquisition Price Notice, Kolltan shall elect, in its sole discretion, by written notice to MedImmune delivered within three (3) Business Days after MedImmune's delivery of such Exercise Notice (the "<u>Election Notice</u>"), one of the following:
- (a) to terminate this Agreement with respect to the Licensed Program, subject to MedImmune's payment to Kolltan of an amount equal to the Product Acquisition Price, in which case the provisions of Section 5.4.3(a) shall apply;
- (b) subject to MedImmune's rights under Section 5.4.2(a), to terminate all further rights of MedImmune under this ARTICLE 5, subject to Kolltan's payment to MedImmune of an amount equal to the greater of (i) fifty percent (50%) of the difference between (A) the Product Acquisition Price and (B) the sum of (x) the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which

the applicable payment is made and (y) Eight Million Dollars (\$8,000,000) (the amount described in this clause (i), the "Co-Agreement Amount") and (ii) Twenty Million Dollars (\$20,000,000) (the greater of the amounts described in clauses (i) and (ii), the "Buyout Amount"); or

(c) subject to MedImmune's rights under Section 5.4.2(b), to require the Parties to enter into a co-development and co-commercialization agreement (the "Co-Development and Co-Commercialization Agreement") in accordance with the terms set forth on Exhibit 5.4.1(c) (the "Co-Development and Co-Commercialization Agreement Terms").

Together with any Election Notice, Kolltan shall provide to MedImmune its then-current good faith estimate, for each potentially applicable scenario described in Section 5.4.3, of the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which the applicable payment will be made by Kolltan or MedImmune as well as a good faith estimate of the Kolltan Development Costs for the [\*\*] month period following delivery of the Election Notice, together with reasonable supporting documentation. Kolltan shall provide MedImmune with monthly written updates to such estimates during any period in which the MedImmune is exercising its rights under Section 5.4.2 or the Parties are negotiating the Co-Development and Co-Commercialization Agreement under Section 5.4.3(c) or 5.4.3(d).

- 5.4.2 <u>MedImmune Rights.</u> In the event MedImmune delivers an Exercise Notice in accordance with Section 5.3.1(a):
- (a) in the event Kolltan, pursuant to the Election Notice, makes an election under Section 5.4.1(b), MedImmune shall have the right, in its sole discretion, exercisable by written notice to Kolltan delivered within seven (7) Business Days after Kolltan delivers the Election Notice to MedImmune, to reject Kolltan's election, in which case the provisions of Section 5.4.3(c) shall apply; provided, however, that if MedImmune fails to deliver such a rejection notice within such time period, the provisions of Section 5.4.3(b) shall apply; and
- (b) in the event Kolltan, pursuant to the Election Notice, makes an election under Section 5.4.1(c), MedImmune shall have the right, in its sole discretion, exercisable by written notice to Kolltan delivered within three (3) Business Days after Kolltan delivers the Election Notice to MedImmune, to reject Kolltan's election, in which case Kolltan shall elect, in its sole discretion, by written notice to MedImmune delivered within three (3) Business Days after delivery of such rejection notice by MedImmune, either (i) to terminate this Agreement with respect to the Licensed Program, subject to MedImmune's payment to Kolltan of an amount equal to the Product Acquisition Price, in which case the provisions of Section 5.4.3(a) shall apply, or (ii) to terminate all further options of MedImmune under this ARTICLE 5, subject to Kolltan's payment of the Buyout Amount to MedImmune, in which case the provisions of Section 5.4.3(b) shall apply; provided, however, that if MedImmune fails to deliver such a rejection notice within such time period, the provisions of Section 5.4.3(d) shall apply.

### 5.4.3 Effect of Elections and Rights.

- (a) In the event Kolltan (i) pursuant to the Election Notice, makes an election under Section 5.4.1(a) or (ii) after receiving a rejection notice by MedImmune pursuant to Section 5.4.2(b), makes an election under clause (i) of Section 5.4.2(b), then (x) this Agreement shall terminate with respect to the Licensed Program thirty (30) days after such election is made and (y) MedImmune shall pay to Kolltan an amount equal to the Product Acquisition Price within forty-five (45) days after receipt of the corresponding invoice from Kolltan.
- (b) In the event Kolltan (i) pursuant to the Election Notice, makes an election under Section 5.4.1(b) that is not rejected by MedImmune pursuant to Section 5.4.2(a) or (ii) after receiving a rejection notice pursuant to Section 5.4.2(b), makes an election under clause (ii) of Section 5.4.2(b), then (x) this Agreement shall remain in effect in its entirety, including with respect to the Licensed Program (though MedImmune shall have no further rights under this ARTICLE 5 other than as set forth in this sentence), and (y) Kolltan shall pay the Buyout Amount to MedImmune within forty-five (45) days after receipt of the corresponding invoice from MedImmune.
- (c) In the event Kolltan, pursuant to the Election Notice, makes an election under Section 5.4.1(b) that is rejected by MedImmune pursuant to Section 5.4.2(a), then (i) the Parties shall enter into the Co-Development and Co-Commercialization Agreement in accordance with the Co-Development and Co-Commercialization Agreement Terms, as promptly as practicable after such election is made, subject to Section 5.4.3(e), and (ii) effective upon the effective date of the Co-Development and Co-Commercialization Agreement, this Agreement shall terminate with respect to the Licensed Program in accordance with Section 11.5.
- (d) In the event Kolltan, pursuant to the Election Notice, makes an election under Section 5.4.1(c) that is not rejected by MedImmune pursuant to Section 5.4.2(b), then (i) the Parties shall enter into the Co-Development and Co-Commercialization Agreement in accordance with the Co-Development and Co-Commercialization Agreement Terms, as promptly as practicable after such election is made, subject to Section 5.4.3(e), and (ii) effective upon the effective date of the Co-Development and Co-Commercialization Agreement, this Agreement shall terminate with respect to the Licensed Program in accordance with Section 11.5.
- (e) Notwithstanding anything in this Agreement to the contrary, in the event the Parties are required to enter into the Co-Development and Co-Commercialization Agreement pursuant to Section 5.4.3(c) or 5.4.3(d) but, for any reason, fail to do so within sixty (60) days after Kolltan's delivery of the applicable Election Notice, unless the Parties otherwise mutually agree, either Party may refer the matter to the Executive Officers for attempted resolution pursuant to the provisions of Section 12.1. In the event that the Executive Officers are not able to resolve within the Resolution Period any issues referred to them by a Party pursuant to this Section 5.4.3(e), then:
- (i) Kolltan shall conduct an auction, in a manner reasonably customary in the industry, for the grant to a Third Party of exclusive rights (including with respect to Kolltan and MedImmune) to the Licensed Program, including (x) license and sublicense grants as appropriate from Kolltan and MedImmune and (y) transfer by MedImmune of MedImmune Manufacturing Know-How to such Third Party or its designee as necessary to enable the Manufacture of the Licensed Antibody and Licensed Products, which transfer

obligation shall be analogous to the transfer obligations described in Section 3.6.3(b) and 3.6.4(b);

- (ii) Kolltan shall determine in good faith the Qualified Bidder that is the preferred bidder and Kolltan shall negotiate, in good faith on behalf of the Parties, the terms of an agreement (the "Auction License Agreement") with such Qualified Bidder that, subject to the other provisions of clauses (i) through (v) of this Section 5.4.3(e), does not treat either Kolltan or MedImmune preferentially vis-à-vis the other (the "Auction License Agreement"); provided, however, that Kolltan shall (x) reasonably consult with MedImmune with respect to such actions and provide sufficient opportunity for MedImmune to review and comment upon the material terms of such Auction License Agreement, and (y) reasonably incorporate any reasonable comments provided by MedImmune with respect to any provisions of the Auction License Agreement relating to the MedImmune Manufacturing Know-How and otherwise consider in good faith any reasonable comments provided by MedImmune with respect to the Auction License Agreement; and provided, further, that the Auction License Agreement shall provide that the proceeds of any payments to be made by such Third Party with respect to the Licensed Program shall be split evenly between the Parties, subject to the provisions of clause (iv) below;
- (iii) upon the completion of such negotiations, Kolltan and MedImmune shall execute the Auction License Agreement with such Third Party;
- (iv) (x) upon execution of the Auction License Agreement, each Party shall provide the other Party with written notice of the reasonable expenses, including reasonable attorneys' fees, incurred by such Party in connection with their activities under clauses (i) through (iii) above (along with reasonable supporting documentation as requested by the other Party), and Kolltan or MedImmune, as the case may be, shall make an appropriate reconciling payment to the other so that, after giving effect to such reconciling payment, each Party will have borne fifty percent (50%) of their collective expenses described in this clause (x), and (y) MedImmune's share of the proceeds of any payments to be made by the applicable Third Party with respect to the Licensed Program shall be paid to Kolltan (whether directly from such Third Party or from MedImmune following its receipt thereof) until such time as Kolltan has received from MedImmune's share of such proceeds the amount that MedImmune would have been obligated to pay Kolltan under the applicable scenario as an upfront payment under the Co-Development and Co-Commercialization Agreement (as set forth in the "Upfront payment" section of Exhibit 5.4.1(c)); and
- (v) effective upon the effective date of the Auction License Agreement, this Agreement shall terminate with respect to the Licensed Program in accordance with Section 11.5.
- 5.4.4 <u>Determination of Kolltan Development Costs</u>. The amount payable by Kolltan or MedImmune, as applicable, under Section 5.4.3 or pursuant to the Co-Development and Co-Commercialization Agreement shall be based on Kolltan's good faith estimate, as delivered to MedImmune together with the Election Notice or in the most recent update described in the last sentence of Section 5.4.1, of the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which the applicable payment

would be made under the applicable scenario (the "Estimated Kolltan Development Costs"); provided, however, that within thirty (30) days after the applicable payment is made. Kolltan shall provide written notice to MedImmune of its final determination of the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which such payment was made (the "Final Kolltan Development Costs"), together with reasonable supporting documentation. In the event there was any underpayment or overpayment by the applicable Party based on Kolltan's final determination, an appropriate reconciling payment shall be made within thirty (30) days after delivery of such notice. Kolltan's determination of the Final Kolltan Development Costs shall be subject to MedImmune's rights as an Auditing Party under Section 6.10; provided, however, that (a) MedImmune's right to audit the Final Kolltan Development Costs pursuant to this Section 5.4.4 shall be independent of the determination of whether MedImmune has exercised its annual right as an Auditing Party in any applicable year pursuant to Section 6.10, (b) MedImmune shall pay the full cost of such audit unless (i) the applicable payment made by Kolltan or MedImmune in accordance with Section 5.4.3 was calculated on the basis of the Kolltan Development Costs and (ii) such audit shows that the Final Kolltan Development Costs exceeded [\*\*] percent ([\*\*]%) of the Kolltan Development Costs as of the end of the calendar month immediately preceding the calendar month in which such payment was made, as determined by the auditors (the "Actual Kolltan Development"). Costs"), in which case Kolltan shall pay the full cost of such audit, and (c) if (i) the applicable payment made by Kolltan or MedImmune in accordance with Section 5.4.3 was calculated on the basis of the Kolltan Development Costs and (ii) such audit shows that the Actual Kolltan Development Costs exceeded [\*\*] percent ([\*\*]%) of the Estimated Kolltan Development Costs, then Kolltan shall be solely responsible for such excess costs; provided, however, that for purposes of this clause (c), Actual Kolltan Development Costs excludes any Kolltan Development Costs incurred in any calendar month after the calendar month that Kolltan projected (for purposes of the Estimated Kolltan Development Costs calculation) to be the calendar month immediately preceding the calendar month in which the applicable payment would be made under the applicable scenario under Section 5.4.3 or pursuant to the Co-Development and Co-Commercialization Agreement, to the extent such payment was actually made in a later calendar month due to (x) the actual time required for the negotiation of the Co-Development and Co-Commercialization Agreement or (y) any delay caused by MedImmune.

5.5 Restriction. Prior to and during the Trigger Period and any Option Period, Kolltan shall not initiate discussions with any Third Party regarding, or consummate, any Third Party Transaction. "Third Party Transaction" means any acquisition by a Third Party of, or the grant of any license or sublicense to a Third Party under, Kolltan's rights to Research, Develop, Manufacture, or Commercialize the Licensed Antibody or Licensed Products; provided, however, that any transaction that does not conflict with MedImmune's rights under Section 5.4, including any Kolltan Sale or Financing or any assignment or deemed assignment of this Agreement by Kolltan in connection with a Kolltan Sale or Financing, shall not be deemed a Third Party Transaction.

# ARTICLE 6 PAYMENTS

6.1 <u>Upfront Fee</u>. Kolltan shall pay MedImmune a non-refundable, non-creditable payment of Four Million Dollars (\$4,000,000) within forty-five (45) days after the Effective Date (the "<u>Upfront Fee</u>").

### 6.2 <u>Development Milestones</u>.

6.2.1 <u>Development Milestones</u>. For each milestone event set forth in the following table, Kolltan shall pay the corresponding non-refundable, non-creditable amount solely for the first achievement thereof (regardless of the number of times such milestone event is achieved) by Kolltan or its Affiliates or Sublicensees:

Milest	one Event	Payment Amount
(a)	[**]	[**]
(b)	[**]	[**]
(c)	[**]	[**]
(d)	[**]	[**]
(e)	[**]	[**]
(f)	[**]	[**]
(g)	[**]	[**]
(h)	[**]	[**]
(i)	[**]	[**]

6.2.2 <u>Notification; Payment</u>. Kolltan shall notify MedImmune in writing promptly, and in no event beyond thirty (30) days, after a milestone event described in Section 6.2.1 has been achieved, and the corresponding milestone payment shall be due within forty-five (45) days after receipt of the corresponding invoice from MedImmune.

6.2.3 <u>Milestones for Non-Major Indications</u>. Notwithstanding anything to the contrary herein, in the event that Kolltan achieves Annual Net Sales of at least [\*\*] Dollars (\$[\*\*]) for any Licensed Product for an indication not considered to be a Major Indication, then Kolltan shall pay to MedImmune (a) the amount set forth in Section 6.2.1(b) (if such payment has not already been made) or 6.2.1(e) (if the payment set forth in Section 6.2.1(b) has already been made but the payment set forth in Section 6.2.1(e) has not already been made); provided, however, that if the payments set forth in Sections 6.2.1(b) and 6.2.1(e) have both already been made, Kolltan shall not be required to make any additional payments pursuant to this clause (a);

(b) if the First Commercial Sale of such Licensed Product for such indication in the United States has occurred as of the achievement of such level of Annual Net Sales, the amount set forth Section 6.2.1(c) (if such payment has not already been made) or 6.2.1(f) (if the payment set forth in Section 6.2.1(c) has already been made but the payment set forth in Section 6.2.1(f) has not already been made); provided, however, that if the First Commercial Sale of such Licensed Product for such indication in the United States has not occurred as of the achievement of such level of Annual Net Sales, the applicable payment shall be made at such time (if any) as such First Commercial Sale occurs; and provided, further, that if the payments set forth in Sections 6.2.1(c) and 6.2.1(f) have both already been made as of the achievement of such level of Annual Net Sales, Kolltan shall not be required to make any additional payments pursuant to this clause (b); and (c) if the First Commercial Sale of such Licensed Product for such indication in the EU has occurred as of the achievement of such level of Annual Net Sales, the amount set forth Section 6.2.1(d) (if such payment has not already been made) or 6.2.1(g) (if the payment set forth in Section 6.2.1(d) has already been made but the payment set forth in Section 6.2.1(g) has not already been made); provided, however, that if the First Commercial Sale of such Licensed Product for such indication in the EU has not occurred as of the achievement of such level of Annual Net Sales, the applicable payment shall be made at such time (if any) as such First Commercial Sale occurs; and provided, further, that if the payments set forth in Sections 6.2.1(d) and 6.2.1(g) have both already been made as of the achievement of such level of Annual Net Sales, Kolltan shall not be required to make any additional payments pursuant to this clause (c).

- 6.2.4 <u>Follow-On Products</u>. The foregoing provisions of this Section 6.2 (excluding subsection (a) of Section 6.2.1) shall apply, mutatis mutandis, to Follow-On Products; provided, however, that except for the payments set forth in subsections (h) and (i) of Section 6.2.1, the amounts payable by Kolltan under this Section 6.2 with respect to Follow-On Products shall be [\*\*] percent ([\*\*]%) of the corresponding amounts payable by Kolltan under this Section 6.2 with respect to Licensed Products.
- 6.2.5 <u>Clarification</u>. For clarity, the maximum aggregate amount payable by Kolltan under this Section 6.2 is (a) with respect to Licensed Products, [\*\*] Dollars (\$[\*\*]), and (b) with respect to Follow-On Products, [\*\*] Dollars (\$[\*\*]).
  - 6.3 <u>Sales Milestones</u>.
- 6.3.1 <u>Sales Milestone Payments</u>. For each milestone event set forth in the following table, Kolltan shall pay the corresponding non-refundable, non-creditable amount solely for the first achievement thereof (regardless of the number of times such milestone event is achieved):

Milestone Event		Payment Amount	
(a)	Annual Net Sales of a single Licensed Product in a single Calendar Year in excess of [**] Dollars (\$[**])	[**]	
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- (b) Annual Net Sales of a single Licensed Product in a single Calendar Year in excess of [\*\*] Dollars (\$[\*\*])

  (c) Annual Net Sales of a single Licensed Product in a single Calendar Year in excess of [\*\*] Dollars (\$[\*\*])
  - 6.3.2 Payment. Milestone payments payable under this Section 6.3 shall be paid by Kolltan in accordance with Section 6.6.
- 6.3.3 Follow-On Products. The foregoing provisions of this Section 6.3 shall apply, mutatis mutandis, to Follow-On Products; provided, however, that the amounts payable by Kolltan under this Section 6.3 with respect to Follow-On Products shall be [\*\*] percent ([\*\*]%) of the corresponding amounts payable by Kolltan under this Section 6.3 with respect to Licensed Products.
- 6.3.4 <u>Clarification</u>. For clarity, the maximum aggregate amount payable by Kolltan under this Section 6.3 is (a) with respect to Licensed Products, [\*\*] Dollars (\$[\*\*]), and (b) with respect to Follow-On Products, [\*\*] Dollars (\$[\*\*]).
  - 6.4 Royalties.

6.4.1 <u>Annual Net Sales</u>. Subject to Sections 6.4.2 and 6.4.3, for each Licensed Product in any Calendar Year, Kolltan shall pay MedImmune royalties on Annual Net Sales of such Licensed Product in such Calendar Year at the following rates:

Annual Net Sales Level		Rate
(a)	On that portion of Annual Net Sales of such Licensed Product in such Calendar Year that is less than or equal to [**] Dollars (\$[**])	[**] Percent ([**]%)
(b)	On that portion of Annual Net Sales of such Licensed Product in such Calendar Year that is more than [**] Dollars (\$[**]) but less than or equal to [**] (\$[**])	[**] Percent ([**]%)
(c)	On that portion of Annual Net Sales of such Licensed Product in such Calendar Year that is greater than [**] Dollars (\$[**])	[**] Percent ([**]%)

6.4.2 MRC Agreement. In addition to the royalties described in Section 6.4.1, for each Licensed Product, Kolltan shall pay MedImmune a royalty equal to [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product. Notwithstanding the foregoing, if for any sale or other transfer for consideration of any Licensed Product by Kolltan or its applicable Affiliate or Sublicensee, MedImmune or its applicable Affiliate is not required to pay royalties under the MRC Agreement, or is required to pay royalties under the MRC Agreement at a rate that is lower than [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product, then the royalty payable by Kolltan to MedImmune under this Section 6.4.2 with respect to such sale or other transfer for consideration shall be accordingly reduced. MedImmune shall promptly notify Kolltan of the occurrence of any event or circumstance that would trigger a reduced royalty payment obligation under the previous sentence.

### 6.4.3 Reductions.

- (a) Third Party Royalty Reduction. If Kolltan or its Affiliate or Sublicensee decides in its sole discretion to acquire a license or other rights from any Third Party (other than under any In-Licensed IP) under any Patents or Know-How controlled by such Third Party in order to Research, Develop, Manufacture, or Commercialize the Licensed Antibody or Licensed Products without infringing or misappropriating such Patents or Know-How and, pursuant to the applicable agreement with such Third Party, is required to pay royalties based on sales of a Licensed Product by Kolltan or its applicable Affiliate or Sublicensee in any Calendar Quarter, then the royalties that, but for this Section 6.4.3(a) and Section 6.4.3(b), would be payable by Kolltan to MedImmune with respect to sales of such Licensed Product in such Calendar Quarter shall be reduced by [\*\*] percent ([\*\*]%) of the royalties payable by Kolltan or its applicable Affiliate or Sublicensee under such Third Party agreement with respect to sales of such Licensed Product in such Calendar Quarter; provided, however, that this Section 6.4.3(a) shall not operate to reduce (i) the royalties that, but for this Section 6.4.3(a) and Section 6.4.3(b), would be payable by Kolltan to MedImmune with respect to sales of such Licensed Product in such Calendar Quarter by more than [\*\*] percent ([\*\*]%), or (ii) the royalties payable under Section 6.4.2.
- (b) Know-How Only Reduction. If, for any portion of any Calendar Quarter, any Licensed Product sold by Kolltan or its Affiliates or Sublicensees in any country is not Covered by a Valid Claim of an issued MedImmune Patent in such country, then the royalties that, but for this Section 6.4.3(b) (but after giving effect to Section 6.4.3(a)), would be payable by Kolltan to MedImmune with respect to sales of such Licensed Product in such country in such Calendar Quarter shall be reduced by [\*\*] percent ([\*\*]%); provided, however, that this Section 6.4.3(b) shall not operate to reduce the royalties payable under Section 6.4.2.
  - 6.4.4 Payments under Certain In-License Agreements. Each Party shall perform its obligations under Exhibit 6.4.4.
- 6.4.5 <u>Effect of Expiration of Royalty Term.</u> On a Licensed Product by Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights, licenses and sublicenses granted to Kolltan hereunder with respect to such Licensed Product in such country shall continue in effect but become fully paid-

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

up, royalty-free, transferable (to the extent not transferable previously), perpetual and irrevocable.

- 6.4.6 Follow-On Products. The foregoing provisions of this Section 6.4 (including Exhibit 6.4.4) shall apply, mutatis mutandis, to Follow-On Products; provided, however, that except with respect to the royalties payable pursuant to Section 6.4.2 and the payments described in Exhibit 6.4.4, the amounts payable by Kolltan under this Section 6.4 with respect to Follow-On Products shall be [\*\*] percent ([\*\*]%) of the corresponding amounts payable by Kolltan under this Section 6.4 with respect to Licensed Products.
- 6.5 <u>Healthcare Reform Tax.</u> Notwithstanding anything herein to the contrary, for purposes of determining the sales milestones and royalties payable by Kolltan under Sections 6.2.4 and 6.4, Kolltan shall have the right to offset from Net Sales of Licensed Products sold in the United States that portion of the annual fee paid by Kolltan and its Affiliates and Sublicensees to the United States Government pursuant to Section 9008 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as may be amended) reasonably attributable to Licensed Products, as determined in accordance with an equitable method as agreed in good faith by the Parties. This Section 6.5 shall apply, mutatis mutandis, to Follow-On Products.
- Reports; Payments. Within sixty (60) days after the end of each Calendar Quarter during which there are Net Sales giving rise to a payment obligation under Section 6.2.4 or 6.4, Kolltan shall submit to MedImmune a report identifying for each Licensed Product, the Net Sales of such Licensed Product for each country for such Calendar Quarter, the calculation of royalties (including gross sales and all deductions taken from gross sales), and the sales milestones and royalties payable to MedImmune. Together with the delivery of each such report, Kolltan shall pay to MedImmune the sales milestones and royalties payable by it under Sections 6.2.4 and 6.4. This Section 6.6 shall apply, mutatis mutandis, to Follow-On Products.
- 6.7 <u>Methods of Payments</u>. All payments due under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by MedImmune. For the purpose of calculating any amounts due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with the Accounting Standards.
- 6.8 <u>Late Payments.</u> Any amount owed by a Party to the other Party under this Agreement that is not paid on or before the date such payment is due as set forth herein shall bear interest at a rate per annum equal to the lower of (i) [\*\*], or (ii) the highest rate permitted by Applicable Law.

### 6.9 Taxes.

6.9.1 <u>Withholding Taxes</u>. All payments due and payable by a Party (the "<u>Paying Party</u>") under this Agreement will be made without any deduction or withholding, unless such deduction or withholding tax is required by Applicable Law. If the Paying Party is so required to deduct or withhold,

"Non-Paying Party") of such requirement; (b) remit to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the Non-Paying Party; and (c) promptly forward to the Non-Paying Party an official receipt (or certified copy), or other documentation reasonably acceptable to the Non-Paying Party evidencing such payment to such authorities. Notwithstanding the foregoing, if the Non-Paying Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, the applicable deduction or withholding tax, it may deliver to the Paying Party or the appropriate governmental authority (with the assistance of the Paying Party to the extent that this is reasonably required) the prescribed forms necessary to reduce the deduction or applicable rate of withholding or to relieve the Paying Party of its obligation to deduct or withhold tax, and the Paying Party shall apply the reduced deduction or rate of withholding, or dispense with deduction or withholding, as the case may be, provided that the Paying Party has received evidence of the Non-Paying Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization).

- 6.9.2 <u>Withholding Taxes Resulting from Withholding Tax Action.</u> If the Paying Party (or its Affiliates or successors) is required to make a payment to the Non-Paying Party subject to a deduction or withholding of tax, then if such deduction or withholding of tax obligation arises or is increased solely as a result of the assignment or transfer of all or a portion of this Agreement by the Paying Party (or its Affiliates or successors) as a result of which payments arise or are deemed to arise in a territory other than in the United States, or there is a change in the tax residency of the Paying Party (or its Affiliates or successors), or the payments arise or are deemed to arise through a branch of the Paying Party in a territory other than the United States (a "Paying Party Withholding Tax Action"), then notwithstanding any other provision in this Agreement, the payment by the Paying Party (in respect of which such deduction and withholding of tax is required to be made) shall be increased by the amount necessary to ensure that the Non-Paying Party receives an amount equal to the same amount that it would have received had no Paying Party Withholding Tax Action occurred.
- 6.9.3 Indirect Taxes. All payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the Paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the Non-Paying Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If such amounts of Indirect Taxes are refunded to the Non-Paying Party by the applicable tax authority or other fiscal authority subsequent to payment, the Non-Paying Party will transfer such amount to the Paying Party within forty-five (45) days of receipt. For purposes of this section, "Indirect Taxes" shall mean value added taxes, sales taxes, consumption taxes and other similar taxes.
- 6.10 <u>Books and Records; Audit Rights.</u> Each Party (the "<u>Audited Party</u>") shall keep (and, in the case of Kolltan, shall cause its Affiliates and Sublicensees to keep) complete, true and accurate books and records in accordance with the Accounting Standards in sufficient detail for the other Party (the "<u>Auditing Party</u>") to determine the amount of any payments due to such Party under this Agreement. Each Auditing Party shall have the right, once annually at its own expense, to

have an independent, certified public accounting firm of nationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, review any such records of the Audited Party in the location(s) where such records are maintained by the Audited Party upon reasonable notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of confidence, for the sole purpose of verifying the accuracy of the amounts paid under this Agreement within a two (2) year period preceding the date of the request for review. The Audited Party shall (and, in the case of Kolltan as the Audited Party, shall cause its Affiliates and Sublicensees to) make its (and their) personnel reasonably available to answer queries reasonably required for such report. The report of such accounting firm shall be limited to a certificate stating whether any report made or invoice or payment submitted by the Audited Party during such period is accurate or inaccurate and the amounts of any discrepancy. No other information shall be provided to the Auditing Party. The Audited Party shall receive a copy of each such report concurrently with receipt by the Auditing Party. Should such inspection lead to the discovery of a discrepancy to the Auditing Party's detriment, the Audited Party shall pay the amount of the discrepancy within thirty (30) days after its receipt from the accounting firm of the certificate showing the amount of the discrepancy. The Auditing Party shall pay the full cost of the review unless the underpayment is greater than [\*\*] percent ([\*\*]%) of the amount due for the applicable period, in which case the Audited Party shall pay the reasonable costs charged by such accounting firm for such review.

# ARTICLE 7 OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

- 7.1 <u>Inventorship</u>. Inventorship for patentable inventions made in the course of Research, Development, Manufacture or Commercialization of the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products shall be determined in accordance with the patent laws of the jurisdiction where the invention was made; provided, however, that the issue as to whether any such invention is jointly made by the Parties shall be determined in accordance with the substantive Applicable Laws of the United States, irrespective of the country in which such invention is made.
- 7.2 Ownership. Subject to the rights and licenses granted to Kolltan under this Agreement, as between the Parties, MedImmune shall own the entire right, title and interest in and to all inventions and discoveries (and Patents claiming patentable inventions therein) first made or discovered solely by employees or consultants of MedImmune or its Affiliates or acquired solely by MedImmune or its Affiliates in the course of Research, Development or Manufacture of the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products. Kolltan shall own the entire right, title and interest in and to all inventions and discoveries (and Patents claiming patentable inventions therein) first made or discovered solely by employees or consultants of Kolltan or its Affiliates or acquired solely by Kolltan or its Affiliates in the course of Research, Development, Manufacture or Commercialization of the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products. Each Party shall own an undivided, one-half interest in any Joint IP and, subject to the terms and conditions of this Agreement, shall retain the right to practice under such interest without the consent of or accounting to the other. Subject to the terms of this Agreement, the rights of the Parties as joint owners shall be determined in accordance with the substantive Applicable Laws

of the United States, irrespective of the country in which any invention or discovery is made or discovered.

#### 7.3 Prosecution and Maintenance of Patents.

### 7.3.1 Kolltan Rights.

- (a) Kolltan shall have (i) the sole right, at Kolltan's discretion and expense, to file, prosecute, and maintain (including with respect to any interference, derivation, re-issuance, re-examination, opposition or other post-grant proceedings) any Kolltan Patents throughout the world, and (ii) the first right, at Kolltan's discretion (subject to the remainder of this Section 7.3.1), to file, prosecute, and maintain (including with respect to any interference, derivation, re-issuance, re-examination, opposition or other post-grant proceedings) (x) any MedImmune Patents throughout the world (subject to Section 12.10 of the Dyax Agreement) and (y) any Joint Patents throughout the world.
- (b) Promptly after the Effective Date, MedImmune shall transfer or disclose to Kolltan, in whatever manner or form Kolltan may reasonably request, all documents, correspondence and other information and materials Controlled by MedImmune as of the Effective Date that relate to the MedImmune Patents as reasonably necessary for Kolltan to exercise its rights under clause (ii)(x) of Section 7.3.1(a). Such transfers and disclosures shall be made (i) in any manner or form reasonably requested by Kolltan and (ii) at MedImmune's expense; provided, however, if at Kolltan's request any such transfer or disclosure is made in any manner or form that is not reasonably standard in the biopharmaceutical industry for transfers or disclosures of a similar kind, such transfer or disclosure shall be made at Kolltan's expense.
- (c) MedImmune shall reimburse Kolltan for the reasonable Out-of-Pocket Costs of Kolltan in the filing, prosecution and maintenance of any MedImmune Patent or Joint Patent; provided, however, that MedImmune shall have the right to assign any such Patent in any country (or, in case of a Joint Patent, to assign MedImmune's interest in such Joint Patent in any country) to Kolltan, in which case such Patent (or Joint Patent) in such country shall thereafter be deemed a Kolltan Patent, or (in the case of a MedImmune Patent) to cause the abandonment of any such Patent in any country, at Kolltan's election, and thereby to terminate MedImmune's obligation to reimburse such costs incurred thereafter, upon thirty (30) days' written notice to Kolltan. Kolltan will provide an invoice to MedImmune for reimbursement of Out-of-Pocket Costs within 90 days of receiving an invoice from a Third Party for such Out-of-Pocket Costs.
- (d) The Parties shall work together in good faith to agree upon a strategy for the prosecution of any MedImmune Patents and Joint Patents, including the list of countries in which such Patents will be filed; provided, however, that (subject to Section 7.3.1(e)) Kolltan shall have the final right to make such determinations. Kolltan shall provide MedImmune with a draft of any prosecution filing related to any MedImmune Patents or Joint Patents at least thirty (30) days in advance of submission (or, if such timing is not practicable, as far in advance of submission as practicable) and shall provide MedImmune an opportunity to provide comments on and make requests of Kolltan concerning such filing and shall consider in good faith any comments or requests regarding such filing that MedImmune may timely provide. In

addition, Kolltan shall provide to MedImmune such other information related to prosecution of any MedImmune Patents or Joint Patents as MedImmune may from time to time reasonably request to allow MedImmune to track prosecution and maintenance of such Patents and shall consider in good faith any comments that MedImmune may provide with respect to such matters.

(e) Kolltan shall give MedImmune written notice reasonably, but in no event less than thirty (30) days, in advance of any decision by Kolltan not to file an application for or to abandon the prosecution of or otherwise not maintain or extend any MedImmune Patent or Joint Patent in any country. Upon receiving such notice, MedImmune shall have the right, at its own cost, to file, prosecute, maintain and extend, as the case may be, such MedImmune Patent or Joint Patent, in MedImmune's name, in such country; provided, however, that MedImmune shall not exercise such right without the prior written consent of Kolltan (which Kolltan may withhold in its sole discretion) if Kolltan's decision not to file an application for or to abandon the prosecution of or otherwise not maintain or extend such MedImmune Patent or Joint Patent is made for strategic business reasons (e.g., in countries with compulsory licensing policies). If MedImmune exercises its rights under this Section 7.3.1(e) with respect to any Joint Patent in any country, Kolltan shall (i) assign its entire right, title and interest in such Joint Patent in such country to MedImmune, (ii) use reasonable efforts to make its authorized attorneys, agents or representatives available to MedImmune and to assist MedImmune in obtaining and maintaining such patent protection, and (iii) sign or use reasonable efforts to have signed all legal documents necessary to file and prosecute such Joint Patent or to obtain or maintain such Joint Patent.

### 7.3.2 MedImmune Rights.

- (a) MedImmune shall have (i) the sole right, at MedImmune's discretion and expense, to file, prosecute, and maintain (including with respect to any interference, derivation, re-issuance, re-examination, opposition or other post-grant proceedings) any MedImmune Manufacturing Patents throughout the world, and (ii) the first right, at MedImmune's discretion (subject to the remainder of this Section 7.3.2) and expense, to file, prosecute, and maintain (including with respect to any interference, derivation, re-issuance, re-examination, opposition or other post-grant proceedings) any MedImmune Additional Patents throughout the world.
- (b) The Parties shall work together in good faith to agree upon a strategy for the prosecution of any MedImmune Additional Patents, including the list of countries in which such MedImmune Additional Patents will be filed; provided, however, that (subject to Section 7.3.2(c)) MedImmune shall have the final right to make such determinations. MedImmune shall provide Kolltan with a draft of any prosecution filing related to any MedImmune Additional Patents at least thirty (30) days in advance of submission (or, if such timing is not practicable, as far in advance of submission as practicable) and shall provide Kolltan an opportunity to provide comments on and make requests of MedImmune concerning such filing and shall consider in good faith any comments or requests regarding such filing that Kolltan may timely provide. In addition, MedImmune shall provide to Kolltan such other information related to prosecution of any MedImmune Additional Patents as Kolltan may from time to time reasonably request to allow Kolltan to track prosecution and maintenance of such Patents and shall consider in good faith any comments that Kolltan may provide with respect to such matters.

(c) MedImmune shall give Kolltan written notice reasonably, but in no event less than thirty (30) days, in advance of any decision by MedImmune not to file an application for or to abandon the prosecution of or otherwise not maintain or extend any MedImmune Additional Patents in any country. Upon receiving such notice, Kolltan shall have the right, at its own cost, to file, prosecute, maintain and extend, as the case may be, such MedImmune Additional Patents, in Kolltan's name, in such country; provided, however, that Kolltan shall not exercise such right without the prior written consent of MedImmune (which MedImmune may withhold in its sole discretion) if MedImmune's decision not to file an application for or to abandon the prosecution of or otherwise not maintain or extend such MedImmune Additional Patent is made for strategic business reasons (e.g., in countries with compulsory licensing policies).

### 7.4 <u>Third Party Infringement</u>.

7.4.1 Notice. Each Party shall promptly report in writing to the other Party any known or suspected (a) infringement of any of the MedImmune Patents, MedImmune Additional Patents, Kolltan Patents or Joint Patents; (b) unauthorized use or misappropriation of any of the MedImmune Know-How, MedImmune Additional Know-How or Joint Know-How of which such Party becomes aware; or (c) notification under the Biologics Price Competition and Innovation Act of 2009, as amended, or any similar law, from a biosimilar applicant arising from the filing of an application for the Regulatory Approval of a product intending to show that such product is biosimilar to any Licensed Product (or, in the case of MedImmune as the notifying Party, any Follow-On Product) that is a reference product for which a claim of infringement of any of the MedImmune Patents, MedImmune Additional Patents, Kolltan Patents or Joint Patents by the manufacture or sale of such product could reasonably be asserted, and shall provide the other Party with all available evidence regarding such known or suspected infringement or unauthorized use.

#### 7.4.2 Enforcement of Patents.

### (a) Kolltan Rights.

(i) Kolltan shall have (x) the sole right, but not the obligation, to initiate a lawsuit or take other reasonable action to enforce any Kolltan Patents throughout the world and (y) the first right, but not the obligation, to initiate a lawsuit or take other reasonable action to enforce (A) any MedImmune Patents throughout the world and (B) any Joint Patents throughout the world; provided, however, that Kolltan shall not initiate any such lawsuit or take such other action with respect to any matter described in this clause (y) without first consulting with MedImmune and giving good faith consideration to any reasonable objection from MedImmune regarding Kolltan's proposed course of action. MedImmune shall cooperate in the prosecution of any suit under this Section 7.4.2(a)(i) as may be reasonably requested by Kolltan (including joining such suit as a plaintiff if Kolltan is unable to initiate or prosecute such action solely in its own name); provided, however, that Kolltan shall promptly reimburse all Out-of-Pocket Costs (including reasonable counsel fees and expenses) of MedImmune in connection with such cooperation. In connection with any such proceeding, Kolltan shall not enter into any settlement admitting the invalidity of, or otherwise impairing MedImmune's rights in, any MedImmune IP or Joint IP without the prior written consent of MedImmune.

matter described in clause (y) of Section 7.4.2(a)(i), then Kolltan shall notify MedImmune thereof (x) if there is no time limit for the filing of such action, within sixty (60) days following the notice of alleged infringement, or (y) if there is a time limit for the filing of such action (including those set forth in Applicable Law), at least fifteen (15) days before the time limit, and upon receipt of such notice MedImmune shall have the right, but not the obligation, to initiate such lawsuit or take such other action, after providing thirty (30) days (or five (5) days in the event there is a time limit) notice to Kolltan and giving good faith consideration to Kolltan's reason(s) for not initiating a lawsuit or taking other action; provided, however, that MedImmune shall not initiate such a lawsuit or take such other action without the prior written consent of Kolltan (which Kolltan may withhold in its sole discretion) if Kolltan's decision not to exercise its first right with respect thereto was made for strategic business reasons. Kolltan shall cooperate in the prosecution of any suit initiated by MedImmune to the extent permitted by the prior sentence as may be reasonably requested by MedImmune (including joining such suit as a plaintiff if MedImmune is unable to initiate or prosecute such action solely in its own name); provided, however, that MedImmune shall promptly reimburse all Out-of-Pocket Costs (including reasonable counsel fees and expenses) of Kolltan in connection with such cooperation. Subject to the proviso in the immediately preceding sentence, any recoveries resulting from such an action brought by MedImmune in accordance with this Section 7.4.2(a)(iii)shall be retained by MedImmune.

### (b) MedImmune Rights.

(i) MedImmune shall have (x) the sole right, but not the obligation, to initiate a lawsuit or take other reasonable action to enforce any MedImmune Manufacturing Patents throughout the world and (y) the first right, but not the obligation, to initiate a lawsuit or take other reasonable action to enforce any MedImmune Additional Patents throughout the world; provided, however, that MedImmune shall not initiate any such lawsuit or take such other action with respect to any matter described in this clause (y) without first consulting with Kolltan and giving good faith consideration to any reasonable objection from Kolltan regarding MedImmune's proposed course of action. Kolltan shall cooperate in the

prosecution of any suit under this Section 7.4.2(b)(i) as may be reasonably requested by MedImmune (including joining such suit as a plaintiff if MedImmune is unable to initiate or prosecute such action solely in its own name); provided, however, that MedImmune shall promptly reimburse all Out-of-Pocket Costs (including reasonable counsel fees and expenses) of Kolltan in connection with such cooperation. In connection with any such proceeding, MedImmune shall not enter into any settlement admitting the invalidity of, or otherwise impairing Kolltan's rights in, any MedImmune Additional IP without the prior written consent of Kolltan.

(ii) With respect to any lawsuit initiated or other action taken by MedImmune under clause (y) of Section 7.4.2(b)(i), (w) MedImmune shall keep Kolltan reasonably informed of the status of such lawsuit or action; (x) without limiting clause (w), MedImmune shall provide Kolltan with copies of any court filings or other material documents or correspondence received from any Third Party in connection with such lawsuit or action promptly after such filings or documents or correspondence are received by MedImmune; (y) MedImmune shall consult with Kolltan with respect to such lawsuit or action and consider any comments from Kolltan with respect to such lawsuit or action in good faith; and (z) without limiting clause (y), MedImmune shall provide Kolltan with drafts of any court filings or other material documents or correspondence to be filed or delivered by MedImmune prior to the date of filing or delivery such that Kolltan has a reasonable opportunity to review and provide comments, and to the extent Kolltan provides comments thereon promptly and in sufficient time to allow MedImmune to meet applicable filing requirements, MedImmune shall consider such comments in good faith.

(iii) Any recoveries resulting from an action brought by MedImmune under Section 7.4.2(b)(i) shall (x) first be applied to reimburse each Party for all Out-of-Pocket Costs incurred by such Party in connection with such proceeding (on a pro rata basis, based on each Party's respective litigation costs, to the extent the recovery was less than all such litigation costs), and (y) second, as to any remainder after such reimbursements are made, (A) to the extent the award is based on lost profits with respect to a Licensed Product or Follow-On Product, such remainder shall be retained by Kolltan; provided, however, that if the award is based on lost profits with respect to a Licensed Product or Follow-On Product, then MedImmune shall receive an amount equal to the royalty that would be payable, pursuant to Section 6.4, on the imputed amount of Net Sales of such Licensed Product or Follow-On Product, as applicable, in the country in which such infringement occurred based on the amount retained by Kolltan under this clause (A); (B) to the extent the award reflects the amount of reasonable royalty payments due to Kolltan with respect to a Licensed Product or Follow-On Product (excluding, for clarity, any award to the extent described in clause (A) above), such remainder shall be retained by Kolltan; provided, however, that if the award is based on the amount of reasonable royalty payments due to Kolltan with respect to a Licensed Product or Follow-On Product, as applicable, then the amount retained by Kolltan under this clause (B) shall be deemed Net Sales hereunder (and accordingly subject to any applicable royalty obligation under Section 6.4); and (C) to the extent the award is not described in clauses (A) or (B) above, such remainder shall be equitably divided between MedImmune and Kolltan

(iv) If MedImmune in good faith does not intend to initiate a lawsuit or take other reasonable action with respect to any matter described in clause (y) of Section 7.4.2(b)(i), then MedImmune shall notify Kolltan thereof (x) if there is no time limit for the filing of such action, within sixty (60) days following the notice of alleged infringement, or (y) if there is a time limit for the filing of such action (including those set forth in Applicable Law), at least fifteen (15) days before the time limit, and upon receipt of such notice Kolltan shall have the right, but not the obligation, to initiate such lawsuit or take such other action, after providing thirty (30) days (or five (5) days in the event there is a time limit) notice to MedImmune and giving good faith consideration to MedImmune's reason(s) for not initiating a lawsuit or taking other action; provided, however, that Kolltan shall not initiate such a lawsuit or take such other action without the prior written consent of MedImmune (which MedImmune may withhold in its sole discretion) if MedImmune's decision not to exercise its first right with respect thereto was made for strategic business reasons. MedImmune shall cooperate in the prosecution of any suit initiated by Kolltan to the extent permitted by the prior sentence as may be reasonably requested by Kolltan (including joining such suit as a plaintiff if Kolltan is unable to initiate or prosecute such action solely in its own name); provided, however, that Kolltan shall promptly reimburse all Out-of-Pocket Costs (including reasonable counsel fees and expenses) of MedImmune in connection with such cooperation. Subject to the proviso in the immediately preceding sentence, any recoveries resulting from such an action brought by Kolltan in accordance with this Section 7.4.2(b)(iv)shall be retained by Kolltan.

- 7.4.3 <u>Conduct of Certain Actions; Costs.</u> The Party initiating legal action shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to Section 7.4.2 (the "<u>Initiating Party</u>"). Unless otherwise expressly provided herein, the Initiating Party shall bear its own Out-of-Pocket Costs incurred in any such legal action, including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate and be represented in any such legal action (in cases where such other Party has standing) by its own counsel at its own expense.
- 7.5 <u>Patent Invalidity Claim.</u> Each Party shall promptly notify the other in the event of any legal action (excluding any actions covered by Section 7.3) by any Third Party with respect to the validity of a MedImmune Patent, MedImmune Additional Patent, Kolltan Patent or Joint Patent of which it becomes aware. With respect to any such action:
- 7.5.1 Kolltan shall have (a) the sole right, but not the obligation, at its expense, to defend against any such action relating to any Kolltan Patents throughout the world, and (b) the first right, but not the obligation, at its expense, to defend against any such action relating to any MedImmune Patents throughout the world and any Joint Patents throughout the world. If Kolltan does not defend against any such action described in clause (b) above, then MedImmune shall have the right, but not the obligation, to defend such action at MedImmune's expense; provided, however, that MedImmune shall not defend against any such action described without the prior written consent of Kolltan (which Kolltan may withhold in its sole discretion) if Kolltan's decision not to exercise its first right with respect thereto was made for strategic business reasons.
- 7.5.2 MedImmune shall have (a) the sole right, but not the obligation, at its expense, to defend against any such action relating to any MedImmune Manufacturing Patents throughout the world and (b) the first right, but not the obligation, at its expense, to defend against any such action relating to any MedImmune Additional Patents throughout the world. If

MedImmune does not defend against any such action described in clause (b) above, then Kolltan shall have the right, but not the obligation, to defend such action at Kolltan's expense; provided, however, that Kolltan shall not defend against any such action described without the prior written consent of MedImmune(which MedImmune may withhold in its sole discretion) if MedImmune's decision not to exercise its first right with respect thereto was made for strategic business reasons. In addition, with respect to any such action described in clause(b) above, (i) MedImmune shall keep Kolltan reasonably informed of the status of such action; (ii) without limiting clause (i), MedImmune shall provide Kolltan with copies of any court filings or other material documents or correspondence received from any Third Party in connection with such action promptly after such filings or documents or correspondence are received by MedImmune; (iii) MedImmune shall consult with Kolltan with respect to such action and consider any comments from Kolltan with respect to such action in good faith; and (iv) without limiting clause (iii), MedImmune shall provide Kolltan with drafts of any court filings or other material documents or correspondence to be filed or delivered by MedImmune prior to the date of filing or delivery such that Kolltan has a reasonable opportunity to review and provide comments, and to the extent Kolltan provides comments thereon promptly and in sufficient time to allow MedImmune to meet applicable filing requirements, MedImmune shall consider such comments in good faith.

- 7.6 <u>Patent Term Extensions</u>. The Parties shall cooperate with each other in obtaining patent term extensions or supplemental protection certificates or their equivalents in any country, where applicable to MedImmune Patents, MedImmune Additional Patents, Kolltan Patents and Joint Patents; provided, however, that (a) Kolltan shall have the right of final decision as to whether to seek patent term extensions or supplemental protection certificates or their equivalents in any country with respect to the MedImmune Patents, Kolltan Patents and Joint Patents, and (b) MedImmune shall have the right of final decision as to whether to seek patent term extensions or supplemental protection certificates or their equivalents in any country with respect to the MedImmune Additional Patents.
- 7.7 Patent Marking. Kolltan shall comply with the patent marking statutes in each country in which a Licensed Product or Follow-On Product is sold by Kolltan, its Affiliates and/or its Sublicensees.
- 7.8 CREATE Act. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "CREATE Act"). MedImmune (a) without the prior written consent of Kolltan, shall not make any election under the CREATE Act with respect to the Licensed Antibody, Licensed Products, Follow-On Antibodies or Follow-On Products and (b) shall cooperate with Kolltan with respect to any actions taken by Kolltan in connection with any election made by Kolltan under the CREATE Act with respect to the Licensed Antibody, Licensed Products, Follow-On Antibodies or Follow-On Products.

#### 7.9 Publications.

7.9.1 <u>Publication by MedImmune</u>. Notwithstanding anything to the contrary in this Agreement, MedImmune may publish, present or otherwise disclose preclinical data relating to Licensed Antibody or Licensed Products, either orally or in writing, in a publication,

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presentation or other disclosure (a "MedImmune Publication"), only in accordance with the terms and conditions of this Section 7.9.1.

- (a) MedImmune shall provide a copy of any proposed MedImmune Publication to Kolltan at least thirty (30) days prior to its submission or other disclosure, and Kolltan shall have thirty (30) days from receipt of such proposed MedImmune Publication to provide comments and/or proposed changes to MedImmune. Without limiting the remainder of this Section 7.9.1, MedImmune shall in good faith take into account any such comments and/or proposed changes.
- (b) Subject to the last sentence of Section 8.1 and Section 8.2, MedImmune shall not include any Confidential Information of Kolltan (other than preclinical data relating to Licensed Antibody or Licensed Products) in any MedImmune Publication without Kolltan's prior written consent.
- (c) If Kolltan reasonably determines that any MedImmune Publication would entail the disclosure of any MedImmune Know-How or Joint Know-How upon which Kolltan desires to file a patent application, or if MedImmune has made the decision not to draft and file a patent application covering any MedImmune Additional Know-How disclosed in any proposed MedImmune Publication, then, at Kolltan's request, disclosure of the proposed MedImmune Publication shall be delayed for a period not to exceed forty-five (45) days after the date of proposed submission or disclosure to enable Kolltan to draft and file a patent application covering such MedImmune Know-How, Joint Know-How or MedImmune Additional Know-How, as applicable.
- (d) MedImmune shall designate appropriate authors in accordance with generally recognized standards for academic publications on any MedImmune Publication.
- 7.9.2 <u>Publication by Kolltan</u>. Notwithstanding anything to the contrary in this Agreement, Kolltan may publish information or data relating to the Licensed Antibody or Licensed Products in a scientific journal (a "<u>Kolltan Publication</u>"), only in accordance with the terms and conditions of this Section 7.9.2.
- (a) Prior to the Option Termination Date, (i) Kolltan shall provide to MedImmune a copy of any proposed Kolltan Publication at least thirty (30) days prior to submission, (ii) MedImmune shall have ten (10) days from receipt of such proposed Kolltan Publication to provide comments to Kolltan, and (iii) without limiting the remainder of this Section 7.9.2, Kolltan may, in its sole discretion, take into account any such comments. From and after the Option Termination Date, Kolltan shall have no obligation to provide a copy of any proposed Kolltan Publication to MedImmune prior to submission or other disclosure.
- (b) Subject to the last sentence of Section 8.1 and Section 8.2, Kolltan shall not include any Confidential Information of MedImmune in any Kolltan Publication without MedImmune's prior written consent.
- (c) Kolltan shall designate appropriate authors in accordance with generally recognized standards for academic publications on any Kolltan Publication.

#### 7.10 Existing Proceedings.

- 7.10.1 Prosecution by MedImmune. Until such time as Kolltan assumes control of a particular Existing Proceeding pursuant to Section 7.10.2, MedImmune shall continue to prosecute such Existing Proceeding. MedImmune shall provide Kolltan with a draft of any filing or document to be submitted related to any such Existing Proceeding at least thirty (30) days in advance of submission (or, if such timing is not practicable, as far in advance of submission as practicable) and shall provide Kolltan an opportunity to provide comments on and make requests of MedImmune concerning such filing or document and shall consider in good faith any comments or requests regarding such filing or document that Kolltan may timely provide. In addition, MedImmune shall provide to Kolltan such other information related to such Existing Proceeding as Kolltan may from time to time reasonably request to allow Kolltan to track such Existing Proceeding and shall consider in good faith any comments that Kolltan may provide with respect to such matters. MedImmune shall also work with Kolltan in good faith with respect to the strategy for the prosecution of such Existing Proceeding.
- 7.10.2 Assumption of Control by Kolltan. MedImmune shall give Kolltan written notice reasonably, but in no event less than thirty (30) days, in advance of any decision by MedImmune not to continue to prosecute any Existing Proceeding. Upon receiving such notice, Kolltan shall have the right, at its own cost, to continue to prosecute such Existing Proceeding. In addition, Kolltan shall have the right, at Kolltan's discretion and at its own cost, at any time to assume control of any Existing Proceeding by providing written notice to MedImmune. If Kolltan exercises its rights under this Section 7.10.2, MedImmune shall transfer or disclose to Kolltan, in whatever manner or form Kolltan may reasonably request, all documents, correspondence and other information and materials Controlled by MedImmune (and not previously disclosed to Kolltan) as reasonably necessary for Kolltan to exercise its rights under this Section 7.10.2. Such transfers and disclosures shall be made (a) in any manner or form reasonably requested by Kolltan and (b) at MedImmune's expense; provided, however, if at Kolltan's request any such transfer or disclosure is made in any manner or form that is not reasonably standard in the biopharmaceutical industry for transfers or disclosures of a similar kind, such transfer or disclosure shall be made at Kolltan's expense. In addition, MedImmune shall (x) use reasonable efforts to make its authorized attorneys, agents or representatives available to Kolltan and to assist Kolltan in transitioning control of such Existing Proceeding to Kolltan and (y) sign or use reasonable efforts to have signed all legal documents necessary to transfer control of such Existing Proceeding to Kolltan.
- 7.10.3 <u>Assistance</u>. If Kolltan assumes control of an Existing Proceeding pursuant to Section 7.10.2, MedImmune shall provide such cooperation in the prosecution of such proceeding as may be reasonably requested by Kolltan (including permitting Kolltan to continue such proceeding in MedImmune's name if Kolltan is unable to prosecute such proceeding solely in Kolltan's own name); provided, however, that Kolltan shall promptly reimburse all Out-of-Pocket Costs (including reasonable counsel fees and expenses) of MedImmune in connection with such cooperation.

# ARTICLE 8 CONFIDENTIALITY

- 8.1 <u>Confidentiality; Exceptions.</u> Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the "<u>Receiving Party</u>") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Know-How in any form (whether written, oral, graphic, photographic, electronic, magnetic, or otherwise) that is disclosed to the Receiving Party by the other Party (the "<u>Disclosing Party</u>") directly, or indirectly in the course of the Receiving Party's performing its obligations or exercising its rights under this Agreement (collectively, "<u>Confidential Information</u>"). Notwithstanding anything to the contrary in this Agreement, (a) any Regulatory Documentation relating to the Licensed Antibody or Licensed Products shall be deemed to be the Confidential Information of Kolltan (and not MedImmune), (b) any MedImmune Know-How, MedImmune Additional Know-How and Joint Know-How shall be deemed to be the Confidential Information of each Party and (c) subject to Section 8.3, the terms of this Agreement shall be deemed to be the Confidential Information of each Party. Notwithstanding the foregoing, the restrictions set forth in the first sentence of this Section 8.1 shall not apply to Confidential Information of the Disclosing Party to the extent that it can be established by the Receiving Party that such Confidential Information:
- 8.1.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party pursuant to this Agreement, or was otherwise developed independently by the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;
  - 8.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- 8.1.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or
- 8.1.4 was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.
- 8.2 <u>Authorized Disclosure</u>. Except as expressly provided otherwise in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows:
- 8.2.1 under appropriate confidentiality provisions similar to those in this Agreement, in connection with the performance of its obligations or exercise of rights expressly granted or reserved under this Agreement; provided, however, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person receiving such Confidential Information;

- 8.2.2 to the extent such disclosure is reasonably necessary in filing or prosecuting patent and copyright applications, prosecuting or defending litigation, complying with applicable governmental regulations (including the rules and regulations of any stock exchange or NASDAQ), preparing and submitting filings to Regulatory Authorities or as otherwise required by Applicable Law, provided, however, that if a Receiving Party is required by Applicable Law to make any such disclosure of a Disclosing Party's Confidential Information (other than a disclosure to a Regulatory Authority in a filing required by Applicable Law) it will give reasonable advance notice to the Disclosing Party of such disclosure requirement and shall furnish only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish;
- 8.2.3 in communications with existing or bona fide prospective acquirers, merger partners, lenders, investors, licensees, sublicensees or collaborators, and consultants and advisors of the Receiving Party in connection with transactions or bona fide prospective transactions with any of the foregoing, in each case on a need to know basis and under appropriate confidentiality provisions substantially equivalent to those of this Agreement; provided, however, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person receiving such Confidential Information: or
  - 8.2.4 to the extent mutually agreed to in writing by the Parties.

#### 8.3 Press Release; Disclosure of Agreement.

- 8.3.1 On or promptly after the Effective Date, the Parties shall issue a joint public announcement of the execution of this Agreement or each Party shall issue a separate public announcement of the execution of this Agreement; provided, however, that the content of any such public announcement (whether joint or separate) shall be mutually agreed by the Parties. Thereafter, (a) subject to Section 7.9.1, MedImmune shall not (i) issue any other press release regarding this Agreement or the Parties' activities hereunder without the prior written consent of Kolltan or (ii) make any other disclosures regarding this Agreement or the Parties' activities hereunder, or any results or data arising hereunder, except for any disclosure that is reasonably necessary to comply with applicable securities exchange listing requirements or other Applicable Law; provided, however, that (x) the restrictions set forth in clauses (i) and (ii) above shall terminate at such time, if any, as this Agreement terminates pursuant to Section 5.4.3(a); and (y) if it is determined that the Parties will enter into the Co-Development and Co-Commercialization Agreement pursuant to Section 5.4.3(c) or 5.4.3(d), Kolltan shall not unreasonably withhold its consent to any press release proposed to be issued by MedImmune with respect to the Parties' entering into the Co-Development and Co-Commercialization Agreement; and (b) subject to Section 7.9.2, Kolltan may, in its sole discretion, issue other press releases regarding its Development and Commercialization activities hereunder (including any results or data arising hereunder); provided, however, that Kolltan shall not issue any other press releases regarding the terms of this Agreement or the exercise by either Party of its rights under ARTICLE 5 without the prior written consent of MedImmune.
- 8.3.2 Each Party shall, if practicable, give the other Party a reasonable opportunity to review those portions of all filings with the United States Securities and Exchange Commission (or any stock exchange, including Nasdaq, or any similar regulatory agency in any

country other than the United States) describing the terms of this Agreement (including any filings of this Agreement) prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including the provisions of this Agreement for which confidential treatment should be sought.

- 8.4 <u>Existing Confidentiality Agreement.</u> For the avoidance of doubt, any information disclosed by either Party to the other Party prior to the Effective Date pursuant to the Mutual Confidentiality Agreement, dated July 12, 2012, between MedImmune and Kolltan (the "<u>Existing Confidentiality Agreement</u>") shall be treated as Confidential Information of the disclosing Party for all purposes under this Agreement.
- 8.5 Remedies. In the event a Party breaches the confidentiality obligations set forth in this ARTICLE 8, the other Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the breaching Party from any violation or threatened violation of this ARTICLE 8.
- Return of Confidential Information. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party all Confidential Information of the Disclosing Party in its possession (and all copies and reproductions thereof). In addition, the Receiving Party shall destroy: (a) any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party; and (b) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party. Alternatively, upon written request of the Disclosing Party, upon such expiration or termination, the Receiving Party shall destroy all Confidential Information of the Disclosing Party in its possession (and all copies and reproductions thereof) and any notes, reports or other documents prepared by the Receiving Party which contain Confidential Information of the Disclosing Party. Nothing in this Section 8.6 shall require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; provided that the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE 8 with respect to any Confidential Information contained in such archival tapes or other electronic back-up media. Any requested destruction of Confidential Information shall be certified in writing to the Disclosing Party. Notwithstanding the foregoing, (i) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this ARTICLE 8 and (ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents to the extent reasonably required (x) to comply with Applicable Law and regulatory requirements; (y) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; and (z) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement. Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this ARTICLE 8.

# ARTICLE 9 REPRESENTATIONS AND WARRANTIES

- 9.1 Representations and Warranties of Both Parties. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:
- 9.1.1 Such Party is duly organized, validly existing and in good standing under the Applicable Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.
- 9.1.2 Such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.
- 9.1.3 This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.
- 9.1.4 The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which such Party or its Affiliates is a party or by which such Party or its Affiliates is bound (including, with respect to MedImmune, any In-License Agreement), nor violate any Applicable Law.
- 9.1.5 No government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as necessary to conduct clinical trials or to seek or obtain Regulatory Approvals.
  - 9.2 <u>Representations, Warranties and Covenants of MedImmune</u>. MedImmune hereby represents, warrants and covenants to Kolltan that:
- 9.2.1 MedImmune is, as of the Effective Date, and at all times will be, (a) the sole and exclusive owner of all of the MedImmune IP and MedImmune Additional IP other than the In-Licensed IP and (b) the sole and exclusive licensee of the In-Licensed IP other than the In-Licensed IP under the Dyax Agreement. MedImmune's rights to the MedImmune IP and MedImmune Additional IP are as of the Effective Date, and at all times will be, (x) free of all liens, mortgages, encumbrances, pledges and security interests of any kind in favor of any Third Party and (y) not subject to any rights of or licenses to any Governmental Authority.
- 9.2.2 As of the Effective Date, MedImmune has obtained from each employee and agent of MedImmune or its Affiliates who has performed activities in connection with the Research, Development or Manufacture of the Licensed Antibody or Licensed Products all right,

title and interest in and to any inventions and discoveries made or discovered by such employee or agent in the course of conducting such activities.

- 9.2.3 The MedImmune Patents existing as of the Effective Date are listed on Exhibit 9.2.3. There are no MedImmune Additional Patents existing as of the Effective Date. As of the Effective Date, all documents required to be filed and all payments required to be made in order to maintain each MedImmune Patent and each MedImmune Additional Patent have been filed or made, as the case may be, in a timely manner, and no action has been taken that would constitute waiver, abandonment or any similar relinquishment of rights with respect to any such Patent.
- 9.2.4 As of the Effective Date, (a) MedImmune has taken reasonable measures to maintain the confidentiality of the MedImmune Know-How and MedImmune Additional Know-How and has disclosed the MedImmune Know-How and MedImmune Additional Know-How to Third Parties only under confidentiality obligations similar to those set forth in ARTICLE 8, and (b) to the knowledge of MedImmune, there is no actual infringement or misappropriation or threatened infringement or misappropriation of any MedImmune IP, MedImmune Additional IP or Regulatory Documentation related to the Licensed Antibody or Licensed Products by any Person.
- 9.2.5 As of the Effective Date, to the knowledge of MedImmune, (a) none of the MedImmune Patents or MedImmune Additional Patents is invalid or unenforceable, in whole or in part, and (b) the conception, development and reduction to practice of the MedImmune IP, MedImmune Additional IP and Regulatory Documentation related to the Licensed Antibody or Licensed Products have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person. There are not as of the Effective Date, nor have there been over the three (3) year period immediately preceding the Effective Date, any actual (or, to MedImmune's knowledge, threatened) claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, complaints or investigations by any Government Authority (except in the ordinary administrative course of the granting of patents or approvals and proceedings relating thereto) or by any Third Party relating to the MedImmune IP, MedImmune Additional IP or Regulatory Documentation related to the Licensed Antibody or Licensed Products.
- 9.2.6 As of the Effective Date, except as listed in Exhibit 9.2.6, to the knowledge of MedImmune, the exercise by Kolltan of the rights, licenses and sublicenses granted to Kolltan by MedImmune under this Agreement, including the making, using, selling, offering for sale or import of the Licensed Antibody or any Licensed Product, will not infringe any intellectual property rights of any Third Party. For clarity, a listing on Exhibit 9.2.6 is not a statement or admission regarding infringement.
- 9.2.7 As of the Effective Date, (a) each In-License Agreement is in effect, (b) to the knowledge of MedImmune, no party to any In-License Agreement is in breach of any provisions thereof and (c) no event has occurred under any In-License Agreement that would (with or without the passage of time) permit any party thereto (other than MedImmune or its applicable Affiliate) to terminate such In-License Agreement.

- 9.2.8 MedImmune and its Affiliates shall (a) not commit any act or permit the occurrence of any omission that would constitute a breach of any In-License Agreement or result in the termination thereof prior to the expiration thereof in accordance with the terms thereof, (b) not amend, modify or waive any rights under any In-License Agreement in such a way as to adversely affect Kolltan's rights or obligations under this Agreement, or terminate any In-License Agreement, without Kolltan's prior written consent, (c) promptly notify Kolltan of any breach of any In-License Agreement by any party thereto, the occurrence of which gives rise to a right of termination thereunder by any party thereto or causes automatic termination thereunder, and (d) subject to clause (b) above, use commercially reasonable efforts to enforce the terms of each In-License Agreement against each other party thereto.
- 9.2.9 This Agreement complies with any requirements or conditions set forth in any In-License Agreement with respect to the grant of a sublicense under MedImmune's and its Affiliates rights under the In-Licensed IP. Except as set forth on Exhibit 9.2.9, no In-License Agreement imposes, directly or indirectly, any obligation on Kolltan (as sublicensee of MedImmune's and its Affiliates' rights under the In-Licensed IP), or any obligation on MedImmune or its Affiliates to cause Kolltan (as sublicensee of MedImmune's and its Affiliates' rights under the In-Licensed IP), to take any action or refrain from taking any action. Except as set forth on Exhibit 9.2.9, there are no restrictions on the rights of Kolltan as sublicensee of MedImmune's and its Affiliates' rights under the In-Licensed IP to use or disclose the In-Licensed IP, including granting further sublicenses thereunder. Except as set forth in Exhibit 6.4.4, as between MedImmune and its Affiliates (on the one hand) and Kolltan (on the other hand), MedImmune and its Affiliates will make all payments required to be made under each In-License Agreement.
  - 9.2.10 The In-Licensed IP under the MRC Agreement is not subject to any Third Party Rights (as defined in the MRC Agreement).
- 9.2.11 MedImmune or its applicable Affiliate under the Dyax Agreement (a) as of the Effective Date, has the right under its option under Clause 12 of the Dyax Agreement to obtain a MedImmune Product License (as defined in the Dyax Agreement) with respect to the Licensed Antibody and any Licensed Product to be Developed by Kolltan for any Target (as defined in the Dyax Agreement) reasonably contemplated by Kolltan's Development activities hereunder, (b) until such time as MedImmune or its applicable Affiliate obtains a MedImmune Product License (as defined in the Dyax Agreement) with respect to the Licensed Antibody and any Licensed Product Developed or to be Developed by Kolltan for any Target (as defined in the Dyax Agreement) reasonably contemplated by Kolltan's Development activities hereunder, shall maintain the right to do so, and (c) upon Kolltan's written request, shall promptly take such actions as are reasonably necessary to obtain a MedImmune Product License (as defined in the Dyax Agreement) with respect to the Licensed Antibody or any Licensed Product Developed or to be Developed by Kolltan for any Target (as defined in the Dyax Agreement) reasonably contemplated by Kolltan's Development activities hereunder.
- 9.2.12 Upon Kolltan's written request, MedImmune or its applicable Affiliate under the Lonza Agreement shall promptly take such actions as are reasonably necessary to enter into a Product Schedule (as defined in the Lonza Agreement) with respect to the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product, so that the

Exploitation (as defined in the Lonza Agreement) of the Licensed Antibody or such Licensed Product, Follow-On Antibody or Follow-On Product, as applicable, is covered by the license grants set forth in Section 6.1 of the Lonza Agreement.

- 9.2.13 As of the Effective Date, (a) the Unredacted Provisions constitute all provisions of the In-License Agreements that are relevant to the rights and obligations of Kolltan as sublicensee under the In-Licensed IP and (b) nothing in any In-License Agreement conflicts with the Unredacted Provisions thereof.
- 9.2.14 Each Third Party that conducted activities under any Research Program is subject to written confidentiality and non-use obligations with respect to any Know-How related to such Research Program that are at least as stringent as those set forth in Sections 8.1 and 8.2, and no such Third Party has any rights in or to the Licensed Antibody or the Licensed Program. Following the Effective Date, MedImmune will not cause or permit any Third Party to conduct any activities under any Research Program without the prior written consent of Kolltan.
- 9.2.15 As of the Effective Date, MedImmune has not (a) employed or used a contractor or consultant that has employed, any individual or entity debarred by the FDA (or subject to a similar sanction of EMA), or (b) employed any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA), in the conduct of any activities related to the Licensed Antibody.
- 9.2.16 As of the Effective Date, MedImmune has prepared, filed and maintained all Regulatory Documentation that (a) is relevant to the Licensed Antibody and Licensed Products and (b) Applicable Law requires MedImmune to have prepared, filed and maintained, in each case in accordance with Applicable Law, and all information contained therein is true, complete and correct in all material respects.
- 9.2.17 As of the Effective Date, all activities conducted by or on behalf of MedImmune with respect to the Licensed Antibody or Licensed Products have been conducted, in all material respects, in accordance with Applicable Law, GLP, GCP and GMP, as applicable.
- 9.2.18 Without limitation of Section 9.1.4, as of the Effective Date, MedImmune has the right to grant all rights, licenses and sublicenses granted to Kolltan under this Agreement (including a sublicense under all of the In-Licensed IP as contemplated by this Agreement) and has not granted to any Third Party any rights, licenses or sublicenses that are inconsistent with the rights, licenses and sublicenses granted to Kolltan under this Agreement.
- 9.2.19 As of the Effective Date, MedImmune has disclosed or made available to Kolltan all material information, documents and materials in its possession relating to the Licensed Antibody, and all such information, documents and materials are true, complete and correct in all material respects.
  - 9.3 Mutual Covenants. Each Party hereby covenants to the other Party that:
    - 9.3.1 Such Party shall comply with all Applicable Law in the performance of this Agreement and the transactions contemplated hereby.

#### 9.3.2 Such Party:

- (a) shall impose on each employee of such Party or its Affiliates who performs activities in connection with the Research, Development or Manufacture of the Licensed Antibody or Licensed Products the obligation to assign all right, title and interest in and to any inventions or discoveries made or discovered by such employee in the course of conducting such activities;
- (b) shall not (i) employ or use any contractor or consultant that employs any individual or entity debarred by the FDA (or subject to a similar sanction of EMA); or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA), in each of clauses (i) and (ii) in the conduct of any activities in connection with the Research, Development, or Manufacture of the Licensed Antibody or Licensed Products. If, at any time, (x) any individual or entity employed by such Party or any contractor or consultant used by such Party in the conduct of any activities in connection with the Research, Development or Manufacture of the Licensed Antibody or Licensed Products becomes debarred by the FDA (or subject to a similar sanction of EMA) or (y) any individual or entity employed by such Party in the conduct of any activities in connection with the Research, Development or Manufacture of the Licensed Antibody or Licensed Products becomes the subject of, or is threatened to be made the subject of, an FDA debarment investigation or proceeding (or similar proceeding of EMA), such Party shall immediately notify the other Party; and
- (c) shall perform all activities in connection with the Research, Development, and Manufacture of the Licensed Antibody and Licensed Products in compliance in all material respects with GLP, GCP and GMP (including those specified by the ICH), in each case as applicable;

provided, however, that the covenants set forth in this Section 9.3.2 shall terminate (1) upon the expiration of the Trigger Period (and any applicable Option Period), if as of such time MedImmune has not delivered an Exercise Notice, and (2) upon Kolltan's payment of the Buyout Amount to MedImmune.

- 9.3.3 Neither Party shall grant any right, license or sublicense to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights, licenses or sublicenses granted or to be granted to the other Party hereunder.
- 9.4 <u>Disclaimer</u>. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. Without limiting the foregoing, except as otherwise expressly set forth in this Agreement, each Party disclaims any warranties with regards to: (a) the success of any study or test commenced under this Agreement; (b) the safety or usefulness for any purpose of the technology or materials, including any compounds, it provides or discovers under this Agreement; or (c) the validity, enforceability, or non-infringement of any

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intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

# ARTICLE 10 INDEMNIFICATION AND INSURANCE

- 10.1 <u>Indemnification by Kolltan</u>. Kolltan shall defend, indemnify and hold harmless the MedImmune Indemnitees from and against any and all losses, damages, fees, expenses, settlement amounts or costs (including reasonable attorneys' fees and witness fees) ("<u>Losses</u>") relating to or in connection with a Third Party claim arising out of (a) any death, personal bodily injury or damage to real or tangible personal property alleged or proven to result, directly or indirectly, from the possession, use or consumption of, or treatment with, the Licensed Antibody or any Follow-On Antibody, Licensed Product or Follow-On Product, in each case by or on behalf of Kolltan or its Affiliates or Sublicensees, including any product liability claims; (b) the Commercialization by or on behalf of Kolltan or its Affiliates or Sublicensees of the Licensed Antibody or any Follow-On Antibody, Licensed Product or Follow-On Product; (c) any actual or alleged infringement or unauthorized use or misappropriation of any Patent or other intellectual property right of a Third Party with respect to the activities of Kolltan or its Affiliates or Sublicensees hereunder; (d) any breach by Kolltan of its representations, warranties or covenants made under this Agreement; or (e) any illegal or negligent act or omission or willful misconduct of Kolltan or its Affiliates or Sublicensees or any of their employees, contractors or agents, in performing any activities under or in connection with this Agreement; provided, however, that the foregoing indemnity shall not apply to the extent that any such Losses (i) are attributable to an illegal act by or the gross negligence or willful misconduct of any MedImmune Indemnitees, or (ii) are otherwise subject to an obligation by MedImmune to indemnify the Kolltan Indemnitees under Section 10.2, as to which Losses the provisions of Section 10.4 shall apply.
- 10.2 Indemnification by MedImmune. MedImmune shall defend, indemnify and hold harmless the Kolltan Indemnitees from and against any and all Losses relating to or in connection with a Third Party claim arising out of (a) any activities conducted by MedImmune or its Affiliates with respect to the Licensed Antibody or Licensed Products on or prior to the Effective Date; (b) any death, personal bodily injury or damage to real or tangible personal property alleged or proven to result, directly or indirectly, from the possession, use or consumption of, or treatment with, any Licensed Antibody or Licensed Product included in or produced from the Inventory, including any product liability claims; (c) any actual or alleged infringement or unauthorized use or misappropriation of any Patent or other intellectual property right of a Third Party with respect to the activities of MedImmune or its Affiliates hereunder; (d) any breach by MedImmune of its representations, warranties or covenants made under this Agreement; or (e) any illegal or negligent act or omission or willful misconduct of MedImmune or its Affiliates or any of their employees, contractors or agents, in performing any activities under or in connection with this Agreement or the subject matter hereof, whether before or after the Effective Date; provided, however, that the foregoing indemnity shall not apply to the extent that any such Losses (i) are attributable to an illegal act by or the gross negligence or willful misconduct of any Kolltan Indemnitees, or (ii) are otherwise subject to an obligation by Kolltan to indemnify the MedImmune Indemnitees under Section 10.1, as to which Losses the provisions of Section 10.4 shall apply.

- Procedure. In the event of a claim by a Third Party against any Person entitled to indemnification under this Agreement, the Party claiming indemnification (in such capacity, the "Indemnified Party") shall promptly notify the other Party (in such capacity, the "Indemnifying Party") in writing of the claim (it being understood that the failure by the Indemnified Party to give prompt notice of a Third Party claim as provided in this Section 10.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give prompt notice). Within thirty (30) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, undertake and solely manage and control, at its sole expense and with counsel reasonably satisfactory to the Indemnified Party, the defense of the claim. If the Indemnifying Party does not undertake such defense in accordance with the preceding sentence, the Indemnified Party shall control such defense. The Party not controlling such defense shall cooperate with the other Party and may, at its option and expense, participate in such defense with counsel of its choice; provided, however, that if the Indemnifying Party assumes control of such defense as set forth above and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party (or the relevant MedImmune Indemnitee or Kolltan Indemnitee seeking indemnification) have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnified Party's counsel may fully participate in such defense and the Indemnifying Party shall be responsible for the reasonable fees and expenses of one counsel to the indemnified Persons solely in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof, shall provide the other Party copies of material documents and filings related to such action, suit, proceeding or claim and shall consider recommendations made by the other Party with respect thereto. Except if the Indemnifying Party did not undertake defense of the claim as set forth above, or if the Indemnifying Party and the Indemnified Party (or the relevant MedImmune Indemnitee or Kolltan Indemnitee seeking indemnification) have conflicting interests with respect to such action, suit, proceeding or claim and the Indemnified Party engages separate counsel, as provided above, the Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnified Party shall not settle any such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not settle, without the prior written consent of the Indemnified Party, any such action, suit, proceeding or claim, or consent to any judgment in respect thereof, that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party.
- 10.4 <u>Allocation</u>. In the event a claim falls within the scope of the indemnity given by each Party in Section 10.1 or 10.2, as the case may be, any payments in connection with such claim shall be apportioned between the Parties in accordance with the degree of fault attributable to each Party.
- 10.5 <u>EXCLUSION OF CONSEQUENTIAL DAMAGES</u>. EXCEPT WITH RESPECT TO A BREACH OF ARTICLE 8 OR THIRD PARTY CLAIMS THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 10, NEITHER MEDIMMUNE NOR KOLLTAN, NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE FOR

ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER SUCH PARTY OR ANY REPRESENTATIVE OF SUCH PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

#### 10.6 <u>Insurance</u>.

- 10.6.1 MedImmune shall, at its own cost and expense, obtain and maintain in effect insurance at such levels sufficient to cover its obligations under this Agreement. MedImmune shall furnish a certificate of insurance for any of the applicable policies as soon as practicable after the Effective Date and upon any renewal thereof.
  - 10.6.2 Kolltan shall at its own cost and expense, obtain and maintain in effect the following insurance:
    - (a) Property insurance written on an all-risk basis sufficient to cover the replacement value of the Inventory;
- (b) Commercial General Liability covering bodily injury and property damage with minimum limits of \$1,000,000 each occurrence and \$2,000,000 general aggregate, including Premises Liability, and Contractual Liability coverage for Kolltan's indemnification obligations under this Agreement;
- (c) upon initiation by Kolltan of any human clinical trial of the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product, Products/Completed Operations Liability covering human clinical trials with minimum limits of \$2,000,000 each occurrence and \$2,000,000 policy aggregate;
- (d) Commercial Automobile Liability covering hired and non-owned vehicles with limits of at least \$1,000,000 combined single limit (bodily injury and property damage);
- (e) Workers' Compensation as required by Applicable Law and Employer's Liability coverage with a limit of not less than \$1,000,000; and
- (f) Umbrella Liability coverage with minimum limits of at least \$3,000,000 each occurrence and \$3,000,000 general aggregate, sitting excess of the general liability, commercial auto liability and employer's liability programs.

Each of the policies in clauses (b), (c), (d) and (f) above shall name MedImmune as an Additional Insured, and all of the above policies shall be primary to any liability insurance carried by MedImmune, which insurance(s) shall be excess and non-contributory for claims and losses arising out of the performance of this Agreement. Kolltan shall furnish a certificate of insurance for any of the required policies as soon as practicable after the Effective Date (or such later time as Kolltan obtains the applicable policy) and upon any renewal thereof. All such insurances as required under this Section 10.6.2 shall be written with a company or companies

having a financial rating of not less than A- in the most current edition of Bests Key Rating Guide.

In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained for a period of not less than three (3) years following the termination or expiration of this Agreement.

MedImmune shall promptly provide to Kolltan such information as Kolltan reasonably requests to enable Kolltan to comply with its obligations under this Section 10.6.2.

# ARTICLE 11 TERM AND TERMINATION

11.1 <u>Term; Expiration</u>. This Agreement shall become effective as of the Effective Date and, unless earlier terminated in accordance herewith, shall remain in effect until the expiration of the last to expire Royalty Term for any Licensed Product or Follow-On Product in any country.

#### 11.2 <u>Termination for Cause</u>.

- 11.2.1 By Kolltan. Kolltan may, without prejudice to any other remedies available to it under Applicable Law or in equity, terminate this Agreement (a) in its entirety, if MedImmune has materially breached or defaulted in the performance of its obligations hereunder or (b) with respect to a Program, if MedImmune has materially breached or defaulted in the performance of its obligations hereunder with respect to such Program, in either case ((a) or (b)) if such breach or default has continued for [\*\*] days after written notice thereof describing such breach or default was provided to MedImmune by Kolltan. Any such termination shall become effective at the end of such [\*\*] day cure period, unless MedImmune has cured such breach or default prior to the expiration of such cure period.
- 11.2.2 <u>By MedImmune</u>. MedImmune may, without prejudice to any other remedies available to it under Applicable Law or in equity, terminate this Agreement with respect to a Program if Kolltan has materially breached or defaulted in the performance of its obligations hereunder with respect to such Program and such breach or default has continued for [\*\*] days after written notice thereof describing such breach or default was provided to Kolltan by MedImmune. Any such termination shall become effective at the end of such [\*\*] day cure period, unless Kolltan has cured such breach or default prior to the expiration of such cure period.
- 11.3 <u>Termination for Insolvency Event</u>. Either Party may terminate this Agreement in its entirety or with respect to a Program effective upon written notice to the other Party if the other Party suffers an Insolvency Event.
- 11.4 <u>Termination for Regulatory Reasons</u>. If Kolltan reasonably determines that it is not feasible for Kolltan to pursue the Development or Commercialization of Licensed Products for reasons of safety or lack of efficacy, then Kolltan may terminate this Agreement with respect to the Licensed Program upon thirty (30) days' written notice to MedImmune. If Kolltan reasonably determines that it is not feasible for Kolltan to pursue the Development or

Commercialization of Follow-On Products for reasons of safety or lack of efficacy, then Kolltan may terminate this Agreement with respect to the Follow-On Program upon thirty (30) days' written notice to MedImmune.

- 11.5 <u>Termination upon Effective Date of Co-Development and Co-Commercialization Agreement or Auction License Agreement.</u> In the event the Parties enter into the Co-Development and Co-Commercialization Agreement pursuant to Section 5.4.3(c) or 5.4.3(d), this Agreement shall terminate with respect to the Licensed Program upon the effective date thereof. In the event the Parties enter into the Auction License Agreement pursuant to Section 5.4.3(e), this Agreement shall terminate with respect to the Licensed Program upon the effective date thereof.
- 11.6 <u>Other Termination</u>. For clarity, this Agreement may be terminated with respect to the Licensed Program pursuant to Section 5.4.3(a) in accordance with the terms thereof.

#### 11.7 Effect of Termination or Expiration.

- 11.7.1 <u>Termination by Kolltan for Cause or Insolvency</u>. Subject to Section 11.8, upon termination of this Agreement in its entirety or with respect to a Program by Kolltan pursuant to Section 11.2.1 or 11.3:
- (a) the rights of Kolltan under ARTICLE 2 (including Section 2.1), ARTICLE 3, ARTICLE 4 and ARTICLE 7 (with respect to the terminated Program, if applicable) shall remain in effect;
- (b) subject to clause (e) below, the rights of MedImmune under ARTICLE 7 (with respect to the terminated Program, if applicable) shall remain in effect solely to the extent related to Joint IP;
- (c) the obligations and covenants of MedImmune under ARTICLE 3, ARTICLE 7 and ARTICLE 9 (with respect to the terminated Program, if applicable) shall remain in effect;
  - (d) the provisions of ARTICLE 6 (with respect to the terminated Program, if applicable) shall remain in effect;
- (e) the provisions of Sections 2.4, 7.1 and 7.2 and ARTICLE 10 (with respect to the terminated Program, if applicable) shall remain in effect indefinitely, and the provisions of ARTICLE 8 (with respect to the terminated Program, if applicable) shall remain in effect for a period of [\*\*] years after such termination; and
- (f) in the case of any termination with respect to a Program, all rights and obligations of the Parties with respect to the other Program shall, to the extent in effect immediately prior to such termination, remain in effect.
- 11.7.2 <u>Termination Involving MedImmune's Payment of the Product Acquisition Price</u>. Subject to Section 11.8, upon termination of this Agreement with respect to the Licensed Program by Kolltan pursuant to Section 5.4.3(a):

- (a) subject to clause (c) below, the rights and obligations of Kolltan under ARTICLE 7 with respect to the Licensed Program shall remain in effect solely to the extent related to any Joint IP other than Joint IP described in clauses (f) and (g) below;
  - (b) MedImmune's payment obligation under clause (y) of Section 5.4.3(a) shall remain in effect;
- (c) the rights of MedImmune under ARTICLE 7 with respect to the Licensed Program shall remain in effect, and subject to clause (d) below, the obligations of MedImmune under ARTICLE 7 with respect to the Licensed Program shall remain in effect solely to the extent related to any Joint IP other than Joint IP described in clauses (f) and (g) below;
- (d) the provisions of Sections 2.4, 7.1 and 7.2 with respect to the Licensed Program shall remain in effect indefinitely, and the provisions of ARTICLE 8 with respect to the Licensed Program shall remain in effect for a period of [\*\*] years after such termination; provided, however, that from and after such termination, (i) any MedImmune Know-How, MedImmune Additional Know-How and Regulatory Documentation, in each case related to the Licensed Program (but excluding any MedImmune Know-How, MedImmune Additional Know-How and Regulatory Documentation related to the Follow-On Program), and any Regulatory Documentation and Know-How assigned to MedImmune pursuant to clause (f) below, shall be deemed to be the Confidential Information of MedImmune (and not Kolltan) and (ii) any Know-How exclusively licensed to MedImmune pursuant to clause (g) below and any Joint Know-How with respect to the Licensed Program shall be deemed to be Confidential Information of each Party;
- (e) the provisions of ARTICLE 10 with respect to the Licensed Program shall remain in effect; provided, however, that from and after such termination, in addition to the other grounds for indemnification set forth in Section 10.2, MedImmune shall defend, indemnify and hold harmless the Kolltan Indemnitees from and against any and all Losses relating to or in connection with a Third Party claim arising out of (i) any death, personal bodily injury or damage to real or tangible personal property alleged or proven to result, directly or indirectly, from the possession, use or consumption of, or treatment with, the Licensed Antibody or any Licensed Product, in each case by or on behalf of MedImmune or its Affiliates or sublicensees, including any product liability claims, and (ii) the Commercialization by or on behalf of MedImmune or its Affiliates or sublicensees of the Licensed Antibody or any Licensed Product;
- (f) Kolltan shall assign to MedImmune all of Kolltan's right, title and interest in and to (i) any Regulatory Documentation Controlled by Kolltan or its Affiliates as of the effective date of such termination that is related to the Licensed Antibody or Licensed Products (but excluding any such Regulatory Documentation that is related to Follow-On Antibodies or Follow-On Products) and (ii) any Know-How or Patents that (x) are Controlled by Kolltan or its Affiliates as of the date of such termination and (y) solely relate to the Licensed Antibody or any Licensed Product or the Manufacture of the Licensed Antibody or any Licensed Product;

- (g) Kolltan hereby grants to MedImmune, effective as of the date of such termination, an exclusive, royalty-free license, with the right to grant sublicenses, under any Know-How or Patents (other than those included in clause (f) above) that (x) are Controlled by Kolltan or its Affiliates as of the date of such termination or within three (3) months thereafter and (y) are necessary to Research, Develop, Manufacture or Commercialize the Licensed Antibody or any Licensed Product in the Field in the Territory, solely for the purpose of Researching, Developing, Manufacturing and Commercializing the Licensed Antibody and Licensed Products in the Field in the Territory;
- (h) Kolltan shall reasonably cooperate with MedImmune to effect an orderly transfer or disclosure, as applicable, to MedImmune of the Know-How and Regulatory Documentation described in clauses (f) and (g) above; and
- (i) all rights and obligations of the Parties with respect to the Follow-On Program shall, to the extent in effect immediately prior to such termination, remain in effect.
- 11.7.3 <u>Termination by MedImmune for Cause or Insolvency or by Kolltan for Regulatory Reasons.</u> Subject to Section 11.8, upon termination of this Agreement in its entirety or with respect to a Program by MedImmune pursuant to Section 11.2.2 or 11.3 or by Kolltan pursuant to Section 11.4:
- (a) subject to clause (c) below, the rights and obligations of Kolltan under ARTICLE 7 (with respect to the terminated Program, if applicable) shall remain in effect solely to the extent related to Joint IP;
- (b) the rights of MedImmune under ARTICLE 7 (with respect to the terminated Program, if applicable) shall remain in effect, and subject to clause (c) below, the obligations of MedImmune under ARTICLE 7 (with respect to the terminated Program, if applicable) shall remain in effect solely to the extent related to Joint IP;
- (c) the provisions of Sections 2.4, 2.5, 4.3 (with respect to the non-terminated Program, if applicable), 7.1 and 7.2 and ARTICLE 10 (with respect to the terminated Program, if applicable) shall remain in effect indefinitely, and the provisions of ARTICLE 8 (with respect to the terminated Program, if applicable) shall remain in effect for a period of [\*\*] years after such termination; provided, however, that from and after such termination, (i) any MedImmune Know-How, MedImmune Additional Know-How and Regulatory Documentation (if applicable, in each case related to the terminated Program but excluding any MedImmune Know-How, MedImmune Additional Know-How and Regulatory Documentation related to the other Program) shall be deemed to be the Confidential Information of MedImmune (and not Kolltan) and (ii) any Joint Know-How (if applicable, related to the terminated Program) shall be deemed to be the Confidential Information of each Party;
- (d) solely in the case of termination with respect to the Licensed Program, in the event that MedImmune, in its sole discretion, requests in writing, Kolltan shall assign to MedImmune all of Kolltan's right, title and interest in and to (i) any Regulatory Documentation Controlled by Kolltan as of the effective date of such termination that is related to the Licensed Antibody or Licensed Products (but excluding any such Regulatory

Documentation that is related to Follow-On Antibodies or Follow-On Products), (ii) all data and information to be provided to MedImmune under Section 5.1 of this Agreement, to the extent then available and not previously provided to MedImmune, and (iii) any Know-How or Patents that (x) were licensed or assigned by MedImmune or its Affiliates to Kolltan pursuant to this Agreement and (y) solely relate to the Licensed Antibody or any Licensed Product or the Manufacture of the Licensed Antibody or any Licensed Product, and Kolltan shall reasonably cooperate with MedImmune to effect an orderly transfer of such Regulatory Documentation and information to MedImmune;

- (e) solely in the case of termination with respect to the Licensed Program, in the event that MedImmune, in its sole discretion, requests in writing, the Parties shall enter into good faith negotiations with respect to an agreement pursuant to which Kolltan would grant to MedImmune a license under the Kolltan IP to Research, Develop, Manufacture and Commercialize the Licensed Antibody and Licensed Products, with terms regarding degree of exclusivity, royalty or other payments, access to or assignment of technical and other information or materials owned or controlled by Kolltan or its Affiliates, transfer or amendment of applicable agreements or arrangements with Third Parties and other appropriate transition matters to be negotiated in good faith;
- (f) Kolltan shall continue to communicate with Regulatory Authorities and complete any activities as required by Applicable Law with respect to its Development and Commercialization activities with respect to such Program hereunder; and
- (g) in the case of any termination with respect to a Program, all rights and obligations of the Parties with respect to the other Program shall, to the extent in effect immediately prior to such termination, remain in effect.
- 11.7.4 <u>Termination with respect to the Licensed Program upon Effective Date of Co-Development and Co-Commercialization Agreement or Auction License Agreement.</u> Subject to Section 11.8, upon termination of this Agreement with respect to the Licensed Program pursuant to Section 11.5:
- (a) except as otherwise expressly set forth in the Co-Development and Co-Commercialization Agreement or Auction License Agreement, the provisions of Sections 2.4, 7.1 and 7.2 and ARTICLE 10 with respect to the Licensed Program shall remain in effect indefinitely, and the provisions of ARTICLE 8 with respect to the Licensed Program shall remain in effect for a period of [\*\*] years after such termination;
- (b) solely in the case of termination pursuant to the second sentence of Section 11.5, the Parties' obligations under Section 5.4.3(e)(iv) shall remain in effect; and
- (c) all rights and obligations of the Parties with respect to the Follow-On Program shall, to the extent in effect immediately prior to such termination, remain in effect.
  - 11.7.5 Expiration. Subject to Section 11.8, upon expiration of this Agreement in accordance with Section 11.1:

- (a) the rights, licenses and sublicenses granted to Kolltan hereunder with respect to the Licensed Antibody, Licensed Products, Follow-On Antibodies and Follow-On Products shall, to the extent in effect immediately prior to such expiration, remain in effect but (to the extent they have not already done so) become fully paid-up, royalty-free, transferable (to the extent not transferable previously), perpetual and irrevocable; and
- (b) the provisions of Section 2.4, ARTICLE 7 (solely with respect to the MedImmune Additional Patents and the Joint IP) and ARTICLE 10 shall, to the extent in effect immediately prior to such expiration, remain in effect indefinitely, and the provisions of ARTICLE 8 shall, to the extent in effect immediately prior to such expiration, remain in effect for a period of [\*\*] years after such termination.
- 11.7.6 Effect of Termination on Sublicenses Granted by Kolltan. In the event that Kolltan grants to any Third Party any sublicense under any license or sublicense granted to Kolltan under Section 2.1 (the "Sublicensed Rights"), upon any termination of this Agreement in its entirety or with respect to the applicable Program that results in the termination of Kolltan's rights to the Sublicensed Rights, if as of such termination the applicable sublicensee is not in breach of its obligations under the applicable sublicense agreement with Kolltan, then MedImmune shall, upon the reasonable request of such sublicensee, grant such sublicensee a license or sublicense, as applicable, under the Sublicensed Rights on substantially the same terms as Kolltan had previously granted such sublicensee a sublicensee under the Sublicensed Rights.

#### 11.8 Accrued Rights; Surviving Provisions.

- 11.8.1 Accrued Rights. Termination or expiration of this Agreement in its entirety or with respect to a Program for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration, including any rights of Kolltan under Section 6.4.5 and any rights of MedImmune under Section 3.5.2 or Sections 6.6 through 6.10, and any and all damages or remedies arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.
- 11.8.2 <u>Surviving Provisions</u>. The provisions of Sections 5.4.4, 6.6 through 6.9 (solely with respect to amounts accrued but unpaid as expiration or termination), 6.10, 9.4, 11.7 and this Section 11.8 and ARTICLE 12, and any applicable definitions in ARTICLE 1, shall survive any expiration or termination of this Agreement in its entirety or with respect to a Program for any reason, in accordance with their respective terms and conditions, and for the duration stated or, if no duration is stated, indefinitely.

#### ARTICLE 12 MISCELLANEOUS

12.1 <u>Dispute Resolution by Executive Officers.</u> In the event of any dispute between the Parties arising out of or in connection with this Agreement, including any dispute regarding the interpretation, effect, termination, validity, performance and/or breach of this Agreement or any amendments hereto (each, a "<u>Dispute</u>"), either Party may, by written notice to the other Party, refer the Dispute to the Executive Officers for attempted resolution by good faith

negotiations for a period of thirty (30) days after such notice is received (or such longer time as may be agreed by the Executive Officers) (the "Resolution Period"). In the event a Dispute is referred to the Executive Officers in accordance with the preceding sentence, (a) the Parties shall cause their respective Executive Officers to meet with each other and attempt to resolve such Dispute through good faith negotiations for the duration of the Resolution Period and (b) if the Parties are able to resolve such Dispute during the Resolution Period, upon the request of either Party, a memorandum setting forth the resolution shall be prepared and signed by the Parties. Notwithstanding anything to the contrary in this Agreement, neither Party shall initiate any action, suit or proceeding under Section 12.2 (other than any action for a temporary restraining order, preliminary injunction or other similar interim or conservatory relief) unless the applicable Dispute has been referred to the Executive Officers under this Section 12.1 and the Resolution Period with respect to such Dispute has expired.

#### 12.2 Jurisdiction and Venue.

- 12.2.1 Subject to Section 12.2.2, each Party (a) irrevocably submits to the exclusive jurisdiction of the federal and state courts located in the City of New York, State of New York (the "Court") with respect to any Dispute, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any action, suit or proceeding for such purpose in any such Court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party, and (c) agrees not to commence any action, suit or proceeding with respect to any Dispute except in such Court. Each Party further agrees that service of any process, summons, notice or document by U.S. registered mail to such Party's notice address provided for in this Agreement shall be effective service of process for any action, suit or proceeding in the Court with respect to any matters to which it has submitted to jurisdiction in this Section 12.2.1.
- 12.2.2 Notwithstanding anything in this Agreement to the contrary, any Patent Matter shall be subject to adjudication in accordance with the laws of the country in which the applicable Patent is pending or has been issued. The Parties agree that the venue of any such adjudication shall be (a) if the applicable Patent is pending in or has been issued by the United States, a U.S. federal district court sitting in the City of New York, State of New York, and (b) if the applicable Patent is pending in or has been issued by any other country, any competent court having jurisdiction over the subject of the Patent Matter sitting in the capital of such country (or if there is not any such competent court in the capital, a location reasonably proximate to the capital). For any Patent Matter and any applicable court as described in the previous sentence, each Party (w) irrevocably submits to the jurisdiction of such court, (x) agrees not to raise any objection at any time to the laying or maintaining of the venue of any action, suit or proceeding relating to such Patent Matter in such court has been brought in an inconvenient forum, including any forum non conveniens argument, and (z) irrevocably waives the right to object, with respect to any action, suit or proceeding relating to such Patent Matter, that such court does not have any jurisdiction over such Party.

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12.3 <u>Governing Law.</u> This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of New York without reference to conflicts of laws principles.

#### 12.4 Assignment.

12.4.1 By MedImmune. MedImmune may not assign this Agreement or any of its rights or obligations hereunder without the prior written consent of Kolltan, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, MedImmune may assign its rights or obligations hereunder without the prior written consent of Kolltan (but shall notify Kolltan in writing promptly after any such assignment) (a) subject to the next sentence, by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets or sale of stock or ownership interest, provided that the assignee shall expressly agree to be bound by MedImmune's obligations hereunder and that such sale is not primarily for the benefit of MedImmune's creditors, and (b) to any of its Affiliates, provided that the assignee shall expressly agree to be bound by MedImmune's obligations hereunder and that MedImmune shall remain responsible for its applicable Affiliate's performance hereunder. In the event of an acquisition of MedImmune or its assets or equity by a Third Party, such acquisition shall not provide Kolltan with rights or access to (x) any Patents or Know-How of such Third Party that becomes an Affiliate of MedImmune as a result of such acquisition, that exists prior to such acquisition, or (y) any Patents or Know-How of such Third Party, or any Affiliate of such Third Party that becomes an Affiliate of MedImmune as a result of such acquisition, that are filed or developed, as the case may be, after the date of such acquisition, in the case of (y) for so long as MedImmune (or, in the case of an acquisition of MedImmune's assets by such Third Party, the applicable program of such Third Party) continues to conduct any activities related to this Agreement independently of such Third Party, and without any sharing or transfer of relevant Know-How.

#### 12.4.2 By Kolltan.

- (a) Kolltan may not assign this Agreement or any of its rights or obligations hereunder without the prior written consent of MedImmune, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Kolltan may assign its rights or obligations hereunder without the prior written consent of MedImmune (but shall notify MedImmune in writing promptly after any such assignment):
- (i) prior to the Option Termination Date and subject to Section 12.4.2(b), by way of sale of itself or the sale of the portion of its business to which this Agreement relates (the "**Triggering Sale**"), through merger, sale of assets or sale of stock or ownership interest, to any Third Party that as of the time of such Triggering Sale (x) is not Commercializing a Competing Product or (y) has not enrolled the first patient in a Clinical Trial of a Competing Product, which Clinical Trial for such Competing Product is: (1) a Phase 3 Clinical Trial, if, as of the time of such Triggering Sale, Kolltan has enrolled the first patient in a Phase 3 Clinical Trial of a Licensed Product; (2) a Phase 2 Clinical Trial or Phase 3 Clinical Trial, if, as of the time of such Triggering Sale, Kolltan has enrolled the first patient in a Phase 2

Clinical Trial of the Licensed Product but has not enrolled the first patient in a Phase 3 Clinical Trial of the Licensed Product; or (3) a Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial, if as of the time of such Triggering Sale, Kolltan either (A) has not enrolled the first patient in any Clinical Trial of the Licensed Product or (B) has enrolled the first patient in a Phase 1 Clinical Trial of the Licensed Product but has not enrolled the first patient in a Phase 2 Clinical Trial of the Licensed Product (a "Same or Later Stage Clinical Trial"), provided that the assignee shall expressly agree to be bound by Kolltan's obligations hereunder and that such Triggering Sale is not primarily for the benefit of Kolltan's creditors:

(ii) on or after the Option Termination Date and subject to Section 12.4.2(b), by way of a Triggering Sale to any
Third Party, provided that the assignee shall expressly agree to be bound by Kolltan's obligations hereunder and that such Triggering Sale is not primarily for
the benefit of Kolltan's creditors; provided, however, that if, as of the time of such Triggering Sale, such Third Party (x) is Commercializing a Competing
Product or (y) has enrolled the first patient in a Same or Later Stage Clinical Trial of a Competing Product, then, at such Third Party's election, which shall be
delivered by written notice to MedImmune within [**] days after the date of such Triggering Sale, such Third Party shall, as promptly as practicable but in no
event more than one year following the date of such Triggering Sale, either:

(x) divest all of its right, title and interest in and to any Competing Product that, as of the time of such Triggering Sale, such Third Party is Commercializing or with respect to which such Third Party has enrolled the first patient in a Same or Later Stage Clinical Trial (and any failure by such Third Party to consummate such divestment within such time period shall be deemed a material breach of Kolltan's obligations hereunder); or

(y) assign all of its rights and obligations under this Agreement with respect to the Licensed Program to a Third Party that as of the time of such assignment (1) is not Commercializing a Competing Product or (2) has not enrolled the first patient in a Same or Later Stage Clinical Trial of a Competing Product; and

(iii) to any of its Affiliates, provided that the assignee shall expressly agree to be bound by Kolltan's obligations hereunder and that Kolltan shall remain responsible for its applicable Affiliate's performance hereunder.

(b) <u>Limitations on Reach-Through.</u> In the event of any acquisition of Kolltan or its assets or equity by a Third Party under Section 12.4.2(a)(ii), such acquisition shall not provide MedImmune with rights or access to (i) any Patents or Know-How of such Third Party, or any Affiliate of such Third Party that becomes an Affiliate of Kolltan as a result of such acquisition, that exists prior to such acquisition, or (ii) any Patents or Know-How of such Third Party, or any Affiliate of such Third Party that becomes an Affiliate of Kolltan as a result of such acquisition, that are filed or developed, as the case may be, after the date of such acquisition, in the case of (ii) for so long as Kolltan (or, in the case of an acquisition of Kolltan's assets by such Third Party, the applicable program of such Third Party) continues to conduct any activities related to this Agreement independently of such Third Party (or, in the case of an

acquisition of Kolltan's assets by such Third Party, any other programs of such Third Party), or such Affiliate of such Third Party, and without any sharing or transfer of relevant Know-How.

- 12.4.3 By Either Party. Subject to the foregoing provisions of this Section 12.4, this Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 12.4 shall be void.
- 12.5 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party uses commercially reasonable efforts to remove the condition. For purposes of this Agreement, "force majeure" shall include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.
- 12.6 <u>Notices</u>. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by facsimile transmission (receipt verified) or reputable international business courier (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to MedImmune,

addressed to: MedImmune, LLC One MedImmune Way Gaithersburg, MD 20878 Attention: EVP, Research Facsimile: (301) 398-8268

with a copy to: MedImmune, LLC One MedImmune Way Gaithersburg, MD 20878 Attention: Legal Department Facsimile: (301) 398-9263 If to Kolltan,

addressed to: Bulldog Pharmaceuticals, Inc. Midocean Chambers, Road Town, Tortola British Virgin Islands Attention: Chief Executive Officer

Attention: Chief Executive Offi Facsimile: +1 (284) 494-4568

with a copy to: Kolltan Pharmaceuticals, Inc. 300 George St., Suite 530 New Haven, CT 06511 Attention: General Counsel Facsimile: (203) 773-1300

with a copy (which shall not constitute notice) to: Covington & Burling LLP One Front Street San Francisco, CA 94111

Attention: Jim Snipes Facsimile: 415-955-6571

or to such other address for such Party as it shall have specified by like notice to the other Parties, provided that notices of a change of address shall be effective only upon receipt thereof. The effective date of any notice shall be (a) the date of delivery, if personally delivered during the recipient's normal business hours (and otherwise the first (1st) Business Day after the date of delivery), (b) the Business Day following verification of receipt, if sent by facsimile, and (c) the Business Day after dispatch, if sent by courier service.

- 12.7 <u>Export Clause</u>. Each Party agrees that, as of the Effective Date, it will not export or re-export restricted commodities or the technical data of the other Party in any form except in compliance with Applicable Law (including obtaining any required United States and non-United States government licenses).
- 12.8 <u>Waiver</u>. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.
- 12.9 <u>Severability</u>. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such

invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

- 12.10 Entire Agreement. This Agreement, together with the Schedules and Exhibits hereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties as to the subject matter of this Agreement and supersedes and terminates all prior agreements and understanding between the Parties with respect to the subject matter hereof. In particular, and without limitation, this Agreement supersedes and replaces the Existing Confidentiality Agreement and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties as to the subject matter of this Agreement other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.
- 12.11 <u>Independent Contractors.</u> Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.
- 12.12 Headings; Construction; Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Applicable Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (b) any reference to any Applicable Law refers to such Applicable Law as from time to time enacted, repealed or amended; (c) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; and (d) the words "include," "includes," "including," "exclude," "excludes," and "excluding," shall be deemed to be followed by the phrase "

- 12.13 <u>Further Actions</u>. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.
- 12.14 <u>Parties in Interest.</u> All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the Parties hereto and their respective successors, heirs, administrators and permitted assigns.
- 12.15 <u>Performance by Affiliates</u>. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.
- 12.16 <u>Counterparts</u>. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via portable document format (PDF) shall be treated as original signatures.

[Signature page to follow]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MEDIMMUNE, LLC

By: /s/ Bahija Jallal Name: Bahija Jallal

Title: EVP

BULLDOG PHARMACEUTICALS, INC.

By: /s/ Gerald McMahon Name: Gerald McMahon

Title: Director

[Signature Page]

# Exhibit 1.41

# In-License Agreements

- 1. MRC Agreement
- 2. Dyax Agreement
- 3. UT Agreement
- 4. Lonza Agreement

Exhibit 1.41 - 1

# Exhibit 1.42

## In-Licensed IP

# 1. CAT/MRC Patent Rights

Country	ApplicationStatus	AppNumber	FilDate	PatNumber
[**]	[**]	[**]	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 5 pages were omitted. [\*\*]

## 2. Dyax Patent Rights

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# 3. UTSW Patent Rights

	Application						
	Ctry	y	Status	Number	Filing Date	Patent Number	Issue Date
Ì	[**]	[*	**]	[**]	[**]	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [\*\*]

## 4. Lonza Patent Rights

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Territory	Appl. No.	Patent No.
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

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Territory	Patent or Pate Appl. No.	nt
[**]	[**]	
[**]	[**]	
[**]	[**]	
[**]	[**]	

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Exhibit 1.422 - 1

Territory	Patent or Patent Appl. No.	
[**]	[**]	
[**]	[**]	
[**]	[**]	
[**]	[**]	

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- a. and (a) all patents and patent applications in any country or supranational jurisdiction corresponding to national stage counterparts to these patents and patent applications, and (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) any other Patents licensed to MedImmune under the Lonza Agreement.
- 5. Unpatented and technical Know-How related to subject matter disclosed in applications listed above.

Exhibit 1.422 - 2

## Exhibit 1.96

#### Research Programs

Research study with external CRO, [\*\*], titled: In Vivo Evaluation of MEDI3379 and [\*\*] Alone in [\*\*] Models of [\*\*] in [\*\*] Mice

#### Exhibit 1.96 - 1

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

#### Exhibit 3.4.1

Certain Know-How to be Transferred

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [\*\*]

Exhibit 3.4.1 - 1

# Exhibit 3.6.1

## Inventory and Materials

# Inventory (Unformulated Drug Substance and Drug Product)

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# **Materials**

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Exhibit 3.6.1 - 1

#### Exhibit 3.6.2(a)

#### Inventory Storage, Formulation, Filling and Delivery

- 1. **Form of Licensed Antibody in the Inventory.** Without limiting Section 3.6.1 or <u>Exhibit 3.6.1</u>, the Licensed Antibody in the Inventory includes unformulated drug substance ("**UDS**") and drug product in non-labeled vials ("**DP**").
- 2. **Testing as of Effective Date**. Without limiting Section 3.6.2(c), MedImmune will communicate to Kolltan the results, as of the Effective Date, of any analytical testing and stability testing of the Inventory and will indicate whether (a) as of the Effective Date, the Inventory and Materials have been stored and maintained in accordance with the applicable storage specifications set forth in Exhibit 3.6.2(a)(i), (b) as of the Effective Date, stability testing of the Inventory has been conducted, and (c) as of the date of the last stability testing of the Inventory conducted prior to the Effective Date, the Inventory conformed to the applicable product specifications set forth in Exhibit 3.6.2(c)(i).
- 3. **Storage.** MedImmune will store the Inventory and Materials at MedImmune or MedImmune's Third Party warehouse(s) (collectively, the "Warehouses") for up to 90 days after the Effective Date without charge. Kolltan will notify MedImmune within 60 days after the Effective Date of Kolltan's decision to (a) continue storage of any or all quantities of the Inventory and the Materials at the Warehouses for a fee payable to MedImmune ("Storage Fee") and/or (b) transfer any or all quantities of the Inventory and Materials to a warehouse designated by Kolltan with transfer fees and storage fees for that warehouse paid directly by Kolltan. If Kolltan elects continued storage of any quantities of the Inventory and Materials by MedImmune, the Parties shall, if applicable, mutally agree on the storage terms for the Materials (to the extent they have not done so already) and MedImmune will store such quantities at the Warehouses until (x) in the case of Inventory, the applicable quantity has expired as determined by the stability study for the Inventory ("Expiration Date") or (y) in the case of Inventory and Materials, until directed by Kolltan to transfer the applicable quantity to a warehouse designated by Kolltan. Any Inventory remaining in storage at the Warehouses after the Expiration Date will be destroyed or transferred to a warehouse designated by Kolltan, all according to Kolltan's reasonable written instructions. The Storage Fee will be a pass-through, without mark-up, of the storage fee paid by MedImmune for Kolltan's Inventory and Materials at the Warehouses. For so long as any part of the Inventory or Materials are stored at any Warehouse, Kolltan shall have the right, at reasonable times and upon reasonable advance notice, to reasonably inspect such Warehouse to confirm MedImmune's compliance with its obligations under Section 3.6.2.

Exhibit 3.6.2(a) - 1

- 4. **Stability Studies.** MedImmune will continue to provide updates on the stability studies within [\*\*] days after results become available under the stability study protocols, which will be provided to Kolltan. MedImmune will charge a fee of \$[\*\*] for completion of the currently underway stability studies for Inventory. To the extent that new stability studies for Inventory are required due to unforeseen circumstances, the Parties will discuss and agree on a reasonable fee.
- 5. **Delivery.** Kolltan will provide written instructions as to the timing and manner of delivery of Inventory and Materials out of storage. MedImmune will deliver all Licensed Antibody in the Inventory as DP, i.e., drug product in non-labeled vialed form, unless otherwise requested by Kolltan. MedImmune will not, and will have no obligation to, label or (subject to Section 6 below) package the Inventory. MedImmune will prepare Inventory and Materials for shipment to Kolltan or to Kolltan's designated Third Party. At Kolltan's request, MedImmune may recommend a contract manufacturer for labeling. Kolltan will pay transfer costs to the contract manufacturer.
- 6. Formulation and Filling. When requested by Kolltan with no less than [\*\*] months' notice, MedImmune will fill DS into unlabeled vials and package them for shipment for a fee of \$[\*\*] per batch. MedImmune will formulate UDS into DS for a fee of \$[\*\*] per batch. At Kolltan's request, MedImmune may recommend a contract manufacturer for filling, labeling and/or formulation and establish a plan for the transfer of the UDS and DS and the information necessary and customary in the industry to enable a Third Party to formulate UDS and fill DS for Kolltan. Kolltan will pay for the cost of transfer to the contract manufacturer.

Exhibit 3.6.2(a) - 2

Exhibit 3.6.2(a)(i)

Inventory and Materials Storage Specifications

# Drug Product:

Storage temperatures between [\*\*]
Shipment temperatures between [\*\*]

<u>Unformulated Drug Substance</u>: Storage temperature at [\*\*]

Master Cell Bank: Stored in the [\*\*].

Reference Standard

Storage temperature at less than [\*\*]

Exhibit 3.6.2(a)(i) - 1

## Exhibit 3.6.2(c)(i)

#### **Inventory Product Specifications**

## **In-process Targets for Process Intermediates**

**Product Name:** MEDI3379 Unformulated Drug Substance (Process 1) **Formulation:** [\*\*]

Material Number: [\*\*]

Storage Container: 16 L Celsius Bag

Storage Temperature: [\*\*] Maximum Dose: [\*\*]

**Body Mass:** 40 – 150 kg

Version: 1.0

Test	Method Number	Target Expectations
Appearance	[**]	[**]
Total protein	[**]	[**]
pН	[**]	[**]
Reducing gel electrophoresis	[**]	[**]
Non-reducing gel electrophoresis	[**]	[**]
High performance size exclusion chromatography (HPSEC)	[**]	[**]
Capillary isoelectric focusing (cIEF)	[**]	[**]
MEDI3379 bioassay	[**]	[**]
Bioburden	[**]	[**]
	Exhibit 3.6.2(c)(i) - 1	

# **In-process Targets for Process Intermediates**

Product Name: MEDI3379 Unformulated Drug Substance (Process 1)		Material Number: [**]	
Formulation: [**] Storage Temperature: [**] Maximum Dose: [**] Version: 1.0			Storage Container: 16 L Celsius Bag Body Mass: 40 – 150 kg
Endotoxin (LAL)	QC-9744		[**]
COMMENTS:			
[**].			
		Revision History	
Version [**]	Reason		

# APPROVALS

Role	Printed Name	Signature
Lot Release	[**]	[**] 02 May 12
Analytical Biochemistry	[**]	[**] 3 May 12
Quality Assurance	[**]	[**] 04 May 12
	Exhibit 3.6.2(c)(i) -	- 2



### **Master Specification for Clinical Trial Material**

**Product Information** 

**Product Name:** MEDI3379 Drug Product (Process 1)

Formulation: [\*\*]

Storage Condition: [\*\*] Material Number: [\*\*]

Maximum Dose: [\*\*] Body Weight Range: 40 – 150 kg

Nominal Fill Volume: 1.0 mL Fill Volume: 1.3 mL

Comments: Not applicable

**Alternate Storage Conditions** 

Storage Condition: Not applicable Material Number: Not applicable

Storage Condition: Not applicable Material Number: Not applicable

Test, Method, and Acceptance Criteria

Test	Method	Acceptance Criteria
Appearance	[**]	[**]
pН	[**]	[**]
Total protein	[**]	[**]
Capillary isoelectric focusing	[**]	[**]
MEDI3379 bioassay	[**]	[**]
Reducing gel electrophoresis	[**]	[**]
Non-reducing gel electrophoresis	[**]	[**]
High performance size exclusion chromatography	[**]	[**]

Test	Method	Acceptance Criteria
Endotoxin (LAL)	[**]	[**]
Sub-visible particles	[**]	[**]
Extractable volume	[**]	[**]
Osmolality	[**]	[**]
Sterility	[**]	[**]

### Comments

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### Version History

Version	Reason
[**]	[**]

### Justification of Specification Worksheet (New Specifications Only)

### Section 1: Material Type Abbreviations

BIVBP = Bulk IV Bag Protectant VIVBP = Vialed IV Bag Protectant

BD = Bulk Diluent
VD = Vialed Diluent
BP = Bulk Placebo
VP = Vialed Placebo
DS = Drug Substance
DP = Drug Product

Section 2: Material Types

Material Type#1

Product Name: MEDI3379 Drug Product (Process 1)

Master Specification #: [\*\*]

Abbreviation:
DP

Formulation: [\*\*]

Storage Condition: [\*\*]

Material
Number: [\*\*]

Nominal Fill Volume: 1.0mL Target Fill Volume: 1.3 mL

Section 3: Maximum Dosage

Maximum DoseApplies to:ReferenceJustification[\*\*][\*\*][\*\*]

Section 4: Test, Acceptance Criteria and Justification

	Method		
Applies to:	Number	Acceptance Criteria	Justification
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	[**]	[**]	[**]
DP	Contract lab	[**]	[**]
	DP D	Applies to: Number    DP	Applies to:         Number         Acceptance Criteria           DP         [**]         [**]           DP         [**]         [**]

### **Section 5: Comments**

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### Section 6: Approvals

Role	Nan	ne Signature	Date
CMC Analytical Representative	[**]	[**]	13 June 12
	Exh	ibit 3.6.2(c)(i) - 6	

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

### Justification of Specification Worksheet (New Specifications Only)

CMC Team Leader	[**]	[**]	14 June 12
MSWC Coordinator	[**]	[**]	15 June 12
ABC Senior Management	[**]	[**]	18 June 12

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [\*\*]

### Exhibit 3.6.3(a)

#### Clinical and Research Supply Agreement Principles

### 1. Supply Agreement - Overview

The Clinical and Research Supply Agreement (for purposes of this Exhibit, the "Supply Agreement") will consist of general principles set forth in a main agreement and project addenda that will be entered into for specific manufacturing projects or for particular services ("Project Addenda"). At this time the Parties anticipate separate Project Addenda for (1) research supply and Phase 1 & Phase 2 clinical supply, (2) Phase 3 clinical supply, and (3) special services not covered by the supply Project Addenda such as technology transfer (except for technology transfer by MedImmune upon termination as described below), process development, formulation development and the like. Drug substance and drug product containing Licensed Antibody and Licensed Product are referred to in this Exhibit as "Product."

#### 1.1 Manufacture

MedImmune will manufacture for Kolltan those quantities of Product required by a Project Addendum. Product will be manufactured and delivered in accordance with the Project Addendum and the Quality Agreement. The Parties will agree on a forecasting procedure which may include a long term forecast and a binding forecast.

### 1.2 Data Transfer.

MedImmune will provide to Kolltan a mutually agreed data set for each lot of Product to enable Kolltan to prepare documents required for Kolltan's regulatory agency filings. The foregoing sentence notwithstanding, MedImmune has no obligation under the Supply Agreement to disclose to Kolltan any MedImmune Manufacturing Know How related to MedImmune proprietary cell culture media and nutrient feeds used in the manufacturing process.

### 1.3 Delivery Terms; Title and Risk of Loss.

Delivery terms will be FCA (Incoterms 2010) MedImmune's facility. Title and risk of loss or damage will pass to Kolltan upon delivery of Product to the designated carrier at MedImmune's facility. Kolltan will be responsible for obtaining governmental permits, consents and approvals required for export out of country of origin and for import into the destination country.

#### 1.4 Final Release of Product.

MedImmune will perform a manufacturer's release of Product and will provide Kolltan with a certificate of analysis. Kolltan will perform the final release of Product.

### 1.5 Regulatory Matters.

When requested by Kolltan, MedImmune will provide to Kolltan documentation in support of GMP Manufacture of Product for filing by Kolltan with regulatory authorities in the U.S., any of the member states of the European Union, or other jurisdictions mutually agreed in writing. If supporting such approval would require material changes or significant resources, then the Parties will first prepare a written action plan, which includes responsibilities and costs.

Exhibit 3.6.3(a) - 1

### 1.6 Assistance to Kolltan.

MedImmune will provide reasonable assistance to Kolltan with respect to any filings related to the Product that Kolltan may wish to make to a regulatory authority; such assistance may include providing to Kolltan requested documentation with respect to the services performed under the Supply Agreement. MedImmune further will provide reasonable assistance to Kolltan with respect to Kolltan responding to regulatory authorities. Any additional assistance will be subject to a separate Project Addendum with a separate fee.

1.7 Product Warranties; Acceptance and Rejection; Failure to Supply.

MedImmune will make customary warranties regarding any Product delivered to Kolltan under the Supply Agreement. The Supply Agreement will contain procedures for acceptance and rejection of Product and procedures for dispute resolution related to rejection of Product. The Supply Agreement will specify appropriate remedies for Kolltan if MedImmune fails to supply Product in a timely manner in accordance with the applicable warranties.

#### 1.8 Subcontractors

MedImmune may engage subcontractors identified on a list agreed by the Parties and attached as an exhibit to the Supply Agreement, to carry out MedImmune's responsibilities under the Supply Agreement, provided that such subcontractors are subject to the applicable terms of the Supply Agreement and Quality Agreement. The list of approved subcontractors may be updated from time to time by MedImmune with Kolltan's prior written consent, which consent will not be unreasonably withheld. MedImmune will remain responsible for the peformance by its subcontractors of its obligations under the Supply Agreement.

### 2. Quality; Audit

A quality agreement will be executed at the same time as, or prior to, the execution of a Project Addendum for GMP manufacture (the "Quality Agreement"). The Supply Agreement will include rights for Kolltan to audit and inspect MedImmune's books, records and facilities as reasonably required to comply with regulatory requirements or confirm MedImmune's compliance with its obligations under the Supply Agreement.

#### 3. Pricing

- 3.1. MedImmune will supply Product to Kolltan at rates not materially different from those charged by third party contract manufacturers.
- 3.2. Kolltan will pay invoices within 30 days after receipt.

### 4. <u>Compliance with Legal and Regulatory Requirements</u>

4.1. Appropriate provisions will be included in the Supply Agreement to ensure that each Party complies with all relevant local, national and international legal or regulatory requirements and other relevant requirements applicable to the manufacture, handing, transport and storage of Product.

### 5. Document Retention

5.1. Appropriate provisions will be included in the Supply Agreement with regard to maintaining appropriate documentation for patent and regulatory purposes and in full compliance with all applicable laws.

Exhibit 3.6.3(a) - 2

### 6. <u>Product Security and Waste Disposal</u>

6.1. Appropriate provisions will be included in the Supply Agreement with regard to product security and waste handling.

### 7. Ownership of Results and Background IPR

7.1. The applicable intellectual property provisions of the Agreement will be reflected as appropriate in the Supply Agreement.

### 8. General Provisions

8.1. Each Party agrees and acknowledges that the Supply Agreement will contain a number of other provisions that are standard in the biopharmaceutical manufacture industry, including with respect to insurance, indemnification, confidentiality, assignment, governing law and jurisdiction, which will not conflict or be inconsistent with the provisions of the Agreement.

### 9. <u>Termination</u>

- 9.1. Either Party shall have the right to terminate the Supply Agreement for convenience on appropriate notice (which in the case of MedImmune shall be on twelve (12) months' notice not to be delivered prior to December 31, 2016); or for material breach of the Supply Agreement by the other Party or insolvency.
- 9.2. The Supply Agreement shall automatically terminate:
  - 9.2.1. upon termination of the Agreement in its entirety by MedImmune due to Kolltan's material breach of the Agreement or insolvency; and
  - 9.2.2. upon termination of the Agreement by Kolltan with respect to each of the Licensed Program and the Follow-On Program under Section 11.4 of the Agreement.
- 9.3. Without limiting Section 3.6.3(b) of the Agreement (to the extent it survives termination of the Agreement, if applicable), in the event that the Supply Agreement is terminated other than (a) by MedImmune for Kolltan's material breach of the Supply Agreement or insolvency or (b) as described in Section 9.2 of this Exhibit, MedImmune will perform such technology and knowledge transfer required to ensure continuity of supply for Kolltan.

Exhibit 3.6.3(a) - 3

### Exhibit 5.4.1(c)

#### Co-Development and Co-Commercialization Agreement Terms

Capitalized terms used but not defined in this Exhibit shall have the meanings given to them in the Agreement.

Scope The Co-Development and Co-Commercialization Agreement shall set forth the rights and obligations of the Parties with

respect to the Development and Commercialization of the Licensed Antibody and Licensed Products in the Field in the

Territory.

Upfront payment Within forty-five (45) days after execution of the Co-Development and Co-Commercialization Agreement, MedImmune shall

> pay to Kolltan (a) if the Co-Development and Co-Commercialization Agreement is entered pursuant to Section 5.4.3(c) of the Agreement, an amount equal to [\*\*] percent ([\*\*]%) of the Product Acquisition Price, or (b) if the Co-Development and Co-Commercialization Agreement is entered pursuant to Section 5.4.3(d) of the Agreement, an amount equal to the Co-

> Agreement Amount (provided, however, that if the Co-Agreement Amount is less than or equal to zero, MedImmune shall not

be required to pay Kolltan an upfront payment under this clause (b)).

License grants Each Party shall grant the other Party a sole, royalty-free license (which license shall be exclusive as to Third Parties but not

as to the licensor and its Affiliates), with the right to grant sublicenses (subject to restrictions to be set forth in the Co-Development and Co-Commercialization Agreement) under any Patents or Know-How owned or controlled by such Party that are necessary or reasonably useful for the Development or Commercialization of the Licensed Antibody or Licensed Products, to Develop and Commercialize the Licensed Antibody and Licensed Products in the Field in the Territory in accordance with

the terms of the Co-Development and Co-Commercialization Agreement.

The Parties' activities under the Co-Development and Co-Commercialization Agreement shall be generally overseen by a steering committee, which shall consist of an equal number of representatives of each Party (the "Steering Committee"). The

Steering Committee shall act by consensus; provided, however, that if the Steering Committee is unable to reach consensus on a matter within the scope of its responsibility, the matter shall be escalated to the Executive Officers for attempted resolution in accordance with procedures set forth in the Co-Development and Co-Commercialization Agreement.

The Parties' Development activities under the Co-Development and Co-Commercialization Agreement shall be specifically overseen by a development committee, which shall consist of an equal number of representatives of each Party (the "JDC"), and the Parties' Commercialization activities under the Co-Development and Co-Commercialization Agreement shall be

specifically

Exhibit 5.4.1(c) - 1

Governance

overseen by a commercialization committee, which shall consist of an equal number of representatives of each Party (the "JCC"). Each of the JDC and the JCC shall act by consensus; provided, however, that if either the JDC or the JCC is unable to reach consensus on a matter within the scope of its responsibility, the matter shall be escalated to the Steering Committee.

Development activities

The Steering Committee shall determine which Party shall have primary operational responsibility for conducting Development activities with respect to the Licensed Antibody and Licensed Products in accordance with a Development plan and budget approved (and, as applicable, amended) by the JDC and thereafter approved by the Steering Committee (the "Development Plan"). To the extent feasible and based on then-existing circumstances, the Steering Committee shall use reasonable efforts to ensure that Kolltan shall assume primary operational responsibility whenever possible.

Development diligence

Each Party shall use Commercially Reasonable Efforts to carry out the activities assigned to it under the Development Plan.

Development costs

Each Party shall bear 50% of the Development Costs.

"Development Costs" will be defined more specifically in the Co-Development and Co-Commercialization Agreement but generally will mean the sum of all out-of-pocket costs incurred by a Party or its Affiliates after the effective date of the Co-Development and Co-Commercialization Agreement that are specifically identifiable to (i) the Development of the Licensed Antibody or Licensed Products or (ii) the Manufacture of the Licensed Antibody or Licensed Products in support of such Development, in each case ((i) and (ii)) in accordance with the Development Plan (subject to any cost overruns that may be permitted under the Co-Development and Co-Commercialization Agreement).

Commercialization activities

The Parties shall conduct Commercialization activities with respect to Licensed Products in accordance with a Commercialization plan approved (and, as applicable, amended) by the JCC and thereafter approved by the Steering Committee (the "Commercialization Plan").

Commercialization diligence

Each Party shall use Commercially Reasonable Efforts to carry out the activities assigned to it under the Commercialization Plan.

Exhibit 5.4.1(c) - 2

Net Profits/Losses

Each Party shall be receive or bear, as applicable, fifty percent (50%) of the Net Profits/Losses.

"Net Profits/Losses" will be defined more specifically in the Co-Development and Co-Commercialization Agreement but generally will mean Net Sales (as defined below) less Commercialization Costs.

"Net Sales" will be defined more specifically in the Co-Development and Co-Commercialization Agreement but generally will be defined in a manner analogous to the manner in which Net Sales are defined in the Agreement.

"Commercialization Costs" will be defined more specifically in the Co-Development and Co-Commercialization Agreement but generally will mean the sum of all out-of-pocket costs incurred by a Party or its Affiliates after the effective date of the Co-Development and Co-Commercialization Agreement that are specifically identifiable to (i)(x) the Commercialization of Licensed Products or (y) the Manufacture of Licensed Products in support of such Commercialization, in each case ((x) and (y)) in accordance with the Commercialization Plan (subject to any cost overruns that may be permitted under the Co-Development and Co-Commercialization Agreement), (ii) prosecution, maintenance, enforcement or defense of Patents, (iii) indemnification claims or other liabilities to Third Parties not attributable to a Party's breach, negligence or willful misconduct or (iv) obligations to Third Parties under license or other agreements relating to relevant Patents or Know-How, to the extent agreed by the Parties, in each case excluding any costs to the extent deducted under the definition of Net Sales.

If MedImmune is interested in supplying the Parties' requirements of the Licensed Antibody and Licensed Products for their Development and Co-Commercialization activities under the Co-Development and Co-Commercialization Agreement, then the Parties shall negotiate in good faith regarding a mutually acceptable supply agreement; provided, however, that if the Parties in good faith are unable to agree on the terms of such a supply agreement within a reasonable period of time, then the Parties shall negotiate in good faith with one or more Third Parties regarding a supply agreement pursuant to which the applicable Third Party would supply the Parties' requirements of the Licensed Antibody and Licensed Products for their Development and Commercialization activities under the Co-Development and Co-Commercialization Agreement.

If MedImmune is not interested in supplying the Parties' requirements of the Licensed Antibody and Licensed Products for their Development and Commercialization activities under the Co-Development and Co-Commercialization Agreement, then the Parties shall mutually agree upon a Third Party to supply such requirements.

Exhibit 5.4.1(c) - 3

Supply

Confidentiality

The Co-Development and Co-Commercialization Agreement shall include provisions regarding protection of confidential information, including confidential information disclosed under or in connection with the Agreement, that are customary for similar transactions and, to the extent applicable, consistent with the corresponding provisions of the Agreement.

Other provisions

The Co-Development and Co-Commercialization Agreement shall include provisions regarding (a) termination, (b) ownership, prosecution, maintenance, enforcement and defense of relevant Patents, (c) representations and warranties, (d) indemnification, (e) assignment and change of control and (f) governing law and resolution of legal disputes, in each case that are customary for similar transactions and, to the extent applicable, consistent with the corresponding provisions of the Agreement, and such other provisions as may be agreed by the Parties.

Exhibit 5.4.1(c) - 4

#### Exhibit 6.4.4

#### Payments under Certain In-License Agreements

### 1. UT Agreement.

- 1.1 Capitalized terms used in this Section 1 but not defined in the Agreement shall have the meanings given to them in the UT Agreement.
- 1.2 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 5.1b of the UT Agreement, Kolltan shall pay Board the following milestone fees within 30 days of the applicable milestone event for each Licensed Product (as defined in the UT Agreement) that is a Licensed Product (as defined in this Agreement); provided, however that Kolltan shall not be required to make any such payment more than once for any Licensed Product (as defined in the UT Agreement):

Milestone Event	Amount
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

1.3 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 5.1c of the UT Agreement, Kolltan shall pay Board the following commercial success milestone fees on or before March 1 of each year during the Term (as defined in the UT Agreement) based on the total worldwide Net Sales (as defined in the UT Agreement) of Licensed Products (as defined in this Agreement) in the previous Calendar Year:

Total Worldwide Net Sales (as defined in the UT Agreement) of Licensed Products (as defined in this Agreement) in the Previous Calendar Year

Agreement) in the Previous Calendar Year	Amount
Greater than \$[**] but less than or equal to \$[**]	[**]
Greater than \$[**] but less than or equal to \$[**]	[**]
Greater than \$[**] but less than or equal to \$[**]	[**]
Greater than \$[**] but less than or equal to \$[**]	[**]
Greater than \$[**]	[**]

Exhibit 6.4.4 - 1

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

Notwithstanding the foregoing, if for any Calendar Year there are Net Sales (as defined in the UT Agreement) of any product other than Licensed Products (as defined in this Agreement), then promptly after the end of such Calendar Year, MedImmune shall notify Kolltan of the total amount of Net Sales (as defined in the UT Agreement) of such products for such Calendar Year, and the amount payable by Kolltan under this Section 1.3 for such Calendar Year shall be the product of (a) the total amount owed by MedImmune or its applicable Affiliate to Board under Section 5.1c of the UT Agreement for such Calendar Year and (b) a fraction, the numerator of which is the amount of Net Sales (as defined in the UT Agreement) of Licensed Products (as defined in this Agreement) for such Calendar Year and the denominator of which is the total amount of Net Sales (as defined in the UT Agreement) for such Calendar Year.

### 2. Dyax Agreement.

- 2.1 Capitalized terms used in this Section 2 but not defined in the Agreement shall have the meanings given to them in the Unredacted Provisions of the Dyax Agreement.
- 2.2 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 13.3 of the Dyax Agreement, for any Licensed Product, Kolltan shall pay Dyax a royalty of [\*\*] percent ([\*\*]%) of Net Sales (as defined in the Dyax Agreement after substituting, for each reference in such definition to MedImmune Products, a reference to Licensed Products) of such Licensed Product; provided, however, that Kolltan shall not be required to pay such royalty with respect to sales of any Licensed Product in any country after the tenth (10th) anniversary of the first commercial sale of such Licensed Product in such country pursuant to a Regulatory Approval in such country.

### 3. <u>Lonza Agreement.</u>

- 3.1 Capitalized terms used in this Section 3 but not defined in the Agreement (or in any provision of this Section 3) shall have the meanings given to them in the Unredacted Provisions of the Lonza Agreement.
- 3.2 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 6.3 of the Lonza Agreement, for any Calendar Year, if any Product or End Product that is a Licensed Product with respect to which Commencement of Phase 2 Clinical Study has occurred, is manufactured for Kolltan by MedImmune using the LB System Technology, then Kolltan shall pay to Lonza Sales a license fee for such Calendar Year in the amount of the Applicable Amount; provided, however, that Kolltan shall not be required to make such payment for any Calendar Year (a) in which Lonza Sales or any of its Affiliates manufactures for Kolltan any Product or End Product that is a Licensed Product or (b) after the

Calendar Year in which the last-to-expire relevant patent (depending on which cell line is used for such Product or End Product) under the LB System Technology in Exhibit 2 to the Lonza Agreement in the country of manufacture expires. For purposes of this Section 3.2, the "Applicable Amount" means (x) if the relevant Licensed Product is the first Product or End Product manufactured by MedImmune (or its Affiliates), regardless of whether any given Product or End Product is manufactured for MedImmune (or its Affiliates), Kolltan (or its Affiliates) or any Third Party, using the LB System Technology with respect to which Commencement of Phase 2 Clinical Study occurred, GBP [\*\*] (£[\*\*]), (y) if the relevant Licensed Product is the second, third or fourth Product or End Product manufactured by MedImmune (or its Affiliates), regardless of whether any given Product or End Product is manufactured for MedImmune (or its Affiliates), Kolltan (or its accurred, GBP [\*\*] (£[\*\*]), and (z) if the relevant Licensed Product is the [\*\*] or later Product or End Product manufactured by MedImmune (or its Affiliates), regardless of whether any given Product or End Product is manufactured for MedImmune (or its Affiliates), Kolltan (or its Affiliates) or any Third Party, using the LB System Technology with respect to which Commencement of Phase 2 Clinical Study has occurred, [\*\*] (£[\*\*]).

- 3.3 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 6.5 of the Lonza Agreement, for any Product or End Product that is a Licensed Product and manufactured in any country for Kolltan by MedImmune using the LB System Technology, Kolltan shall pay to Lonza Sales a royalty of (a) if such Product or End Product was manufactured during the Royalty Patent Term of such Product or End Product in such country, [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product or End Product in such country, [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product or End Product in such country, [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product.
- 3.4 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 6.7 of the Lonza Agreement, for any Calendar Year, if any Product or End Product that is (a) a Licensed Product and (b) manufactured (i) by Kolltan on its own behalf or (ii) by any Third Party other than Lonza Sales or any of its Affiliates on behalf of Kolltan, in either case ((i) or (ii)) in accordance with GMP (as defined in the Lonza Agreement) requirements and using the LB System Technology, then Kolltan shall pay to Lonza Sales a sublicense fee for such Calendar Year in the amount of the product of (x) GBP [\*\*] (£[\*\*]), and (y) the number of different Products and End Products described in clauses (a) and (b) above for such Calendar Year; provided, however, that Kolltan shall not be required to make such payment for any Calendar Year (A) in which Lonza Sales or any of its Affiliates manufactures for Kolltan any Product or End Product that is a Licensed Product or (B) with respect to any Product or End Product, after the Calendar Year in which the last-to-expire relevant patent (depending on which cell line is used for such Product or End Product) under the LB System

Exhibit 6.4.4 - 3

Technology in Exhibit 2 to the Lonza Agreement in the country of manufacture expires. Any Product and any End Product that have the same active ingredient shall be counted as one for purposes of calculating the fraction described in clause (y) above.

- 3.5 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 6.8 of the Lonza Agreement, for any Product or End Product that is a Licensed Product and manufactured in any country (a) by Kolltan on its own behalf or (b) by any Third Party other than Lonza Sales (as defined in the Lonza Agreement) or any of its Affiliates on behalf of Kolltan, in either case ((a) or (b)) using the LB System Technology, in lieu of the royalty described in Section 3.3 of this Exhibit, if such Product or End Product was manufactured during the Royalty Patent Term of such Product or End Product in such country, then Kolltan shall pay to Lonza Sales a royalty of [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product or End Product.
- 3.6 In respect of MedImmune's (or its applicable Affiliate's) obligations under Section 6.9 of the Lonza Agreement, for any Product or End Product that is a Licensed Product and manufactured in any country for Kolltan by Lonza Sales or any of its Affiliates, Kolltan shall pay to Lonza Sales a royalty of (a) during the Royalty Patent Term of such Product or End Product in such country, [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product or End Product in such country, [\*\*]% of Net Sales (as defined in the Lonza Agreement) of such Product or End Product.

#### 4. Limitations; Cooperation.

4.1 Notwithstanding the foregoing provisions of this Exhibit, if for any reason MedImmune or its applicable Affiliate is not required under the applicable provision of the applicable In-License Agreement to make any payment to the applicable licensor as a result of Kolltan's activities under this Agreement with respect to the Licensed Program, or is required under the applicable provision of the applicable In-License Agreement to pay an amount to the applicable licensor as a result of Kolltan's activities under this Agreement with respect to the Licensed Program that is less than the amount described in the corresponding provision of this Exhibit, then Kolltan shall not be required to make any payment, or shall be required to pay only such lesser amount, as the case may be, to the applicable licensor in respect of such provision of such In-License Agreement. MedImmune shall promptly notify Kolltan of the existence of, and shall promptly respond to any inquiry made by Kolltan regarding, any event or circumstance that would trigger a reduced payment obligation under this Section 4.1.

Without limiting the foregoing, reasonably prior to the First Commercial Sale of the initial Licensed Product, MedImmune and Kolltan shall consult as to whether any reductions to the payment obligations described in this Exhibit apply.

Exhibit 6.4.4 - 4

- 4.2 In no event shall Kolltan be required to make any payment to any licensor in respect of any provision of any In-License Agreement in an amount that is greater than the amount described in the corresponding provision of this Exhibit.
- 4.3 As requested by Kolltan, MedImmune shall cooperate with Kolltan to determine the appropriate amount, manner and timing of any payment described in this Exhibit.

Exhibit 6.4.4 - 5

### Exhibit 9.2.3

### MedImmune Patents

MedImmune Patents

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The Patents listed in Exhibit 1.42 (excluding any MedImmune Manufacturing Patents) are incorporated into this Exhibit by reference.

Exhibit 9.2.3 - 1

### Exhibit 9.2.6

Third Party Intellectual Property

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Exhibit 9.2.6 - 1

### Exhibit 9.2.9

#### Obligations and Restrictions under In-License Agreements

### 1. UT Agreement.

- 1.1 Capitalized terms used in this Section 1 but not defined in the Agreement shall have the meanings given to them in the UT Agreement.
- 1.2 The rights granted by MedImmune to Kolltan as sublicensee under the UT Agreement are subject to the rights, conditions and limitations imposed by United States law on inventions and discoveries conceived or first actually reduced to practice during the course of research funded by a United States federal agency, as described in the first Section 3.2 of the UT Agreement.
- 1.3 MedImmune is indirectly obligated to require Kolltan to take steps as necessary and solely as they relate to Kolltan's activities under the Agreement to enable MedImmune to perform its obligations under the following provisions of the UT Agreement:
  - 1.3.1 first two sentences of Section 5.3;
  - 1.3.2 the reporting obligations described in Section 5.4;
  - 1.3.3 the second, third and fourth sentences of Section 5.5;
  - 1.3.4 Section 5.7; and
  - 1.3.5 the first and third sentences of Section 7.1.

The Parties acknowledge and agree that (a) the Agreement includes provisions whereby Kolltan is bound to take such steps, and (b) the foregoing provisions of the UT Agreement include all the terms and conditions of the UT Agreement that are applicable to Kolltan as sublicensee under the UT Agreement.

### 2. MRC Agreement

Any capitalized term used in this Section 2 but not defined in the Agreement, or used in any provision of the MRC Agreement referenced in this Section 2, (a) if such capitalized term is defined in the Unredacted Provisions of the MRC Agreement, shall have the meaning given to such capitalized term in such Unredacted Provisions, or (b) if such capitalized term is defined in the MRC Agreement other than in the Unredacted Provisions, shall be construed on the basis of the plain English meaning of the words in the capitalized term itself and the portion, if any, of the definition of such capitalized term (including any definition (or portion thereof) of any other capitalized term used directly or indirectly in the definition of such capitalized term) that is not redacted.

- 2.2 The rights granted by MedImmune to Kolltan as sublicensee under the MRC Agreement do not include the right to exercise or use the Technology or Patent Rights in the commercial sale of single variable domains (heavy or light) of antibodies.
- 2.3 MedImmune is indirectly obligated to require Kolltan to take steps as necessary to enable MedImmune to perform its obligations under Clause 21 of the MRC Agreement as they apply to Kolltan's activities under the Agreement.

### 3. <u>Dyax Agreement</u>.

- 3.1 Any capitalized term used in this Section 3 but not defined in the Agreement, or used in any provision of the Dyax Agreement referenced in this Section 3, (a) if such capitalized term is defined in the Unredacted Provisions of the Dyax Agreement, shall have the meaning given to such capitalized term in such Unredacted Provisions, or (b) if such capitalized term is defined in the Dyax Agreement other than in the Unredacted Provisions, shall be construed on the basis of the plain English meaning of the words in the capitalized term itself and the portion, if any, of the definition of such capitalized term (including any definition (or portion thereof) of any other capitalized term used directly or indirectly in the definition of such capitalized term) that is not redacted.
- 3.2 Any sub-sublicenses granted by Kolltan under its sublicense from MedImmune under the Dyax Agreement must be granted pursuant to a written agreement that (a) requires the sub-sublicensee to abide by the terms of the applicable MedImmune Product License, consistent with the terms of the Agreement and this Exhibit 9.2.9, and (b) is consistent with the Unredacted Provisions of Clauses 11, 12 and 13 of the Dyax Agreement.
- 3.3 MedImmune is indirectly obligated to require Kolltan to take steps as necessary and solely as they relate to Kolltan's activities under the Agreement to enable MedImmune to perform its obligations under the following provisions of the Dyax Agreement:
  - 3.3.1 Clause 12.4;
  - 3.3.2 the first sentence of Clause 12.9;
  - 3.3.3 the last sentence of Clause 13.4; and
  - 3.3.4 Clause 13.6 (excluding Clause 13.6.5).
- 3.4 As set forth in Clause 12.6 of the Dyax Agreement, Kolltan shall indemnify the Dyax Indemnitees against any liability, damage, loss or expense (including attorney's fees and expenses of litigation) incurred by or imposed upon the Dyax Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments by or in favor of any Third Party (as defined in the Dyax

Exhibit 9.2.9 - 2

Agreement) concerning any manufacture, use or sale of any MedImmune Product by Kolltan or its sublicensee.

- 3.5 As set forth in Clause 12.11 of the Dyax Agreement, Kolltan may assign the benefit and/or burden of its rights under any MedImmune Product License to any Affiliate (as defined in the Dyax Agreement) or Third Party (as defined in the Dyax Agreement), provided that such Affiliate (as defined in the Dyax Agreement) or Third Party (as defined in the Dyax Agreement) undertakes to Dyax to be bound by the terms of the MedImmune Product License.
- 3.6 As set forth in Clause 12.12 of the Dyax Agreement, Dyax has the right to terminate any MedImmune Product License under which Kolltan receives a sublicense in the event that Kolltan (or its sublicensee) directly or indirectly opposes or assists any Third Party (as defined in the Dyax Agreement) to oppose the grant of letters patent or any patent application within the Dyax Patent Rights, or disputes or directly or indirectly assists any Third Party (as defined in the Dyax Agreement) to dispute the validity of any patent within the Dyax Patent Rights or any of the claims thereof.

### 4. <u>Lonza Agreement</u>.

- 4.1 MedImmune is indirectly obligated to require Kolltan to take steps as necessary and solely as they relate to Kolltan's activities under the Agreement to enable MedImmune to perform its obligations under the following provisions of the Lonza Agreement:
  - 4.1.1 the reporting obligations described in Section 6.11; and
  - 4.1.2 Section 6.13.1.

Exhibit 9.2.9 - 3

### AMENDMENT To LICENSE AND OPTION AGREEMENT

This Amendment (the "Amendment") to the License and Option Agreement dated July 24, 2013 ("Agreement") by and between MedImmune, LLC, a Delaware limited liability company, with its principal executive offices located at One MedImmune Way, Gaithersburg, MD 20878 ("MedImmune"), and Bulldog Pharmaceuticals, Inc., a company organized and existing under the laws of the British Virgin Islands, having a registered office located at Midocean Chambers, Road Town, Tortola, British Virgin Islands ("Kolltan"), as previously amended on February 10, 2014, June 25, 2014 and June 30, 2014, is entered into effective as of October 27, 2015 (the "Amendment Effective Date"). MedImmune and Kolltan are each referred to herein by name or as a "Party" or, collectively, as "Parties."

### RECITALS

WHEREAS, MedImmune and Kolltan desire to eliminate from the Agreement certain Option Rights regarding the Licensed Antibody and the Licensed Products;

WHEREAS, Kolltan desires to purchase from MedImmune certain additional quantities of Licensed Antibody and Licensed Products for non-commercial clinical research purposes; and

WHEREAS, MedImmune is willing to supply such additional quantities of Licensed Antibody and Licensed Product to Kolltan,

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the Parties hereto agree as follows:

### Definitions.

- 1.1 Capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.
- 1.2 The definition of Inventory set forth in Section 3.6.1 of the Agreement is hereby amended to mean any and all Drug Substance and Drug Product (each as defined below) delivered or to be delivered to Kolltan by MedImmune, regardless of whether such Drug Substance or Drug Product was existing as of the Effective Date of the Agreement.
- 1.3 The definition of "MedImmune Manufacturing Information and Inventions" set forth in Section 1.70 of the Agreement is hereby amended as follows: Know-How (a) that is Controlled by MedImmune or its Affiliates on the Effective Date or thereafter during the Term and (b) either (i) the practice of which is necessary in order to Manufacture the Licensed Antibody, any Licensed Product, any Follow-On Antibody or any Follow-On Product in the Field in the Territory or (ii) relates to the Manufacture of the Licensed Antibody, any Licensed Product, and Follow-On Antibody or any Follow-On Product in the Field in the Territory and is expressly disclosed in the Existing IND; provided, however, that MedImmune Manufacturing Information and Inventions excludes any Joint Information and Inventions. For avoidance of doubt, MedImmune Manufacturing Information and Inventions shall not include any Know-How related to MedImmune proprietary cell culture media and nutrient feeds used in the Manufacturing process.
- 2. <u>Deletion of Option Rights Provisions</u>. Article 5 (Option Rights) is hereby deleted in its entirety. The Parties agree that all obligations with respect to Article 5, as of the Amendment Effective Date, have been met, subject to the Representations and Warranties made in Section 11 of this Amendment, and neither Party shall have any further rights or obligations pursuant thereto. Without limitation of the foregoing, MedImmune shall retain no Option Rights under the Agreement. The Amendment Effective Date will be the Option Termination Date for the purposes of the Agreement.

### 3. <u>Inventory Supply</u>.

- (a) MedImmune will deliver to Kolltan:
  - existing Inventory of [\*\*] lots of Licensed Antiobody in formulated bulk drug substance form ("Drug Substance") filled into the current vial configuration and fill volume ("Drug Product"); and
  - ii. additional Inventory of [\*\*] lots of Drug Substance, delivered as Drug Product, each manufactured at the [\*\*] bioreactor scale, for delivery on or before July 31, 2017. The pricing and payment terms for Drug Substance and Drug Product are set forth in Appendix A to this Amendment.
- (b) MedImmune may, in its sole discretion, (1) produce Drug Substance at either the Gaithersburg Pilot Facility located at One MedImmune Way, Gaithersburg, MD ("GPF") or the Gaithersburg Pilot Facility—North located at 45 West Watkins Mill Rd, Gaithersburg, MD ("GPF-North"), (2) pool two 200L cell culture lots into one purification (Drug Substance) lot, and (3) pool more than one Drug Substance lot into one Drug Product lot.
- (c) In the event that Drug Substance manufacturing is performed at GPF-North and requires analytical comparability and stability testing activities, MedImmune and Kolltan will discuss the specific activities and associated pricing. Such activities and costs shall correspond to standard comparability and stability testing activities.
- (d) Kolltan shall bear the responsibility for conducting any compatibility assessment between Drug Substance and Drug Product provided by MedImmune and any other Drug Substance or Drug Product. MedImmune shall have no additional supply obligations under the Agreement beyond those set forth above. For the avoidance of doubt, MedImmune will have no obligation to supply Drug Substance or Drug Product for commercial use to Kolltan.
- (e) MedImmune will make Drug Substance and Drug Product available to Kolltan under the terms and conditions set forth in Section 3.6.1 and 3.6.2 of the Agreement with respect to the Inventory, except as expressly set forth in this Section 3, and such Drug Substance and Drug Product shall be treated as Inventory for all other purposes under the Agreement. MedImmune warrants that all Drug Substance and Drug Product will, as of the date of delivery to Kolltan, conform to the applicable product specifications.
- (f) With respect to Drug Substance and Drug Product supplied under this Amendment (excluding Inventory existing as of the Effective Date of the Agreement), the indemnification provided in Section 10.2(b) by MedImmune will be modified by insertion of the underlined language below:

"MedImmune shall defend, indemnify and hold harmless the Kolltan Indemnitees from and against any and all Losses relating to or in connection with a Third Party claim arising out of \*\*\* (b) any death, personal bodily injury or damage to real or tangible personal property alleged or proven to result, directly or indirectly, from the gross negligence or willful misconduct of MedImmune and the possession, use or consumption of, or treatment with, any Licensed Antibody or Licensed Product included in or produced from the Inventory, including any product liability claims; \*\*\*"

4. <u>Deletion of Clinical and Research Supply Provision</u>. Section 3.6.3. (Clinical and Research Supply of Licensed Antibody and Licensed Products) is hereby deleted in its entirety. The Parties agree that all

obligations with respect to Section 3.6.3, as of the Amendment Effective Date, have been met with no further rights and obligations outstanding.

- 5. <u>Deletion of Commercial Supply Provision</u>. Section 3.6.4 (Commercial Supply) is hereby deleted in its entirety. The Parties agree that all obligations with respect to Section 3.6.4, as of the Amendment Effective Date, have been met with no further rights and obligations outstanding.
- 6. **Deletion of Supply of Media Provisions.** Section 3.6.5 (Supply of Media) is hereby deleted in its entirety. The Parties agree that all obligations with respect to Section 3.6.5, as of the Amendment Effective Date, have been met with no further rights and obligations outstanding.
- 7. Amendment of Prosecution and Maintenance of Patents Provision. Section 7.3.1(c) is amended and restated in its entirety to read as follows:

Kolltan shall bear responsibility for all costs associated with the filing, prosecution and maintenance of any MedImmune Patent or Joint Patent. MedImmune shall have the right to assign any such Patent in any country (or, in case of a Joint Patent, to assign MedImmune's interest in such Joint Patent in any country) to Kolltan, in which case at Kolltan's election, such Patent (or Joint Patent) in such country shall thereafter be deemed a Kolltan Patent, or (in the case of a MedImmune Patent) may be abandoned.

In addition, within ninety (90) days of the Amendment Effective Date, Kolltan will provide an invoice to MedImmune for any Out-of-Pocket Costs incurred prior to the Amendment Effective Date, for which MedImmune shall promptly reimburse Kolltan.

- 8. <u>Survival</u>. If Kolltan terminates the Agreement pursuant to Section 11.2.1 of the Agreement, this Amendment, and the rights and obligations of the Parties hereunder, shall survive such termination.
- 9. **Reference to Aareement.** Upon and after the Amendment Effective Date, each reference in the Agreement to "this Agreement", "hereunder", "hereof' or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.

- 10. Effectiveness of Amendment. Upon execution and delivery of this Amendment by both Parties, the amendments set forth above shall be effective as of the Amendment Effective Date. This Amendment supersedes all previous amendments and addenda to the Agreement, except as otherwise provided. Drug Substance and Drug Product delivered pursuant to the Addendum dated June 25, 2014, will be subject to the terms and conditions of the Agreement as amended by this Amendment. Except as specifically amended above, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the Parties.
- 11. **Representations and Warranties.** A new Section 9.5 is added to read as follows:
  - 9.5 Kolltan hereby represents to MedImmune, as of the Amendment Effective Date, that it has disclosed to MedImmune all material clinical data under the Control of Kolltan with respect to the Licensed Antibody or a Licensed Product.
- 12. <u>No Waiver</u>. The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.
- 13. <u>Counterparts.</u> This Amendment may be executed in counterparts, each of which is an original, but all of which together constitute one and the same instrument.

The Parties have executed this Amendment to be effective as of the Amendment Effective Date.

BULLDOG PHARMACEUITCALS, INC.
By: /s/ Gerald McMahon Name: Gerald McMahon

MEDIMMUNE, LLC
By: /s/ Kripa Ram
Name: Kripa Ram
Title: Vice President
Date: October 29, 2015

Title: Director

Date: October 27, 2015

### APPENDIX A

### **Pricing**

### A. Prices for the Services

The following services will be provided by MedImmune at the prices set forth below for [\*\*] lots of Drug Substance and thus, the total costs for this work will be calculated based on the relative number of lots of Drug Substance produced.

Activities and Services	Price (in \$)
Activity 1: Pre-production activities and on-going project management	Estimate
Ongoing project management	[**]
Periodic meetings	
Activity #2: Resins, raw materials and consumables for two runs:	Estimate
Purchase of resins, raw materials and consumables	[**]
Note: Estimated costs. Actual raw material costs will be billed to Kolltan	
Activity #3: Clinical GMP Drug Substance Production	Estimate
Manufacture according to cGMP standards	[**]
<ul> <li>Perform release testing as described in IND 116023 and preparation of Certificate of Analysis</li> </ul>	
Includes additional in-process testing of intermediates	
Includes preparation of a campaign summary report	
Note: No stability testing necessary if Manufacture using same scale and equipment as in IND 116023	
Activity #4: Drug Product Manufacturing	Estimate
Ship material to fill finish site	[**]
<ul> <li>Perform Drug Product fills into unlabeled vials using the fill-finish Manufacturing process described in IND 116023</li> </ul>	
Production batch records prepared by MedImmune and approved by Kolltan	
Perform release testing as described in the current IND and preparation of Certificate of Analysis	
Includes all Raw Materials and consumable needed for Manufacturing	
Ship material to Kolltan-defined site	
TOTAL	[**]
TOTAL	[ ]



### THIRD AMENDED AND RESTATED LICENSE AGREEMENT

THIS THIRD AMENDED AND RESTATED LICENSE AGREEMENT (this "AGREEMENT"), dated as of March 14, 2013 (the "THIRD AMENDMENT EFFECTIVE DATE"), by and between YALE UNIVERSITY, a corporation organized and existing under and by virtue of a charter granted by the general assembly of the Colony and State of Connecticut and located in New Haven, Connecticut ("YALE"), and KOLLTAN PHARMACEUTICALS, INC., a corporation organized and existing under the laws of the State of Delaware, and with principal offices located at 300 George Street, New Haven, CT 06511 ("LICENSEE") is effective as of the THIRD AMENDMENT EFFECTIVE DATE.

### RECITALS:

WHEREAS, in the course of research conducted under YALE auspices, Dr. Joseph Schlessinger, an employee of YALE ("SCHLESSINGER"), and the other inventors performing research under SCHLESSINGER's immediate supervision (together with any and all people from time to time performing research under SCHLESSINGER's immediate supervision at YALE, the "SCHLESSINGER LAB") and Dr. Irit Lax, an employee of YALE ("LAX"), and the other inventors performing research under LAX's immediate supervision, in the course of studying RTK biology, have produced and may continue to produce compositions of matter, know-how, methods, data and intellectual property that have and may continue to lead to the discovery and development of active substances that may induce, prevent, modify or otherwise modulate the activation of an RTK for the purpose of diagnosing, preventing or treating a disease or condition (the "INVENTIONS");

WHEREAS, as of the THIRD AMENDMENT EFFECTIVE DATE, SCHLESSINGER serves on the LICENSEE Board of Directors and the LICENSEE Scientific Advisory Board, and as a paid consultant to LICENSEE;

WHEREAS, YALE permits its faculty such as SCHLESSINGER to engage in consulting consistent with YALE policies such as the Yale University Patent Policy, and LICENSEE acknowledges that SCHLESSINGER's involvement with LICENSEE is subject to the Yale University Patent Policy;

WHEREAS, YALE wishes to have the INVENTIONS and any resulting patents commercialized to benefit the public good;

WHEREAS, to induce YALE to enter into this AGREEMENT, LICENSEE has represented that it has been formed for the purpose of developing and commercializing PRODUCTS IN CLASS or LICENSED METHODS and that it intends to develop the skill and expertise to seek to develop and commercialize the PRODUCTS IN CLASS or LICENSED METHODS for public use in the LICENSED TERRITORY;

WHEREAS, YALE is willing to grant a license to LICENSEE, subject to the terms and conditions of this AGREEMENT;

WHEREAS, YALE and LICENSEE have previously entered into an Exclusive License Agreement (the "ORIGINAL LICENSE AGREEMENT"), dated May 30, 2008 (the "ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE");

WHEREAS, YALE and LICENSEE have previously entered into an Amended and Restated Exclusive License Agreement (the "AMENDED AND RESTATED LICENSE AGREEMENT"), dated November 23, 2010;

WHEREAS, YALE and LICENSEE have previously entered into a Second Amended and Restated Exclusive License Agreement (the "SECOND AMENDED AND RESTATED LICENSE AGREEMENT"), dated December 23, 2011(the "EFFECTIVE DATE") and they now wish to amend and restate the SECOND AMENDED AND RESTATED LICENSE AGREEMENT in its entirety; and

WHEREAS, in order to minimize potential disagreements between the parties as to the genesis of unpatented know-how, materials and methods incorporated by LICENSEE into its RTK PRODUCTS during periods when SCHLESSINGER is MEANINGFULLY INVOLVED AT KOLLTAN and MEANINGFULLY INVOLVED AT YALE, the parties have agreed that certain RTK PRODUCTS developed by Kolltan during such period shall be deemed PRODUCTS IN CLASS under this AGREEMENT;

NOW THEREFORE, in consideration of these statements and mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which the parties hereby acknowledge, YALE and LICENSEE agree to the terms of this AGREEMENT.

### ARTICLE 1 REPRESENTATIONS AND WARRANTIES

- 1.1. LICENSEE represents and warrants to YALE as follows:
- (a) LICENSEE is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; has all corporate power to carry on its business as presently conducted and to own and operate its properties and assets;
- (b) The execution, delivery and performance by LICENSEE of this AGREEMENT have been duly authorized by all necessary corporate action by LICENSEE;
- (c) There is no pending or, to LICENSEE's knowledge, threatened litigation involving LICENSEE which would have any material adverse effect on this AGREEMENT or on LICENSEE's ability to perform its obligations hereunder; and
- (d) There is no indenture, contract or other agreement to which LICENSEE is a party or by which LICENSEE is bound which prohibits or would prohibit the execution and delivery by LICENSEE of this AGREEMENT or the performance or observance by LICENSEE of any material term of provision of this AGREEMENT.

1.2. YALE represents and warrants to LIC	ENSEE	as ioi	lows
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- (a) The execution, delivery and performance by YALE of this AGREEMENT have been duly authorized by all necessary requisite action on the part of YALE and YALE has all right, power and authority necessary to grant the LICENSE and to perform its obligations hereunder;
- (b) There is no pending or, to YALE's knowledge, threatened patent or contract litigation involving YALE which would have any material adverse effect on this AGREEMENT or on YALE's ability to perform its obligations hereunder;
- (c) There is no indenture, contract or other agreement to which YALE is a party or by which YALE is bound which prohibits or would prohibit the execution and delivery by YALE of this AGREEMENT or the performance or observance by YALE of any material term or provision of this AGREEMENT;

(d)

- (i) YALE holds all right, title and interest in and to the LICENSED PATENTS existing as of the EFFECTIVE DATE and is the sole and exclusive owner thereof, subject only to the rights, if any, of the United States government and its agencies, as specified in Section 3.5; and
- (ii) Except as set forth on Appendix D, YALE has adequate right, title and interest in and to the LICENSED KNOW-HOW, LICENSED MATERIALS and LICENSED METHODS existing as of the EFFECTIVE DATE sufficient to grant the LICENSE thereof to LICENSEE under this AGREEMENT and LICENSEE does not have and will not have any present or future obligations to any third party arising out of such grant; and
- (iii) Except as set forth on Appendix D, as of the EFFECTIVE DATE, neither YALE's Office of Cooperative Research, SCHLESSINGER nor LAX has received written notice of, and has no reasonable knowledge of any basis for, any claim that the use by LICENSEE of TECHNOLOGY, if and to the extent such use is known to YALE's Office of Cooperative Research, SCHLESSINGER or LAX, infringes on any patent or misappropriates any other intellectual property or ownership right of any third party; and

(e)

- (i) Except to the extent such LICENSED PATENTS have been invented or co-invented by an individual who is not SCHLESSINGER, LAX, or an employee in the SCHLESSINGER LAB or the LAX LAB, YALE will hold all right, title and interest in and to the LICENSED PATENTS that arise after the EFFECTIVE DATE and YALE will be the sole and exclusive owner thereof, subject only to the rights, if any, of the United States government and its agencies, as specified in Section 3.5; and
- (ii) YALE will have adequate right, title and interest in and to the LICENSED PATENTS (to the extent such LICENSED PATENTS have been invented or co-invented by an individual who is not SCHLESSINGER, LAX, or an employee in the SCHLESSINGER LAB or the LAX LAB) and LICENSED MATERIALS that arise after the EFFECTIVE DATE, in each case sufficient to grant the LICENSE thereof to LICENSEE under this AGREEMENT and, except as YALE may inform LICENSEE in writing upon the provision of any such LICENSED MATERIALS to LICENSEE, LICENSEE will not have any present or future obligations to any third party arising out of such grant with respect to such LICENSED PATENTS or LICENSED MATERIALS; and

- (f) YALE will promptly notify LICENSEE in writing if, after the EFFECTIVE DATE, YALE's Office of Cooperative Research, SCHLESSINGER or LAX receives written notice of, or has reasonable knowledge of any basis for, any claim that the use by LICENSEE of TECHNOLOGY, if and to the extent such use is known to YALE's Office of Cooperative Research, SCHLESSINGER or LAX, infringes on any patent or misappropriates any other intellectual property or ownership right of any third party relating to RTK TECHNOLOGY; and
- (g) So as to minimize the chances of any future disputes, YALE will use good faith reasonable efforts to segregate any work SCHLESSINGER or LAX may undertake with respect to [\*\*]-FUNDED PATENTS, and intellectual property related thereto, from any other work SCHLESSINGER or LAX may undertake with respect to RTK TECHNOLOGY and RTK PRODUCTS; and
- (h) Each YALE employee who is an inventor of potentially patentable intellectual property licensed pursuant to this AGREEMENT has agreed to assign to YALE (and, in the case of such potentially patentable intellectual property existing as of the EFFECTIVE DATE, has assigned to YALE), by written instrument sufficient in form, scope and substance for such purpose, all of such inventor's right, title and interest in and to such potentially patentable intellectual property and any resulting patents.

#### ARTICLE 2 DEFINITIONS

The following terms used in this AGREEMENT shall be defined as set forth below:

- 2.1. "AFFILIATE" shall mean any entity or person that directly or indirectly controls, is controlled by or is under common control with LICENSEE. For purposes of this definition, "control" means possession of the power to direct the management of such entity or person, whether through ownership of more than fifty percent (50%) of voting securities, by contract or otherwise.
- 2.2. "APPROVED PRODUCT" shall mean a PRODUCT, the sale, marketing, and use of which in humans (or other animals) has been approved by the FDA, or, as to a PRODUCT sold, marketed, or used in a country other than the United States, that has been approved to the extent necessary by the comparable required government authority in such country.

#### 2.3. "CHANGE OF CONTROL" shall mean:

- (a) any consolidation, merger, combination, reorganization or other business combination transaction to which LICENSEE is a party and in which LICENSEE is not the surviving entity; or
- (b) (i) all of the outstanding shares of voting stock of LICENSEE are exchanged for or changed into other stock or securities, cash, financial vehicle and/or any other property and (ii) persons who were stockholders of LICENSEE immediately prior to such exchange or change do not hold securities entitled to at least 50% of the voting power of the entity surviving such exchange or change or the entity into whose securities for or into which the voting stock of LICENSEE is exchanged or changed; or

(c) a sale or other disposition (other than by license and/or sublicense) of all or substantially all of the assets of LICENSEE for cash, securities or other property;

and in any such case in the preceding clause (a), (b) or (c) the surviving entity in such transaction (if LICENSEE is not the surviving entity) or LICENSEE and the entity of which LICENSEE shall have become an AFFILIATE in such transaction or the person who shall have purchased or otherwise acquired all or substantially all of LICENSEE's assets, as the case may be, shall meet all of the following:

- 1. immediately after such transaction, shall have cash and cash equivalent assets at least equal to \$200 million, determined on a pro forma consolidated basis; and
- 2. during the two fiscal years immediately preceding such transaction, shall have had positive cash flow, determined on a pro forma consolidated basis; and
- 3. immediately after such transaction, the amount of its cash and cash equivalent assets shall equal at least twice its cash requirements for the 12 consecutive full calendar months immediately following such transaction, determined on a pro forma consolidated basis.
  - 2.4. "CLAIMS" is defined in Section 14.1.
- 2.5. "CONFIDENTIAL INFORMATION" shall mean all information disclosed by one party to the other during the negotiation of or under this AGREEMENT, the SECOND AMENDED AND RESTATED LICENSE AGREEMENT, the AMENDED AND RESTATED LICENSE AGREEMENT or the ORIGINAL LICENSE AGREEMENT in any manner, whether in writing or orally, visually or in tangible form, that relates to the TECHNOLOGY or this AGREEMENT or the SECOND AMENDED AND RESTATED LICENSE AGREEMENT or the AMENDED AND RESTATED LICENSE AGREEMENT or the ORIGINAL LICENSE AGREEMENT, unless such information is subject to an exception described in Section 8.2 and shall include the terms of any sublicense or proposed sublicense and any information or reports of or about any SUBLICENSEE that LICENSEE may from time to time provide to YALE pursuant to this AGREEMENT; provided, however, that CONFIDENTIAL INFORMATION that is disclosed in tangible form shall be marked "Confidential" at the time of disclosure and CONFIDENTIAL INFORMATION that is disclosed orally or visually shall be identified as confidential within thirty (30) days of such disclosure. CONFIDENTIAL INFORMATION shall include, without limitation, materials, know-how and data, technical or non-technical, inventions, methods and processes, whether or not patentable and all information provided by LICENSEE to YALE pursuant to Sections 7.3 and 9.3. Notwithstanding anything in this Section, CONFIDENTIAL INFORMATION shall be deemed to include any scientific data, information or know-how that a reasonable scientist would believe is confidential, whether in written, oral, visual or tangible form, disclosed by LICENSEE to SCHLESSINGER or LAX, unless such information is subject to an exception described in Section 8.2.

- 2.6. "DESIGNATED THIRD PARTY RTK PRODUCT" shall mean an RTK PRODUCT where LICENSEE acquired or in-licensed from a third party (i.e., a party other than YALE) intellectual property claiming such RTK PRODUCT and either:
- (a) Such RTK PRODUCT is (or another RTK PRODUCT against the same RTK and acquired or in-licensed from the same source is) the subject of an IND, or similar filing outside the United States, either at the time of such acquisition or in-license or within six (6) months thereafter (an "IND PRODUCT"); or
- (b) Such RTK PRODUCT is not an IND PRODUCT, and, subsequent to such acquisition or in-licensing, LICENSEE does not file a patent application listing one or more LICENSEE employees as inventors where such patent application claims the composition of matter or method of use of such RTK PRODUCT;

provided, however, if, in the case of (a) or (b) above, (x) prior to such acquisition or in-licensing, LICENSEE has filed a patent application listing one or more LICENSEE employees as inventors where such patent application claims the composition of matter of such RTK PRODUCT or (y) after such acquisition or in-licensing, LICENSEE conducts (or contracts with a third party to conduct on behalf of LICENSEE) pre-clinical or clinical development on such RTK PRODUCT, then (in the case of (x) or (y)), such RTK PRODUCT shall not be a DESIGNATED THIRD PARTY RTK PRODUCT.

- 2.7. "EARNED ROYALTY" is defined in Section 6.1.
- 2.8. "EFFECTIVE DATE" shall mean have the meaning set forth in the recitals of this AGREEMENT.
- 2.9. "FDA" shall mean the United States Food and Drug Administration or any comparable governmental agency in any territory with regulatory authority in or for a country or group of countries other than the United States.
  - 2.10. "FEDERAL PATENT POLICY" is defined in Section 3.5.
- 2.11. "FIRST SALE" shall mean the first sale to a third party of any PRODUCT IN CLASS in any country in which such product is an APPROVED PRODUCT, or the first sale to a third party of a service using a LICENSED METHOD. For the avoidance of doubt, if LICENSEE is providing services to a third party in the context of a sublicense of the TECHNOLOGY or a drug development collaboration with such third party, the provision of such services shall not qualify as a FIRST SALE.
  - 2.12. "GAAP" is defined in Section 9.3
- 2.13. "[\*\*]-FUNDED PATENTS" shall mean any United States or foreign patent application(s) and patents(s) filed by or on behalf of YALE during the TERM that claim RTK TECHNOLOGY, where such RTK TECHNOLOGY is made, created, developed, discovered, conceived or first reduced to practice by or on behalf of SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB and such activities (i.e., the making, creation, development, discovery, conception or first reduction to practice of such RTK TECHNOLOGY)

are funded in whole or in part by [\*\*] pursuant to an agreement between [\*\*] and YALE in effect as of the EFFECTIVE DATE. To the extent that YALE has the right with respect to such patent applications or patents to grant rights to parties other than [\*\*], such rights held by YALE shall not be deemed to be [\*\*]-FUNDED PATENTS and shall thus be included in the definition of LICENSED PATENTS (to the extent such rights would otherwise fall within the definition of LICENSED PATENTS). In order to establish clarity, when any patent application that is a [\*\*]-FUNDED PATENT publishes, YALE shall notify LICENSEE within thirty (30) days of the date of such publication.

- 2.14. "IND" shall mean an Investigational New Drug and/or Diagnostic application filed with the FDA prior to beginning clinical trials in humans (or other animals) in the United States or in or for any country or group of countries outside the United States.
  - 2.15. "IND APPROVAL" shall mean approval of an IND filed with the FDA.
  - 2.16. "INDEMNIFIED PERSONS" is defined in Section 14.1.
  - 2.17. "INVENTIONS" is defined in the recitals to this AGREEMENT.
- 2.18. "INSOLVENT" shall mean that that LICENSEE (i) has admitted in writing its inability to pay its debts generally when due or (ii) has commenced bankruptcy, reorganization, receivership or insolvency proceedings, or any other proceeding under any Federal, state or other law for the relief of debtors.
  - 2.19. "KOLLTAN PATENTS" shall mean:
    - (a) the United States or foreign patent application(s) and patents(s) listed in Appendix F;
- (b) any United States or foreign patent application(s) and patents(s) filed by or on behalf of LICENSEE after the EFFECTIVE DATE that claim RTK TECHNOLOGY, where the RTK TECHNOLOGY claimed in such patent application(s) or patents(s) was made, created, developed, discovered, conceived or first reduced to practice by a LICENSEE employee while SCHLESSINGER is or was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN;
- (c) any continuations, divisionals, and continuations-in-part, and continued prosecution application(s), to the extent the claims of any such patent or patent application are directed to subject matter specifically described in the patent applications described in clause (a) or (b);
- (d) any reissues, re-examinations, renewals, or extensions of patent applications or patents described in clause (a), (b) or (c), or substitutes therefor, and
  - (e) the relevant international equivalents of any of the patents or patent applications described in clause (a), (b), (c) or (d).

Appendix F is incorporated into this AGREEMENT.

- 2.20. "LAX" is defined in the recitals to this AGREEMENT.
- 2.21. "LAX LAB" shall mean LAX, and any other individuals performing research from time to time under LAX's immediate supervision at YALE, for so long as LICENSEE provides the RESEARCH SUPPORT described in Section 3.4(b).
  - 2.22. "LICENSE" is defined in Section 3.4.
- 2.23. "LICENSED KNOW-HOW" shall mean (i) except as set forth on Appendix D, any inventions (other than LICENSED PATENTS) and any information, know-how, technical and non-technical data, processes and any drawings, plans, diagrams, specifications, and/or other documents or data forms containing such information (collectively, the "KNOW-HOW"), discovered, developed or acquired by or on behalf of SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB (including, for the avoidance of doubt, under the RESEARCH AGREEMENT), in each case prior to or after the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE, that may be used for the discovery, development, selection, improvement of, or use as, an RTK PRODUCT or LICENSED METHOD; and (ii) the VISITING SCIENTIST IP, that: (x) in the case of both (i) and (ii), is not claimed in a LICENSED PATENT and (y) in the case of (i) only, is disclosed to LICENSEE by SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB and that, with respect to such KNOW-HOW that is discovered, developed or acquired after the EFFECTIVE DATE, is discovered, developed or acquired while SCHLESSINGER is or was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN.
- 2.24. "LICENSED MATERIALS" shall mean, except as set forth on Appendix D, tangible materials (including, but not limited to, pharmaceutical, chemical and biochemical products) (collectively, the "MATERIALS") discovered, developed or acquired by or on behalf of SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB (including, for the avoidance of doubt, under the RESEARCH AGREEMENT) prior to or after the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE that may be used for the discovery, development, selection, improvement of or use as an RTK PRODUCT or LICENSED METHOD, that is provided to LICENSEE by SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB and that, with respect to such materials that are discovered, developed or acquired after the EFFECTIVE DATE, are discovered, developed or acquired while SCHLESSINGER is or was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN. To the extent that any materials provided by SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB to LICENSEE after the EFFECTIVE DATE are not owned 100% by YALE, YALE shall, at the time such materials are provided to LICENSEE, notify LICENSEE of such fact in writing (with such notice identifying the source of such materials and which other party(ies) might have an ownership interest in such materials) and this definition shall only apply to the extent of YALE's ownership interest in such materials. It is the parties' intention, promptly following the EFFECTIVE DATE, to enter into a material transfer agreement to establish other terms and conditions with respect to tangible materials transferred between the parties.
- 2.25. "LICENSED METHODS" shall mean any method, procedure, service or process (collectively, the "METHODS"), discovered, developed or acquired by or on behalf of

SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB, whether existing on or after the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE, the practice of which, in the absence of a license from YALE, would infringe a VALID CLAIM of a LICENSED PATENT or which uses or is derived from LICENSED KNOW-HOW, LICENSED MATERIALS, and/or the LICENSED PATENTS, in each case that is disclosed to LICENSEE by SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB and, that, with respect to such methods that are discovered, developed or acquired after the EFFECTIVE DATE, are discovered, developed or acquired while SCHLESSINGER is or was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN. To the extent that any METHODS provided by SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB to LICENSEE after the EFFECTIVE DATE are not owned 100% by YALE, YALE shall, at the time such METHODS are provided to LICENSEE, notify LICENSEE of such fact in writing (with such notice identifying the source of such METHODS and which other party(ies) might have an ownership interest in such METHODS) and this definition shall only apply to the extent of YALE's ownership interest in such METHODS.

### 2.26. "LICENSED PATENTS" shall mean:

- (a) the United States or foreign patent application(s) and patents(s) listed in Appendix A and owned by YALE during the TERM;
- (b) to the full extent owned or controlled (with the ability to grant licenses or sublicenses) by YALE, any United States or foreign patent application(s) and patents(s) filed by or on behalf of YALE after the EFFECTIVE DATE that claim RTK TECHNOLOGY, (i) where such RTK TECHNOLOGY is made, created, developed, discovered, conceived or first reduced to practice by or on behalf of SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB (including, for the avoidance of doubt, under the RESEARCH AGREEMENT) and, (ii) solely with respect to United States or foreign patent application(s) and patents(s) filed after the EFFECTIVE DATE and not arising under the RESEARCH AGREEMENT, where the RTK TECHNOLOGY claimed in such patent application(s) or patents(s) was made, created, developed, discovered, conceived or first reduced to practice while SCHLESSINGER is or was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN; but in all cases excluding the [\*\*]-FUNDED PATENTS;
- (c) any continuations, divisionals, and continuations-in-part, and continued prosecution application(s), to the extent the claims of any such patent or patent application are directed to subject matter specifically described in the patent applications described in clause (a) or (b);
- (d) any reissues, re-examinations, renewals, or extensions of patent applications or patents described in clause (a), (b) or (c), or substitutes therefor; and
  - (e) the relevant international equivalents of any of the patents or patent applications described in clause (a), (b), (c) or (d).

Appendix A is incorporated into this AGREEMENT.

- 2.27. "LICENSED TERRITORY" shall mean Worldwide.
- 2.28. "LMR" is defined in Section 5.2.
- 2.29. "MEANINGFULLY INVOLVED AT KOLLTAN" shall mean a situation whereby SCHLESSINGER has an active consulting agreement with LICENSEE, or is a member of the Scientific Advisory Board of LICENSEE, or has a similar arrangement whereby

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SCHLESSINGER provides advice on a regular basis to LICENSEE. For the avoidance of doubt, and without limiting the foregoing, the parties agree that SCHLESSINGER has been MEANINGFULLY INVOLVED AT KOLLTAN from the date LICENSEE was incorporated (i.e., November, 2007) through the EFFECTIVE DATE.

- 2.30. "MEANINGFULLY INVOLVED AT YALE" shall mean a situation whereby SCHLESSINGER is serving as an employee or faculty member (including an emeritus faculty member) at YALE.
  - 2.31. "MINIMUM DIRECT COSTS" is defined in Section 7.5.
  - 2.32. "MRP" is defined in Section 6.3.
- 2.33. "NDA" shall mean (i) a New Drug Application or Biologic License Application filed with the FDA to obtain marketing approval for a PRODUCT IN CLASS in the United States; or (ii) a foreign equivalent of (i).
  - 2.34. "NET SALES" shall mean:
- (a) gross invoice price from the sale, lease or other transfer or disposition, other than by sublicense, of a PRODUCT IN CLASS or LICENSED METHOD, or from services performed using a PRODUCT IN CLASS or LICENSED METHOD, by LICENSEE or any SUBLICENSEE or AFFILIATE to third parties, except as set forth in Section 2.34(b), in each case from and after the FIRST SALE of such PRODUCT IN CLASS or LICENSED METHOD, less the following deductions, provided they actually pertain to the disposition of the PRODUCTS IN CLASS or LICENSED METHODS and, in the case of the items specified in the immediately succeeding clauses (i) and (ii), are separately stated on the applicable invoice:
  - (i) all discounts, credits and allowances on account of returns;
  - (ii) transportation and insurance; and
  - (iii) duties, taxes and other governmental charges levied on the sale, transportation or delivery of PRODUCTS IN CLASS or

### practice of the LICENSED METHODS, but not including income taxes.

No deductions shall be made for any other costs or expenses, including, but not limited to, commissions to independent sales agents or those on LICENSEE's or a SUBLICENSEE's or AFFILIATE's payroll or for the cost of collection.

(b) "NET SALES" shall not include the gross invoice price for PRODUCTS IN CLASS or LICENSED METHODS sold to, or services performed using PRODUCTS IN CLASS or LICENSED METHODS for, any AFFILIATE unless such AFFILIATE is an end-user of any PRODUCT IN CLASS or LICENSED METHOD, in which case such consideration shall be included in NET SALES at the average selling price charged to a third party during the same quarter.

- 2.35. "ORIGINAL LICENSE AGREEMENT" is defined in the recitals to this AGREEMENT.
- 2.36. "ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE" is defined in the recitals to this AGREEMENT.
- 2.37. "PHASE 1 STUDY" shall mean a human clinical trial in any country that is intended to initially evaluate the safety of an investigational PRODUCT IN CLASS in volunteer subjects or patients that would satisfy the requirements of 21 CFR 312.21(a), or other comparable regulation imposed by the FDA or its foreign counterpart.
- 2.38. "PHASE 2 STUDY" shall mean a human clinical trial in any country that is conducted to evaluate the effectiveness of the PRODUCT IN CLASS for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug that would satisfy the requirements of 21 CFR 312.21(b), or other comparable regulation imposed by the FDA or its foreign counterpart.
- 2.39. "PHASE 3 STUDY" shall mean a pivotal human clinical trial in any country the results of which could be used to establish safety and efficacy of a PRODUCT IN CLASS as a basis for a marketing application that would satisfy the requirements of 21 CFR 312.21(c) or other comparable regulation imposed by the FDA or its foreign counterpart.
- 2.40. "PIVOTAL TRIAL" shall mean a controlled clinical trial to evaluate the safety and/or efficacy of a given PRODUCT IN CLASS and/or a given LICENSED METHOD in humans. Each such clinical trial should show safety and efficacy to a statistical significance and suffice as demonstration of such PRODUCT IN CLASS's or such LICENSED METHOD's safety and efficacy such that the results of said trial are the basis for the filing of an NDA for such a PRODUCT IN CLASS and/or such a LICENSED METHOD.
  - 2.41. "PLAN" is defined in Section 7.1.
- 2.42. "PRODUCT" shall mean any form of product, including but not limited to, a service, a method, a diagnostic (or the like), a drug and other type of therapeutic for human (or other) disease or condition, including, without limitation, gene therapy constructs, small molecules, proteins, peptides, peptidomimetics, antisense constructs, antibody-drug conjugates or any other natural or synthetic molecule, and assays run in reference labs for fee-for-service diagnostic tests.
- 2.43. "PRODUCT IN CLASS" shall mean any RTK PRODUCT (i) as to which LICENSEE commenced work on, or acquired or in-licensed such product (or intellectual property claiming the composition or method of use of such product) while SCHLESSINGER was MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN; or (ii) that is claimed by a VALID CLAIM in a LICENSED PATENT. Notwithstanding the foregoing, for purposes of this AGREEMENT, PRODUCT IN CLASS shall not include (x) an RTK PRODUCT that is owned, in-licensed (directly or indirectly) from LICENSEE) or otherwise controlled by a third party that acquires control of LICENSEE through a CHANGE OF CONTROL, where such third party owned, in-licensed

(unless in-licensed (directly or indirectly) from LICENSEE) or otherwise controlled such RTK PRODUCT prior to such CHANGE OF CONTROL; (y) an RTK PRODUCT that is owned, in-licensed or otherwise controlled by a third party that acquires control of LICENSEE through a CHANGE OF CONTROL, where such third party first owned, in-licensed or otherwise controlled such RTK PRODUCT following such CHANGE OF CONTROL; or (z) a DESIGNATED THIRD PARTY RTK PRODUCT, unless in either (x), (y) or (z) such RTK PRODUCT is claimed by a VALID CLAIM in a LICENSED PATENT.

### 2.44. "REASONABLE COMMERCIAL EFFORTS" shall mean documented efforts:

- (a) that are consistent with those utilized by companies of similar size and type and at a similar stage of corporate development to LICENSEE, which companies have successfully developed therapeutic or prophylactic products similar to the proposed PRODUCTS IN CLASS described in the PLAN and/or services of a type similar to LICENSED METHODS described in the PLAN; and
- (b) that are consistent with the interests of LICENSEE's stockholders and the development of a PRODUCT IN CLASS and/or commercial application of LICENSED METHODS and that constitute a prudent and commercially reasonable use of LICENSEE's capital resources; and
- (c) that are evidenced by a record of incurring MINIMUM DIRECT COSTS, which shall include the RESEARCH SUPPORT, and additional documented expenditures appropriate to the stage of development of one or more PRODUCTS IN CLASS and/or commercial application of LICENSED METHODS.
  - 2.45. "REDUCED EARNED ROYALTY" is defined in Section 6.1.
- 2.46. "RESEARCH AGREEMENT" shall mean (i) the Amended and Restated Research Agreement, dated as of the EFFECTIVE DATE, by and between YALE and LICENSEE, as the same may be amended, extended, renewed or replaced from time to time and (ii) the Research Agreement between YALE and LICENSEE dated as of June 4, 2008.
- 2.47. "RESEARCH PROGRAM" shall mean the research program that has been and will continue to be conducted under the RESEARCH AGREEMENT.
  - 2.48. "RESEARCH SUPPORT" shall mean amounts payable by LICENSEE to YALE under the RESEARCH AGREEMENT.
  - 2.49. "RTK" shall mean a tyrosine kinase receptor.
- 2.50. "RTK PRODUCT" shall mean any PRODUCT that may induce, prevent, modify or otherwise modulate the activation of one or more RTKs for the purpose of diagnosing, preventing or treating a disease or condition in humans or non-human animals.
- 2.51. "RTK TECHNOLOGY" shall mean all inventions and any information, know-how, technical and non-technical data, methods and processes and any drawings, plans, diagrams, specifications, and/or other documents or data form containing such information that

directly relates to (i) one or more RTKs and the activity, modification and/or modulation thereof or (ii) RTK PRODUCTS (including, but not limited to, the composition, method of use or method of manufacture of RTK PRODUCTS).

- 2.52. "SCHLESSINGER" is defined in the recitals to this AGREEMENT.
- 2.53. "SCHLESSINGER LAB" is defined in the recitals to this AGREEMENT.
- 2.54. "SUBLICENSEE" shall mean any third party sublicensed by LICENSEE to make, have made, use, sell, offer for sale, have sold, import or export any PRODUCT IN CLASS or to practice any LICENSED METHOD.
- 2.55. "SUBLICENSE INCOME" shall mean consideration in any form actually received by LICENSEE or an AFFILIATE in connection with a grant to any third party or parties of a sublicense or other right, license, privilege or immunity to make, have made, use, sell, have sold, distribute, import or export PRODUCTS IN CLASS or to practice the TECHNOLOGY, but excluding consideration that may be received by LICENSEE or an AFFILIATE as a royalty (or similar consideration) on sales of such PRODUCTS IN CLASS. SUBLICENSE INCOME shall include, without limitation, but subject to the following sentence, any license signing fee, license maintenance fee, unearmed portion of any minimum royalty payment received by LICENSEE, equity interest in a person and/or entity other than LICENSEE or an AFFILIATE and any distribution or joint marketing fee. SUBLICENSE INCOME shall not include:
- (a) any payments or reimbursements for past, present or future research, development, manufacturing or commercial launch activity, including, without limitation, laboratory research, clinical research and development, process development, regulatory approvals or certifications, reimbursement for payments due to YALE pursuant to Section 5.5 or Section 5.8, and commercial launch expenses, except where, and to the extent that, such payments or reimbursements are in excess of LICENSEE's external costs and reasonably attributable internal costs incurred in undertaking such activities;
  - (b) any consideration received for an equity interest in, extension of credit to, or other investment in, LICENSEE or an AFFILIATE; or
- (c) any reimbursement for patent expenses or other costs or expenses of LICENSEE or an AFFILIATE associated with creating or maintaining intellectual property protection.

In case an extension of credit to LICENSEE by a SUBLICENSEE, as described in clause (b) above, is forgiven in whole or in part by the SUBLICENSEE, within thirty (30) days thereafter LICENSEE shall by notice to YALE provide information in reasonable detail showing the categories and uses of such funds for purposes of determining the amount thereof, if any, that constitutes SUBLICENSE INCOME. YALE may request in writing and LICENSEE shall not unreasonably refuse to provide in writing additional information about the categories and uses of such forgiven extension of credit.

- 2.56. "TECHNOLOGY" shall mean LICENSED KNOW-HOW, LICENSED MATERIALS, LICENSED METHODS, and/or LICENSED PATENTS.
- 2.57. "TERM" is defined in Section 3.7.
- 2.58. "TERMINATION EVENT" shall mean:
- (a) LICENSEE fails to make any payment whatsoever due and payable pursuant to this AGREEMENT and LICENSEE shall fail to make all such payments (and to pay all interest due on such payments under Section 6.4) for thirty (30) days after receipt of written notice of such failure from YALE: or
- (b) LICENSEE commits a material breach of any provision of this AGREEMENT (other than as provided in the immediately preceding clause (a)) which breach (1) if capable of being cured, shall continue uncured for sixty (60) days after LICENSEE receives written notice thereof from YALE, which notice shall identify such breach in reasonable detail, or (2) is not capable of being cured; or
  - (c) LICENSEE fails to obtain or maintain insurance as described in Article 14; or
  - (d) LICENSEE gives notice to YALE pursuant to Section 7.4(a) or (b); or
  - (e) the occurrence of any of the events set forth in Section 7.4(a) or (b).
  - 2.59. "TERMINATION EVENT INFORMATION NOTICE" is defined in Section 13.4(a).
  - 2.60. "TERMINATION EVENT NOTICE" is defined in Section 13.4(b).
- 2.61. "VALID CLAIM" shall mean, as the context requires, (i) an issued and unexpired claim of a LICENSED PATENT so long as such claim shall not have been irrevocably abandoned or declared to be invalid in an unappealable decision of a court or other authority of competent jurisdiction through no fault or cause of LICENSEE or (ii) an issued and unexpired claim of a KOLLTAN PATENT so long as such claim shall not have been irrevocably abandoned or declared to be invalid in an unappealable decision of a court or other authority of competent jurisdiction.
- 2.62. "VISITING SCIENTIST IP" shall mean any intellectual property resulting from work done by LICENSEE employees in laboratory space in the Department of Pharmacology at the Yale School of Medicine during the period from November 17, 2008 through June 22, 2009 where such intellectual property was created by such LICENSEE employees. Such VISITING SCIENTIST IP may include inventions, discoveries, developments, technical information, trade secrets, know-how, methods, techniques, formulae, data, information, processes, intellectual property and other proprietary ideas, whether patentable or not patentable or not yet patented. Some VISITING SCIENTIST IP is described in more detail in Appendix C, which is hereby incorporated into this AGREEMENT. YALE and LICENSEE have previously entered into (1) a Visiting Scientist Agreement, effective November 14, 2008, as amended by

Amendment One to Visiting Scientist Agreement, effective January 5, 2009 and (2) a separate Visiting Scientist Agreement, effective January 5, 2009 (collectively, the "Two Visiting Scientist Agreements"). It is understood and agreed that any VISITING SCIENTIST IP shall be governed by the terms of this AGREEMENT, in addition to the Two Visiting Scientist Agreements, however, in the case of any inconsistencies between this AGREEMENT and one or both of the Two Visiting Scientist Agreements, the provisions of this AGREEMENT shall prevail. LICENSEE hereby acknowledges that, during the term of each of the Two Visiting Scientist Agreements, LICENSED KNOW-HOW was provided to LICENSEE pursuant to the terms of the ORIGINAL LICENSE AGREEMENT, and LICENSEE hereby acknowledges having received and made use of such LICENSED KNOW-HOW from YALE.

#### ARTICLE 3 LICENSE GRANT AND TERM

- 3.1. Subject to all the terms and conditions of this AGREEMENT, YALE hereby grants to LICENSEE an exclusive license under all of YALE's interest in the LICENSED PATENTS, LICENSED MATERIALS and LICENSED METHODS to make, have made, use, sell, offer for sale, have sold, import or export therapeutic and prophylactic RTK PRODUCTS in the LICENSED TERRITORY, with the right to sublicense as provided in this AGREEMENT.
- 3.2. Subject to all the terms and conditions of this AGREEMENT, YALE hereby grants to LICENSEE a non-exclusive license under all of YALE's interest in the LICENSED PATENTS and LICENSED METHODS and LICENSED MATERIALS to make, have made, use, sell, offer for sale, have sold, import or export diagnostic RTK PRODUCTS within the LICENSED TERRITORY, with the right to sublicense as provided in this AGREEMENT.
- 3.3. Subject to all the terms and conditions of this AGREEMENT, YALE hereby grants to LICENSEE a non-exclusive license under all of YALE's interest in the LICENSED KNOW-HOW to make, have made, use, sell, offer for sale, have sold, import or export any RTK PRODUCT, method, procedure, service or process in the LICENSED TERRITORY, with the right to sublicense as provided in this AGREEMENT.
- 3.4. (a) Collectively, the rights granted to LICENSEE under Section 3.1, Section 3.2 and Section 3.3 shall be the "LICENSE". The LICENSE is further subject to all the terms and conditions of this AGREEMENT, including, without limitation, YALE's right to terminate the LICENSE if a TERMINATION EVENT has occurred and is continuing by reason of, among other things, LICENSEE's failure to pay all amounts due to YALE pursuant to Articles 5, 6, and 10 and LICENSEE's failure to comply with Section 7.5.
- (b) Part of the consideration received by YALE for the grant of the LICENSE is LICENSEE's obligation under the RESEARCH AGREEMENT to provide RESEARCH SUPPORT in the aggregate amount of Nine Million Dollars (\$9,000,000), consisting of One Million Five Hundred Thousand Dollars per year over the six-year period provided in the RESEARCH AGREEMENT. Notwithstanding that such obligation of LICENSEE under the RESEARCH AGREEMENT forms part of the consideration for this AGREEMENT, a failure by LICENSEE to pay all or any portion of the RESEARCH SUPPORT shall not constitute a failure of consideration for this AGREEMENT or give rise to a right of YALE to terminate this AGREEMENT; provided, however, that in case of termination of the RESEARCH AGREEMENT, LICENSEE shall have paid all costs for which LICENSEE is responsible under the RESEARCH AGREEMENT and which costs were incurred by YALE and unpaid by the LICENSEE through the date of termination, including, without limitation, all non-reimbursed costs and non-cancelable commitments of YALE relating to the RESEARCH AGREEMENT, that are incurred prior to the date of termination of the RESEARCH AGREEMENT, but in the case of personnel costs, no more than salary and benefits of such personnel provided for under the RESEARCH AGREEMENT for up to one year from date of notice of termination of the RESEARCH AGREEMENT. YALE shall use reasonable best efforts to mitigate such costs and commitments, consistent with YALE's normal policies and practices with regard to termination or transfer of, or assistance in seeking other employment for, such personnel. Expiration or termination of the RESEARCH AGREEMENT in accordance with its terms shall not be deemed a termination of this AGREEMENT.
- 3.5. To the extent that any invention included within the LICENSED PATENTS has been funded in whole or in part by the United States government, the United States government retains certain rights in such invention as set forth in 35 U.S.C. §200-212 and all regulations

promulgated thereunder, as amended, and any successor statutes and regulations (the "FEDERAL PATENT POLICY"). As a condition of the grant of the LICENSE, LICENSEE acknowledges and shall comply with all aspects of the FEDERAL PATENT POLICY applicable to the LICENSED PATENTS, including the obligation that PRODUCTS IN CLASS used or sold in the United States be manufactured substantially in the United States. Nothing contained in this AGREEMENT obligates or shall obligate YALE to take any action that would conflict in any respect with its past, current or future obligations to the United States Government under the FEDERAL PATENT POLICY with respect to the LICENSED PATENTS.

- 3.6. The LICENSE is expressly made subject to YALE's reservation of the right, on behalf of itself and all other non-profit academic research institutions, to make, use and practice the TECHNOLOGY for academic research, clinical, teaching or other non-commercial purposes, and not for purposes of commercial development, use, manufacture, sale or distribution. Nothing in this AGREEMENT shall be construed to grant by implication, estoppel or otherwise any licenses under patents of YALE other than the LICENSED KNOW-HOW, LICENSED MATERIALS, LICENSED METHODS, and LICENSED PATENTS.
- 3.7. The term of the LICENSE (the "TERM") shall commence on the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE and, unless terminated earlier as provided in Article 13, shall automatically expire, on a country-by-country basis, on the date that is the latest of whichever of the following is applicable:
- (a) the date on which the last of the VALID CLAIMS of the patents included in the LICENSED PATENTS in such country expires, lapses or is declared to be invalid by a final decision of a court or other authority of competent jurisdiction, not subject to further appeal, through no fault or cause of LICENSEE; and
- (b) the date that is fifteen (15) years after the last LICENSED KNOW-HOW, LICENSED MATERIALS, or LICENSED METHODS have been provided to LICENSEE by YALE under this AGREEMENT; and
  - (c) the date that is fifteen (15) years from the date of FIRST SALE of a PRODUCT IN CLASS;

but in no event shall the TERM end later than the date that is thirty (30) years after the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE.

3.8. YALE hereby agrees that, after the EFFECTIVE DATE and for so long as SCHLESSINGER is MEANINGFULLY INVOLVED AT YALE and MEANINGFULLY INVOLVED AT KOLLTAN, except for [\*\*]-FUNDED PATENTS, YALE will not grant any third party (including [\*\*]) any rights, for any therapeutic or prophylactic uses, in any patent application or patents (or, for the avoidance of doubt, related filings described in clause (c), (d) or (e) of the definition of LICENSED PATENTS) filed by or on behalf of YALE that claim RTK TECHNOLOGY made, created, developed, discovered, conceived or first reduced to practice by or on behalf of SCHLESSINGER, LAX, the SCHLESSINGER LAB or the LAX LAB (including, for the avoidance of doubt, under the RESEARCH AGREEMENT).

- 3.9. In the event that YALE materially breaches a representation or warranty contained in Section 1.2 with respect to the TECHNOLOGY (a "Section 1.2 Breach"), which in turn creates potential liability for LICENSEE (including, potentially, for its AFFILIATES or SUBLICENSEES) to YALE or a third party ("Section 1.2 Liability"), YALE hereby agrees it will never institute any action or suit at law or in equity against LICENSEE or its AFFILIATES or its SUBLICENSEES alleging Section 1.2 Liability with respect to the use by LICENSEE or its AFFILIATES or SUBLICENSEES of the component(s) of the TECHNOLOGY that was(were) the subject of the Section 1.2 Breach, nor institute, prosecute or in any way aid in the institution or prosecution of any claim, demand, suit, action, or cause of action for damages, costs, other compensation or injunctive relief for or on account of any Section 1.2 Liability, whether developed or undeveloped, resulting or to result, known or unknown, past, present or future, arising out of the use by LICENSEE or its AFFILIATES or its SUBLICENSEES of the component(s) of the TECHNOLOGY that was(were) the subject of the Section 1.2 Breach. For the avoidance of doubt, the preceding sentence shall in no way limit LICENSEE's ability to seek other remedies with respect to YALE, nor shall it in any way limit LICENSEE's obligations to comply in good faith with all provisions of this AGREEMENT with which it is able to comply notwithstanding the Section 1.2 Breach.
- 3.10. No earlier than twenty-seven (27) months after the EFFECTIVE DATE and no later than thirty (30) months after the EFFECTIVE DATE, YALE may, by written notice to LICENSEE, elect to deem SCHLESSINGER to no longer be MEANINGFULLY INVOLVED AT KOLLTAN and MEANINGFULLY INVOLVED AT YALE as of the third anniversary of the EFFECTIVE DATE. Following delivery of such notice, for purposes of this AGREEMENT, SCHLESSINGER shall be deemed to be no longer MEANINGFULLY INVOLVED AT KOLLTAN and MEANINGFULLY INVOLVED AT YALE as of the third anniversary of the EFFECTIVE DATE.
- 3.11. In the event of a CHANGE OF CONTROL, upon the occurrence of such CHANGE OF CONTROL, for purposes of this AGREEMENT, SCHLESSINGER shall be deemed to be no longer MEANINGFULLY INVOLVED AT KOLLTAN and MEANINGFULLY INVOLVED AT YALE as of the date of such occurrence.

#### ARTICLE 4 SUBLICENSES

- 4.1. Any sublicense by LICENSEE of the rights granted to it under this AGREEMENT shall comply with the provisions of Sections 4.2, 4.3 and 4.4.
- 4.2. Subject to Section 4.5, any sublicense granted by LICENSEE shall include terms under which the SUBLICENSEE agrees with the LICENSEE, and shall include provisions in favor of LICENSEE, as sublicensor thereunder, substantially the same as are provided in Section 7.1, Section 7.2, Section 7.3, Section 7.4, Article 8, Section 9.1, Section 9.2, Section 10.6, Article 12 and Article 14 of this AGREEMENT with respect to the subject matter of such sublicense and the related definitions in this AGREEMENT. LICENSEE will provide YALE with a copy of each sublicense agreement (and all amendments thereof) within thirty (30) days of execution of such agreement or amendment. LICENSEE shall not be responsible for the performance of any SUBLICENSEE under any such sublicense and shall be obligated to pay

royalties and other amounts that arise from such sublicense and are due to YALE only as and to the extent such SUBLICENSEE pays the same to LICENSEE.

4.3. LICENSEE shall pay royalties to YALE on NET SALES of SUBLICENSEES based on the same royalty rate as apply to NET SALES by LICENSEE and its AFFILIATES under Article 6, regardless of the royalty rates payable by SUBLICENSEES to LICENSEE under a sublicense agreement. In addition, LICENSEE shall pay to YALE [\*\*] Percent ([\*\*]%) of any SUBLICENSE INCOME.

#### 4.4. LICENSEE agrees that it shall:

- (a) within thirty (30) days of execution by the parties, provide YALE with a copy of any amendments to sublicenses granted by LICENSEE under this AGREEMENT, and within thirty (30) days after termination of any sublicense, notify YALE of such termination; and
- (b) within thirty (30) days of receipt, provide complete copies of all reports provided to LICENSEE by SUBLICENSEES pursuant to any sublicense; provided, however, that LICENSEE may omit or redact from the copies so provided to YALE any portion of the reports of a SUBLICENSEE which portion contains information that LICENSEE would not have otherwise been required to report to YALE under Section 7.3 if such report were provided by LICENSEE directly; and
- (c) use commercially reasonable efforts to seek compliance in all material respects by each SUBLICENSEE with the terms of the sublicense to which such SUBLICENSEE is a party.
- 4.5. If LICENSEE proposes to enter into a sublicense that does not include terms that require SUBLICENSEE thereunder to agree substantially as provided in Sections 7.1 and 7.2 of this AGREEMENT (and the related definitions) with respect to the subject matter of such sublicense, then LICENSEE shall submit the proposed form of such sublicense to YALE for review and approval prior to entering into such sublicense. YALE's review and approval of any such sublicense shall be limited to the terms of the due diligence obligations of SUBLICENSEE thereunder, provided that such sublicense otherwise complies with the requirements of Sections 4.2 and 4.3 of this AGREEMENT. YALE shall notify LICENSEE of any objections it may have to the due diligence terms of a proposed sublicense within fifteen (15) days after LICENSEE submits such sublicense to YALE for its review and approval, and LICENSEE shall notify YALE of LICENSEE's response to said objections within fifteen (15) days after receipt of YALE's objections. YALE shall not unreasonably withhold its consent to any such sublicense provided that LICENSEE substantively responds to YALE's objections.

#### ARTICLE 5 LICENSE ISSUE ROYALTY; LICENSE MAINTENANCE ROYALTY; MILESTONE ROYALTIES

5.1. The parties acknowledge that LICENSEE paid to YALE, within ninety (90) days after the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE, a non-refundable license issue royalty of Fifty Thousand Dollars (\$50,000.00).

5.2. During the TERM, LICENSEE agrees to pay to YALE an annual license maintenance royalty ("LMR") commencing with the first anniversary of the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE according to the following schedule:

Anniversary of the ORIGINAL LICENSE			
AGREEMENT EFFECTIVE DATE	LMR		
[**]	[**]		
[**]	[**]		

until LICENSEE starts to pay MRP under Section 6.3. The parties acknowledge that, as of the EFFECTIVE DATE, LICENSEE has paid YALE the first three (3) LMR payments.

- 5.3. LICENSEE shall pay YALE, for each therapeutic or prophylactic PRODUCT IN CLASS that is developed by LICENSEE or an AFFILIATE, a non-refundable milestone royalty of Three Million Dollars (\$3,000,000.00) when LICENSEE has collected at least [\*\*] Dollars (\$[\*\*]) in NET SALES of such PRODUCT IN CLASS, determined on an accrual basis consistent with the GAAP used in the preparation of the financial statements furnished by LICENSEE to YALE pursuant to Section 9.3, subject to Section 5.11.
- 5.4. Notwithstanding Section 5.3, in case a CHANGE OF CONTROL shall occur, then for each therapeutic or prophylactic PRODUCT IN CLASS for which IND APPROVAL for a PHASE 1 STUDY occurs after such CHANGE OF CONTROL, in lieu of making payment in respect of such therapeutic or prophylactic PRODUCT IN CLASS of the milestone royalty provided in Section 5.3, and subject to Section 5.11, LICENSEE shall pay the following milestone royalties:
  - (a) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) upon [\*\*]; and
  - (b) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) upon the [\*\*]; and
  - (c) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) upon the [\*\*]; and
  - (d) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) upon the [\*\*]; and
  - (e) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) upon the [\*\*].

For the avoidance of doubt, each of the foregoing milestone royalties shall be payable only once for each therapeutic or prophylactic PRODUCT IN CLASS, even if such PRODUCT IN CLASS achieves a given milestone more than once.

5.5. In case of a sublicense by LICENSEE with respect to a proposed or actual therapeutic or prophylactic PRODUCT IN CLASS for which, on the effective date of such sublicense, a milestone royalty under Section 5.3 shall not yet have become due and payable by LICENSEE, then from and after the date of such sublicense, LICENSEE shall pay milestone

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

royalties for such therapeutic or prophylactic PRODUCT IN CLASS in accordance with Section 5.4 and Section 5.3 shall be inapplicable to such PRODUCT IN CLASS. In case of any such sublicense, if on the effective date of such sublicense, one or more of the milestones specified in Section 5.4 shall have been met, then, within thirty (30) days after the effective date of the sublicense for each such therapeutic or prophylactic PRODUCT IN CLASS, LICENSEE shall pay YALE the milestone royalties for all milestones specified in Section 5.4 which shall have been achieved for such PRODUCT IN CLASS prior to the effective date of such sublicense.

- 5.6. LICENSEE shall pay YALE, for each diagnostic PRODUCT IN CLASS that is developed by LICENSEE, a non-refundable milestone royalty of Three Hundred Thousand Dollars (\$300,000.00) when LICENSEE and/or an AFFILIATE has received at least [\*\*] Dollars (\$[\*\*]) in NET SALES of such PRODUCT IN CLASS, determined on an accrual basis consistent with the GAAP used in the preparation of the financial statement, furnished by LICENSEE to YALE pursuant to Section 9.3, subject to Section 5.11.
- 5.7. Notwithstanding Section 5.6, in case a CHANGE OF CONTROL shall occur, then for each diagnostic PRODUCT IN CLASS for which, after such CHANGE OF CONTROL, LICENSEE receives IND APPROVAL for the first clinical trial of such PRODUCT IN CLASS, then in lieu of making payment in respect of such PRODUCT IN CLASS of the milestone royalty provided in Section 5.6, and subject to Section 5.11, LICENSEE shall pay the following milestone royalties:
  - (a) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) when [\*\*]; and
  - (b) a non-refundable milestone royalty of [\*\*] Dollars (\*[\*\*]) when [\*\*]; and
  - (c) a non-refundable milestone royalty of [\*\*] Dollars (\$[\*\*]) when [\*\*].

For the avoidance of doubt, each of the foregoing milestone royalties shall be payable only once for each diagnostic PRODUCT IN CLASS, even if such PRODUCT IN CLASS achieves a given milestone more than once.

5.8. In case of a sublicense by LICENSEE with respect to a proposed or actual diagnostic PRODUCT IN CLASS for which, on the effective date of such sublicense, a milestone royalty under Section 5.6 shall not yet have become due and payable by LICENSEE, then from and after the date of such

sublicense, LICENSEE shall pay milestone royalties for each such diagnostic PRODUCT IN CLASS in accordance with Section 5.7 and Section 5.6 shall be inapplicable to such PRODUCT IN CLASS. In case of any such sublicense, if on the effective date of such sublicense, one or more of the milestones specified in Section 5.7 shall have been met, then, within thirty (30) days after the effective date of the sublicense for such diagnostic PRODUCT IN CLASS, LICENSEE shall pay YALE the milestone royalties for all milestones specified in Section 5.7 which shall have been achieved for such PRODUCT IN CLASS prior to the effective date of such sublicense.

5.9. In case a particular PRODUCT IN CLASS is both a therapeutic or prophylactic and a diagnostic and such therapeutic or prophylactic PRODUCT IN CLASS is or is intended to be marketed and sold separate from diagnostic PRODUCT IN CLASS and such diagnostic

PRODUCT IN CLASS is or is intended to be marketed and sold for a use other than determining the suitability of the use of such therapeutic or prophylactic PRODUCT IN CLASS in particular patients, then milestone royalties for both the therapeutic or prophylactic and the diagnostic PRODUCT IN CLASS under Sections 5.3, 5.4, 5.6 or 5.7 shall be due to YALE under this AGREEMENT.

- 5.10. None of the license issue royalty set forth in Section 5.1, the LMR set forth in Section 5.2 or the milestone royalties set forth in Sections 5.3, 5.4, 5.6 or 5.7 shall be credited against EARNED ROYALTIES payable under Article 6. LICENSEE shall pay the amounts payable to YALE under Sections 5.3 and 5.6 within ninety (90) days after the end of LICENSEE's fiscal year in which the applicable NET SALES threshold is met.
- 5.11. Notwithstanding any other provision of this AGREEMENT, for purposes of determining what constitutes a single or separate therapeutic or prophylactic and/or diagnostic PRODUCTS IN CLASS or a single or separate services using LICENSED METHODS:
- (a) any two or more therapeutic or prophylactic PRODUCTS IN CLASS or therapeutic or prophylactic LICENSED METHOD which have as an active ingredient the same molecule, chemical entity or compound as one another shall be deemed a single therapeutic PRODUCT IN CLASS or single therapeutic LICENSED METHOD, as the case may be, even if researched, developed, marketed, delivered or sold for different indications or with different formulations or under different regulatory approvals.
- (b) any two or more diagnostic PRODUCTS IN CLASS or two or more diagnostic LICENSED METHODS which have as an active ingredient the same molecule, chemical entity or compound as one another shall be deemed a single diagnostic PRODUCT IN CLASS or single service using a LICENSED METHOD, as the case may be, even if researched, developed, marketed, delivered, or sold for different indications or with different formulations or under different regulatory approvals.

#### ARTICLE 6 EARNED ROYALTIES; MINIMUM ROYALTY PAYMENTS

6.1. During the TERM, and subject to the following sentence, as partial consideration for the LICENSE, LICENSEE shall pay to YALE an earned royalty on worldwide cumulative NET SALES of each PRODUCT IN CLASS or LICENSED METHOD developed by LICENSEE or its SUBLICENSEES or AFFILIATES equal to [\*\*] percent ([\*\*]%) of such NET SALES (the "EARNED ROYALTY"). If for such a PRODUCT IN CLASS or LICENSED METHOD there is not a VALID CLAIM in either a LICENSED PATENT or a KOLLTAN PATENT, in each case claiming such PRODUCT IN CLASS or LICENSED METHOD, then the EARNED ROYALTY on such a PRODUCT IN CLASS or LICENSED METHOD shall be reduced (a "REDUCED EARNED ROYALTY"). The REDUCED EARNED ROYALTY on worldwide cumulative NET SALES of each PRODUCT IN CLASS or LICENSED METHOD developed by LICENSEE or its SUBLICENSEES or AFFILIATES shall be equal to [\*\*] percent ([\*\*]%) of such NET SALES from and after the date there is no such VALID CLAIM. Unless otherwise stated in this AGREEMENT, any reference to "EARNED ROYALTIES" shall refer to either or both EARNED ROYALTIES and REDUCED EARNED ROYALTIES, as the case may be.

- 6.2. LICENSEE shall pay all EARNED ROYALTIES accruing to YALE within thirty (30) days from the end of each calendar quarter (March 31, June 30, September 30 and December 31), beginning in the first calendar quarter in which NET SALES occur.
- 6.3. During the TERM, LICENSEE agrees to pay YALE annual Minimum Royalty Payments ("MRP"), commencing on the first anniversary of the ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE to occur at least six (6) months after the date of the FIRST SALE of the first PRODUCT IN CLASS or first service using a LICENSED METHOD that results in NET SALES for such a first PRODUCT IN CLASS or LICENSED METHOD.
- (a) If the PRODUCT IN CLASS or service using a LICENSED METHOD the FIRST SALE of which gives rise to LICENSEE's obligation to pay an MRP is a therapeutic or prophylactic PRODUCT IN CLASS or service using a LICENSED METHOD, then the MRP shall be made according to the following schedule:

Years after FIRST SALE	MRP
Year 1	[**]
Year 2	[**]
Years 3-5	[**]
Year 6 and every year thereafter	[**]

(b) If the PRODUCT IN CLASS or service using a LICENSED METHOD the FIRST SALE of which gives rise to LICENSEE's obligation to pay an MRP is a diagnostic PRODUCT IN CLASS or service using a LICENSED METHOD, then the MRP shall be made according to the following schedule:

Years after FIRST SALE	MRP
Year 1	[**]
Year 2	[**]
Years 3-5	[**]
Year 6 and every year thereafter	[**]

(c) Once the LICENSEE has made a FIRST SALE of both a therapeutic or prophylactic PRODUCT IN CLASS or a service using a LICENSED METHOD and a diagnostic PRODUCT IN CLASS or service using a LICENSED METHOD, then thereafter MRP shall be the sum of the amounts indicated in Sections 6.3(a) and 6.3(b). If the FIRST SALE of a PRODUCT IN CLASS or service using a LICENSED METHOD is both a therapeutic or prophylactic and a diagnostic and such therapeutic or prophylactic PRODUCT IN CLASS or service using a LICENSED METHOD is, or is intended to be, marketed and sold separate from such diagnostic PRODUCT IN CLASS or service using a LICENSED METHOD, as the case may be, and such diagnostic PRODUCT IN CLASS or service using a LICENSED METHOD is, or is intended to be, marketed and sold for a use other than determining the suitability of the use of such therapeutic or prophylactic PRODUCT IN CLASS or service using a LICENSED METHOD in particular patients, then thereafter MRP shall be the sum of the amounts indicated in Sections 6.3(a) and 6.3(b).

- (d) Once the MRP commences, LICENSEE shall continue to pay the MRP for PRODUCTS IN CLASS or services using LICENSED METHODS until the end of the TERM, subject to Section 6.3(e). YALE shall fully credit MRP paid against any EARNED ROYALTIES payable by LICENSEE in the same year.
- (e) If at any time after the MRP commences all PRODUCTS IN CLASS and services using a LICENSED METHOD for which a FIRST SALE has occurred are temporarily or permanently removed from the market and there is no longer any PRODUCT IN CLASS or service using a LICENSED METHOD subject to EARNED ROYALTY under the terms of this AGREEMENT, then the MRP due under Section 6.3 shall be suspended and LICENSEE shall resume payment of the applicable LMR under Section 5.2. The payment of LMR as so resumed shall continue until such time as marketing of any removed PRODUCT IN CLASS or service using a LICENSED METHOD has resumed or LICENSEE shall have made a FIRST SALE of another PRODUCT IN CLASS or service using a LICENSED METHOD, subject to suspension of the MRP through subsequent operation of this Section 6.3(e). MRP that is suspended or resumed and LMR that arises by reason of this Section 6.3(e), in any such case for a period of less than 12 months, shall be prorated.
- (f) If at any time the applicable rate of EARNED ROYALTIES for all PRODUCTS IN CLASS and services using any LICENSED METHOD shall become the REDUCED EARNED ROYALTY, then the applicable MRP shall thereafter be [\*\*] percent ([\*\*]%) of the applicable amount from the above schedules, prorated for any period of less than 12 months.
- 6.4. All EARNED ROYALTIES and other payments due under this AGREEMENT shall be paid to YALE in United States Dollars. In the event that conversion from foreign currency is required in calculating a payment under this AGREEMENT, the exchange rate used shall be the Interbank rate quoted by Citibank, N.A. at the end of the last business day of the quarter in which the royalty was earned. If overdue, the EARNED ROYALTIES and any other payments due under this AGREEMENT shall bear interest until payment at a per annum rate equal to [\*\*], and YALE shall be entitled to recover reasonable attorneys' fees and costs related to the collection of overdue EARNED ROYALTIES or other overdue amounts payable by LICENSEE under this AGREEMENT, following such failure to pay. The payment of such interest shall not foreclose YALE from exercising any other right it may have as a consequence of the failure of LICENSEE to make any payment when due.

#### ARTICLE 7 DUE DILIGENCE

7.1. LICENSEE has designed a plan for pre-clinical and clinical development of one or more PRODUCTS IN CLASS by use of the TECHNOLOGY, which plan (i) includes a description of research and development, testing, government approval and manufacturing of PRODUCTS IN CLASS and/or LICENSED METHODS and (ii) after completion of a PIVOTAL TRIAL for a PRODUCTS IN CLASS and/or LICENSED METHODS, will additionally include a description of the plan for the marketing and sale or lease of such PRODUCTS IN CLASS and/or LICENSED METHODS (as such plan may be supplemented or modified from time to time pursuant to Section 7.3, the "PLAN"). A copy of the PLAN as of the

EFFECTIVE DATE is attached to this AGREEMENT as Appendix B and incorporated herein by reference.

- 7.2. LICENSEE shall use REASONABLE COMMERCIAL EFFORTS to pursue development and commercialization of PRODUCTS IN CLASS and LICENSED METHODS. The efforts of AFFILIATES and SUBLICENSEES shall be considered LICENSEE efforts for purposes of determining whether LICENSEE is using REASONABLE COMMERCIAL EFFORTS as required by this Section 7.2. LICENSEE shall not pursue development and commercialization of an RTK PRODUCT that is not a PRODUCT IN CLASS for the sole purpose of avoiding the payment of a royalty to YALE pursuant to Section 6.1.
- 7.3. No later than one hundred twenty (120) days after the end of each calendar year during the TERM, LICENSEE shall provide to YALE a written report describing LICENSEE's, SUBLICENSEE's, and/or AFFILIATE's activities and progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales, as applicable, of one or more PRODUCTS IN CLASS or LICENSED METHODS during such year and indicating LICENSEE's progress and problems to date in implementing the PLAN during such year. If during the course of the year covered by such report LICENSEE, SUBLICENSEE or AFFILIATE shall have been involved in REASONABLE COMMERCIAL EFFORTS for more than one actual or proposed PRODUCT IN CLASS or LICENSED METHOD, such report for such year shall provide the information set forth above for each such actual or proposed PRODUCT IN CLASS or LICENSED METHOD. If progress or developments differ from those anticipated in the PLAN, as supplemented by prior reports LICENSEE has provided pursuant to this Section 1.3, then in such report LICENSEE shall identify in reasonable detail the principal differences, state the reasons for the differences and set forth a modified research, development, regulatory approval, manufacturing, sublicensing, marketing and sales plan. Such report shall also include a forecast and schedule of major events required to market the PRODUCTS IN CLASS or LICENSED METHODS under development during such year. Such report shall also include the aggregate MINIMUM DIRECT COSTS actually incurred to the end of the most recent calendar year preceding such report. LICENSEE shall also promptly provide any reasonable additional data that YALE by written notice to LICENSEE requests in order to evaluate LICENSEE's exercise of REASONABLE COMMERCIAL EFFORTS during such year. Within thirty (30) days following any assignment by LICENSEE pursuant to Section 17.6, the assignee shall provide YALE with an updated and revised copy of the PLAN.
- 7.4. LICENSEE shall immediately notify YALE if at any time LICENSEE (a) abandons or suspends, or determines to abandon or suspend, its research, development and marketing of the PRODUCTS IN CLASS and LICENSED METHODS, (b) fails to comply with its due diligence obligations under this Article for a period exceeding ninety (90) days, or (c) abandons or suspends, or determines to abandon or suspend, its clinical research, development or marketing of a particular PRODUCT IN CLASS or a particular LICENSED METHOD.
- 7.5. LICENSEE shall during the TERM incur costs (including external costs and reasonably attributable internal costs) towards research, clinical development, regulatory approvals, manufacturing, intellectual property filings or maintenance fees, or marketing of one or more PRODUCT IN CLASS and/or LICENSED METHODS ("MINIMUM DIRECT COSTS") according to the following schedule:

Period from ORIGINAL LICENSE AGREEMENT EFFECTIVE DATE to end

Cumulative MINIMUM DIRECT COSTS

01	DIN	DIRECT COSTS	
Year 5	\$	15,000,000	
Year 8	\$	25,000,000	

In determining the amount of such costs that LICENSEE has incurred, costs of LICENSEE shall be calculated on an accrual basis, consistent with the GAAP used in the preparation of LICENSEE's financial statements furnished to YALE pursuant to Section 9.3, and amounts paid by LICENSEE as RESEARCH SUPPORT of the RESEARCH PROGRAM and such documented costs incurred by SUBLICENSEES and/or AFFILIATES towards a PRODUCT IN CLASS or a LICENSED METHOD shall all be considered costs incurred by LICENSEE.

#### ARTICLE 8 CONFIDENTIALITY AND PUBLICITY

- 8.1. Subject to the parties' rights and obligations pursuant to this AGREEMENT, YALE and LICENSEE agree that during the TERM and for five (5) years thereafter, each of them:
- (a) will keep confidential and will cause their AFFILIATES and, in the case of LICENSEE, require its SUBLICENSEES to agree in writing with LICENSEE, to keep confidential, CONFIDENTIAL INFORMATION disclosed to it by the other party, by taking whatever action the party receiving the CONFIDENTIAL INFORMATION would take to preserve the confidentiality of its own CONFIDENTIAL INFORMATION, which in no event shall be less than reasonable care; and
- (b) will only disclose that part of the other's CONFIDENTIAL INFORMATION to its officers, employees or agents that is necessary for those officers, employees or agents who need to know to carry out its responsibilities under this AGREEMENT; and
- (c) will not use the other party's CONFIDENTIAL INFORMATION other than as expressly set forth in this AGREEMENT or disclose the other's CONFIDENTIAL INFORMATION to any third parties under any circumstance without advance written permission from the other party; and
- (d) will, within sixty (60) days of termination of this AGREEMENT, return all the CONFIDENTIAL INFORMATION disclosed to it by the other party pursuant to this AGREEMENT except for one copy which may be retained by the recipient for monitoring compliance with this Article 8.
  - 8.2. The obligations of confidentiality described above shall not pertain to that part of the CONFIDENTIAL INFORMATION that:

- (a) was known to the recipient prior to the disclosure by the disclosing party; or
- (b) is at the time of disclosure or has become thereafter publicly known through no fault or omission attributable to the recipient; or
- (c) is rightfully given to the recipient from sources independent of the disclosing party; or
- (d) is independently developed by the receiving party without use of or reference to the CONFIDENTIAL INFORMATION of the other party; or
- (e) is required to be disclosed by law in the opinion of recipient's attorney, but only after the disclosing party is given prompt written notice and an opportunity to seek a protective order; or
- (f) is provided under the RESEARCH AGREEMENT (which CONFIDENTIAL INFORMATION shall be governed by the provisions of the RESEARCH AGREEMENT governing confidential information).
- 8.3. Except as required by law, neither party may disclose the financial terms of this AGREEMENT without the prior written consent of the other party, except that LICENSEE may disclose such terms to persons who agree in writing with LICENSEE to keep such information confidential.

#### ARTICLE 9 REPORTS, RECORDS AND INSPECTIONS

- 9.1. LICENSEE shall, within thirty (30) days after the calendar year in which NET SALES first occur, and within thirty (30) days after each calendar quarter (March 31, June 30, September 30 and December 31) thereafter, provide YALE with a written report detailing the NET SALES and uses, if any, made by LICENSEE, its SUBLICENSEES and AFFILIATES of LICENSED PRODUCTS and LICENSED METHODS during the preceding calendar quarter and calculating the payments due pursuant to Article 6. NET SALES of PRODUCTS IN CLASS or LICENSED METHODS shall be deemed to have occurred as determined in accordance with the GAAP used in the preparation of the financial statement furnished by LICENSEE to YALE pursuant to Section 9.3. Each such report shall be signed by an officer of LICENSEE (or the officer's designee), and must include:
  - (a) the number of PRODUCTS IN CLASS manufactured, sold, leased or otherwise transferred or disposed of, and the amount of LICENSED METHODS sold, by LICENSEE, SUBLICENSEES and AFFILIATES;
  - (b) a calculation of NET SALES for the applicable reporting period in each country, including the gross invoice prices charged for the PRODUCTS IN CLASS and LICENSED METHODS and any permitted deductions made pursuant to Section 2.34;

- (c) a calculation of total royalties or other payment due, including any exchange rates used for conversion; and
- (d) names and addresses of all SUBLICENSEES and the type and amount of any SUBLICENSE INCOME received from each SUBLICENSEE.
- 9.2. LICENSEE and its SUBLICENSEES shall keep and maintain complete and accurate records and books containing an accurate accounting of all data in sufficient detail to enable verification of EARNED ROYALTIES and other payments under this AGREEMENT. LICENSEE shall preserve such books and records for three (3) years after the calendar year to which they pertain. Such books and records shall be open to inspection by YALE or an independent certified public accountant selected by YALE, at YALE's expense, during normal business hours upon ten (10) days' prior written notice, for the purpose of verifying the accuracy of the reports and computations rendered by LICENSEE. In the event LICENSEE underpaid the amounts due to YALE with respect to the audited period by more than five percent (5%), LICENSEE shall pay the reasonable cost of such examination, together with the deficiency not previously paid, within thirty (30) days of receiving notice thereof from YALE.
- 9.3. LICENSEE shall deliver to YALE within one hundred fifty (150) days after the end of each fiscal year of LICENSEE during the TERM, an income statement for such fiscal year, a balance sheet of LICENSEE and statement of stockholders' equity as of the end of such fiscal year, and a statement of cash flows for such fiscal year, such financial statements to be prepared in accordance with generally accepted accounting principles ("GAAP"), and accompanied by an audit report of independent public accountants of nationally recognized standing selected by LICENSEE.

#### ARTICLE 10 PATENT PROTECTION

- 10.1. LICENSEE shall be responsible for all past, present and future costs of filing, prosecution and maintenance of all United States patent applications contained in the LICENSED PATENTS. Any and all such United States patent applications, and resulting issued patents, shall remain the property of YALE.
- 10.2. LICENSEE shall be responsible for all past, present and future costs of filing, prosecution and maintenance of all foreign patent applications, and patents contained in the LICENSED PATENTS in the countries outside the United States in the LICENSED TERRITORY selected by YALE and agreed to by LICENSEE. All such applications or patents shall remain the property of YALE.
- 10.3. If LICENSEE does not agree to pay the expenses of filing, prosecuting or maintaining a patent application or patent in any country outside the United States, or fails to pay the expenses of filing, prosecuting or maintaining a patent application or patent in the United States, then the LICENSE with respect to such patent application or patent shall terminate automatically with respect to that country.
- 10.4. The costs mentioned in Sections 10.2 and 10.3 shall include, but are not limited to, any past, present and future taxes, annuities, working fees, maintenance fees, renewal and extension charges. Payment of such costs shall be made, at YALE's option, either directly to

patent counsel or by reimbursement to YALE. In either case, LICENSEE shall make payment directly to the appropriate party within thirty (30) days of receiving its invoice. If LICENSEE fails to make payment to YALE or patent counsel, as appropriate, within the thirty (30) day period, LICENSEE shall be charged a five percent (5%) surcharge on the invoiced amount per month or fraction thereof or such other amount (higher or lower) as may be charged by patent counsel. Failure of LICENSEE to pay the surcharge shall be grounds for termination by YALE under Section 13.1 as and to the extent the same constitutes a TERMINATION EVENT.

- 10.5. All patent applications under the LICENSED PATENTS shall be prepared, prosecuted, filed and maintained by independent patent counsel chosen by YALE and reasonably acceptable to LICENSEE. Said independent patent counsel shall be ultimately responsible to YALE. LICENSEE shall have the right to retain, at its own expense, separate patent counsel to advise LICENSEE regarding such patent matters. YALE shall instruct its patent counsel to keep YALE, LICENSEE and LICENSEE's patent counsel, if any, fully informed of the progress of all patent applications and patents, and to give both YALE and LICENSEE reasonable opportunity to comment on the type and scope of useful claims and the nature of supporting disclosures and other matters in the course of patent prosecution and maintenance. YALE will not finally abandon any patent application for which LICENSEE is bearing expenses without LICENSEE's consent. In making its decisions regarding patent matters YALE shall (1) give due regard to the advice of its patent counsel, (2) instruct its patent counsel to consider any advice offered by LICENSEE's patent counsel, if any, and (3) conduct such preparation, prosecution and maintenance of patent applications and patents in a manner that is commercially reasonable and with a view to assisting LICENSEE in complying with its obligations under this AGREEMENT and to facilitate LICENSEE's ability to commercialize PRODUCTS IN CLASS and/or LICENSED METHODS for which royalties will be payable by LICENSEE under Section 6.1. YALE shall have no liability to LICENSEE for damages, whether direct, indirect or incidental, consequential or otherwise, allegedly arising from its good faith decisions, actions and omissions taken in compliance with this AGREEMENT in connection with such patent prosecution.
- 10.6. LICENSEE shall mark, and shall require SUBLICENSEES to mark, all LICENSED PRODUCTS with the numbers of all patents included in LICENSED PATENTS that cover the PRODUCTS IN CLASS. Without limiting the foregoing, all PRODUCTS IN CLASS shall be marked in such a manner as to conform with the patent marking notices required by the law of any country where such PRODUCTS IN CLASS are made, sold, used or shipped, including, but not limited to, the applicable patent laws of that country.

#### ARTICLE 11 INFRINGEMENT AND LITIGATION

11.1. Each party shall promptly notify the other in writing in the event that it obtains knowledge of infringing activity by third parties, or is sued or threatened with an infringement suit, in any country in the LICENSED TERRITORY as a result of activities that concern the TECHNOLOGY and shall supply the other party with documentation of the infringing activities that it possesses.

#### 11.2. During the TERM:

- LICENSEE shall have the first right and obligation to (i) defend its or its SUBLICENSEE's use of the TECHNOLOGY against infringement or interference claims in the LICENSED TERRITORY by third parties and (ii) take action (including legal action) against third parties who may infringe the LICENSED PATENTS or otherwise misappropriate the LICENSED KNOW-HOW, LICENSED METHODS or LICENSED MATERIALS. This right and obligation includes bringing any legal action for infringement and defending any counter claim of invalidity or action of a third party for declaratory judgment for non-infringement or non-interference. If, in the reasonable opinion of both LICENSEE's and YALE's respective counsel, YALE is required to be a named party to any such suit for standing purposes, LICENSEE may join YALE as a party; provided, however, that (i) YALE shall not be the first named party in any such action, (ii) the pleadings and any public statements about the action shall state that the action is being pursued by LICENSEE and that LICENSEE has joined YALE as a party; and (iii) LICENSEE shall keep YALE reasonably apprised of all developments in any such action. LICENSEE may settle such suits solely in its own name and solely at its own expense and through counsel of its own selection; provided, however, that no settlement shall be entered without YALE's prior written consent. LICENSEE shall bear the expense of such legal actions. Except for providing reasonable assistance, at the request and expense of LICENSEE, YALE shall have no obligation regarding the legal actions described in this Section unless required to participate by law. However, YALE shall have the right to participate in any such action through its own counsel and at its own expense. Any recovery shall first be applied to LICENSEE's out-of-pocket expenses and second shall be applied to YALE's out-of-pocket expenses, including legal fees. Thereafter, any remaining amount of such recovery by LICENSEE up to the amount of compensatory damages recovered by LICENSEE shall be retained by LICENSEE, but if related to a PRODUCT IN CLASS or LICENSED METHOD shall be deemed, to the extent so related, NET SALES of a PRODUCT IN CLASS or LICENSED METHOD, as the case may be, during the calendar quarter in which such recovery is actually paid to LICENSEE, and shall be subject to payment by LICENSEE of an EARNED ROYALTY thereon pursuant to Section 6.1. LICENSEE shall pay YALE [\*\*] percent ([\*\*]%) of the amount, if any, of any such recovery by LICENSEE related to a PRODUCT IN CLASS or LICENSED METHOD which amount is in excess of (i) LICENSEE's and YALE's out-of-pocket expenses as aforesaid and (ii) the amount of such compensatory damages as aforesaid. LICENSEE shall make such payment to YALE within thirty (30) days after the end of the calendar quarter in which LICENSEE actually receives the amount giving rise to such payment to YALE.
- (b) Promptly after LICENSEE (a) receives notification from YALE of infringement by a third party or (b) otherwise first becomes aware of an infringement by a third party, whichever is earlier, LICENSEE shall investigate such infringement and take other steps, including, without limitation, contacting the person believed to be infringing, to determine the nature and extent of any such infringement and, if LICENSEE determines that such infringement is occurring, notify such infringing person to cease. If such infringement shall nonetheless continue, then LICENSEE shall proceed in a timely manner in accordance with Section 11.2(a). If LICENSEE fails to initiate such actions to investigate and determine the nature and extent of such infringement within sixty (60) days after the earlier of such notice from YALE or the date LICENSEE first becomes aware of such infringement or if LICENSEE fails to commence a legal action under Section 11.2(a) in a timely manner, as the case may be, then YALE may by notice to LICENSEE demand that LICENSEE take such actions or commence such legal action. If

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LICENSEE shall fail to take such action or commence such legal action, as the case may be, within sixty (60) days after such demand by YALE, then YALE shall have the right to take such action or to initiate such legal action, as the case may be, at its own expense. If YALE initiates such legal action YALE may use the name of LICENSEE as party plaintiff to uphold the LICENSED PATENTS. In such case, LICENSEE shall provide reasonable assistance to YALE if requested to do so. YALE may settle such actions solely through its own counsel. Any recovery shall be retained by YALE. In case YALE initiates such legal action in accordance with this Section 11.2(b), then YALE may terminate the LICENSE in the country where such legal action is taken.

- 11.3. In the event LICENSEE is permanently enjoined from exercising its LICENSE under this AGREEMENT pursuant to an infringement action brought by a third party, or if both LICENSEE and YALE elect not to undertake the defense or settlement of a suit alleging infringement for a period of six (6) months from notice of such suit, then either party shall have the right to terminate the LICENSE in the country where the suit was filed with respect to the allegedly infringing LICENSED PATENT following thirty (30) days' written notice to the other party in accordance with the terms of Article 15.
- 11.4. If LICENSEE, AFFILIATE, and/or SUBLICENSEE challenge a VALID CLAIM of a LICENSED PATENT or challenge a claim by YALE that a product is a PRODUCT IN CLASS (each a "CHALLENGE"), then LICENSEE, AFFILIATE, and/or SUBLICENSEE shall pay or continue to pay all amounts due under this AGREEMENT during the pendency of such CHALLENGE, whether or not any of such amounts is in dispute in such CHALLENGE.

#### ARTICLE 12 USE OF YALE'S NAME

LICENSEE shall not use the name "Yale" or "Yale University," nor any variation or adaptation thereof, nor any trademark, trade name or other designation owned by YALE, nor the names of any of its trustees, officers, faculty, students, employees or agents, for any purpose without the prior written consent of YALE in each instance, except (a) that LICENSEE may disclose the terms of this AGREEMENT, the activities of the parties hereunder, and the TECHNOLOGY to its stockholders, potential investors and consultants who are subject to obligations to LICENSEE to keep such information confidential, where such confidentiality obligations are substantially similar to the obligations of LICENSEE to YALE hereunder and (b) as required by applicable law.

### ARTICLE 13 TERMINATION

- 13.1. YALE shall have the right to terminate the LICENSE upon written notice to LICENSEE in the event a TERMINATION EVENT shall have occurred and be continuing; provided, however, that any termination by reason of a TERMINATION EVENT (other than a TERMINATION EVENT described in Section 2.58(a)) shall be made in accordance with Section 13.4.
- 13.2. The LICENSE shall terminate automatically without any notice to LICENSEE in the event LICENSEE shall cease to carry on its business for a period of thirty (30) consecutive days or becomes INSOLVENT, or a petition in bankruptcy is filed against LICENSEE and is

consented to, acquiesced in or remains undismissed for one hundred twenty (120) days, or LICENSEE makes a general assignment for the benefit of creditors, or a receiver is appointed for LICENSEE.

- 13.3. LICENSEE shall have the right to terminate the LICENSE upon written notice to YALE:
- (a) at any time on six (6) months' notice to YALE, provided LICENSEE is not in breach of the AGREEMENT in any material respect and upon payment of all amounts due YALE through the effective date of termination; or
- (b) in the event YALE commits a material breach of any of the provisions of this AGREEMENT and such breach is not cured (if capable of being cured) within the sixty (60) day period after receipt of written notice thereof from LICENSEE which notice shall identify such breach in reasonable detail, or upon receipt of such notice if such breach is not capable of being cured.
- 13.4. Subject to Section 13.1, if YALE believes that a TERMINATION EVENT (other than a TERMINATION EVENT described in Section 2.58(a)) shall have occurred and be continuing, then such matter shall be resolved in accordance with this Section 13.4.
- (a) If YALE believes such a TERMINATION EVENT shall have occurred and be continuing and wishes to obtain additional information from LICENSEE to assess whether such a TERMINATION EVENT shall have occurred and be continuing, then YALE may so notify LICENSEE and request such information as YALE may specify in such notice to assist YALE in determining whether such a TERMINATION EVENT shall have occurred and be continuing (each a "TERMINATION EVENT INFORMATION NOTICE"). LICENSEE shall respond to such TERMINATION EVENT INFORMATION NOTICE within thirty (30) days and in such response shall provide such information as YALE shall have requested and which LICENSEE has in its possession or may obtain without unreasonable effort or expense.
- (b) If either (1) notwithstanding LICENSEE having provided such additional information, YALE continues to believe such a TERMINATION EVENT shall have occurred and be continuing or (2) YALE believes such a TERMINATION EVENT shall have occurred and be continuing and does not wish to obtain additional information from LICENSEE under Section 13.4(a), then in either such case in the preceding clause (1) or (2) YALE may give notice to LICENSEE stating that YALE believes that such a TERMINATION EVENT shall have occurred and be continuing and setting forth in reasonable detail the basis for YALE's belief that such a TERMINATION EVENT shall have occurred and be continuing (each a "TERMINATION EVENT NOTICE"). Within thirty (30) days after LICENSEE receives a TERMINATION EVENT NOTICE, LICENSEE shall provide YALE such information as LICENSEE believes establishes the absence of such a TERMINATION EVENT having occurred and be continuing.
- (c) YALE shall give a TERMINATION EVENT INFORMATION NOTICE (or if YALE determines not to give a TERMINATION EVENT INFORMATION NOTICE, then a TERMINATION EVENT NOTICE) within ninety (90) days after (1) the cure period, in the

case of such a notice relating to Section 2.58(b), (2) YALE first learns of the event, in the case of such a notice relating to Section 2.58(c) or 2.58(e), (3) LICENSEE's notice to YALE, in the case of such a notice relating to Section 2.58(d), or (4) it receives LICENSEE's annual progress report, in the case of such a notice relating to Section 7.2 or 7.5, or the due date for LICENSEE's annual progress report, in case LICENSEE fails to provide any such report when due. If YALE gives a TERMINATION EVENT INFORMATION NOTICE, then it shall give any TERMINATION EVENT NOTICE relating thereto within 60 days after giving such TERMINATION EVENT INFORMATION NOTICE.

- (d) Within sixty (60) days after LICENSEE receives a TERMINATION EVENT NOTICE, YALE and LICENSEE shall meet at YALE's campus in New Haven, Connecticut to discuss and seek to resolve the matter. If, after such meeting the parties are unable to resolve such matter, then the Managing Director of YALE's Office of Cooperative Research, or the Managing Director's designee, and the Chairman of the Board, the Chief Executive Officer or the President or another designee of LICENSEE shall meet at YALE's campus in New Haven, Connecticut and seek to resolve such matter.
- If, after following the procedures specified in this Section 13.4 with respect to an alleged TERMINATION EVENT of the type covered by this Section 13.4, the parties are unable to resolve the matter and YALE continues to believe that such a TERMINATION EVENT has occurred and is continuing, then YALE shall so notify LICENSEE within thirty (30) days after conclusion of the meetings provided for in Section 13.4(d). Such notice shall specify in reasonable detail the TERMINATION EVENT(S) alleged to have occurred and be continuing. After YALE gives such notice, the parties shall submit the dispute to JAMS or another such mutually agreed upon alternative dispute resolution provider experienced in business dispute mediation (an "ADR") for non-binding mediation. The parties will cooperate with ADR and with one another in selecting a mediator from ADR's panel of neutrals, and in promptly scheduling the mediation proceedings. The parties covenant that they will participate in the mediation in good faith, and that they will share ADR costs equally. All offers, promises, conduct and statements, whether oral or written, made in the course of the mediation by any of the parties, their agents, employees, experts and attorneys, and by the mediator or any ADR employees, are confidential, privileged and inadmissible for any purpose, including impeachment, in any arbitration or other proceeding involving the parties, provided that evidence that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in the mediation. If the dispute is not resolved within ninety (90) days from the date of the submission of the dispute to mediation (or such later date as the parties may mutually agree in writing), then if such TERMINATION EVENT shall be continuing YALE shall have the right to terminate the LICENSE by giving fifteen (15) days notice to LICENSEE, which notice shall specify in reasonable detail the particular TERMINATION EVENT(S) (the "TERMINATION NOTICE"). The mediation may continue, if the parties so agree, after YALE gives the TERMINATION NOTICE. The pendency of a mediation shall not preclude a party from seeking provisional remedies in connection with this AGREEMENT or such dispute from a court of competent jurisdiction, and the parties agree not to defend against any application for provisional relief on the ground that a mediation is pending.
  - (f) Either party shall have the right to seek declaratory relief relating to this AGREEMENT in a court of competent jurisdiction.

- 13.5. Upon termination of the LICENSE, for any reason, all rights and licenses granted to LICENSEE under the terms of this AGREEMENT shall terminate. In case of any termination of the LICENSE, each sublicense that LICENSEE shall have entered into in compliance with this AGREEMENT shall become a direct license by YALE to the applicable SUBLICENSEE, so long as at the time of such termination of the LICENSE such SUBLICENSEE shall be in compliance in all material respects with the terms of its sublicense; provided, however that (1) YALE shall not be liable for any breach or default under such sublicense by LICENSEE and (2) in no event shall YALE have any obligation or liability under such sublicense that it did not have to LICENSEE under this AGREEMENT prior to termination of the LICENSE. Upon such termination, LICENSEE shall cease to manufacture or sell PRODUCTS IN CLASS and cease to practice LICENSED METHODS, except that (1) LICENSEE may complete the manufacture of quantities of PRODUCTS IN CLASS which were work-in-process on the date of such termination and (2) LICENSEE may, for up to one hundred eighty (180) days after the date of such termination, sell any inventory of PRODUCTS IN CLASS that existed on the date of such termination or which were completed as permitted by the immediately preceding clause (1). Within sixty (60) days of the effective date of termination LICENSEE shall:
- (a) Return to YALE all materials relating to or containing the LICENSED PATENTS, LICENSED METHODS or CONFIDENTIAL INFORMATION disclosed by YALE; provided, however, that LICENSEE may retain a single file copy thereof in its records;
  - (b) Provide to YALE the last report required under Section 9.1; and
  - (c) Make all payments arising under this AGREEMENT up to the effective date of termination.
- 13.6. Termination of the LICENSE shall not affect any rights or obligations accrued prior to the effective date of such termination and specifically LICENSEE's obligation to pay all royalties and other payments specified by Article 5 and 6 for NET SALES to the date of termination. The parties agree that claims giving rise to indemnification may arise after the TERM or termination of the LICENSE granted herein.
- 13.7. The rights provided in this Article 13 shall be in addition and without prejudice to any other rights which the parties may have with respect to any default or breach of the provisions of this AGREEMENT.
- 13.8. Waiver by either party of one or more defaults or breaches shall not deprive such party of the right to terminate because of any subsequent default or breach.
- 13.9. Upon termination of the LICENSE for any reason other than breach by YALE, the TECHNOLOGY that may no longer be practiced upon termination of the LICENSE or termination of the LICENSE with respect to a particular PRODUCT IN CLASS or LICENSED METHOD that LICENSEE has chosen to abandon, as the case may be, shall be a "RETURNED TECHNOLOGY". LICENSEE shall permit YALE and its future licensees of the RETURNED TECHNOLOGY to utilize, reference and otherwise have the benefit of all regulatory approvals of, or clinical trials or other studies conducted by or on behalf of LICENSEE on, and all filings made by or on behalf of LICENSEE with regulatory agencies with respect to, RETURNED

TECHNOLOGY. In addition, at YALE's request and subject to Section 13.5, LICENSEE shall, at YALE's sole cost and expense, deliver to YALE copies of records held by or on behalf of LICENSEE that are required by regulatory authorities to be maintained with respect to the sale, storage, handling, shipping and use of the RETURNED TECHNOLOGY, copies of all reimbursement approval files held by LICENSEE, and copies of all documents, data and information held by or on behalf of LICENSEE that are related to clinical trials and other studies by or on behalf of LICENSEE of RETURNED TECHNOLOGIES, all of which are collectively the "RETURNED MATERIALS". YALE agrees that, subject to the provisions of Article 8, LICENSEE may retain one copy thereof to the extent LICENSEE is required by law to maintain such copy. If LICENSEE so returns the RETURNED TECHNOLOGY and the RETURNED MATERIALS within six (6) months after YALE's request, then in total consideration for the provision of the RETURNED TECHNOLOGY and the RETURNED MATERIALS, YALE shall from time to time pay to LICENSEE [\*\*] percent ([\*\*]%) of all revenue or other financial consideration that is research support. YALE shall pay such amounts to LICENSEE within ninety (90) days after YALE receives such revenue.

13.10. Upon expiration of the TERM or upon termination of the LICENSE, LICENSEE shall have a non-exclusive, fully paid-up, perpetual license to LICENSED KNOW-HOW to make, have made, use, sell, have sold, import or export any PRODUCT, method, procedure, service or process in the LICENSED TERRITORY.

#### ARTICLE 14 INDEMNIFICATION; INSURANCE; NO WARRANTIES

14.1. LICENSEE shall defend, indemnify and hold harmless YALE, its trustees, directors, officers, employees, and agents and their respective successors, heirs and permitted assigns (the "INDEMNIFIED PERSONS") against any and all liabilities, claims, demands, damages, judgments, losses and expenses of any nature, including, without limitation, reasonable legal expenses and attorneys' fees (collectively "CLAIMS"), (1) arising out of any theory of liability (including, without limitation, tort, warranty, or strict liability) or the death, personal injury, or illness of any person or out of damage to any property related in any way to the rights granted under this AGREEMENT; or (2) resulting from the production, manufacture, sale, use, lease, or other disposition or consumption or advertisement of the PRODUCTS IN CLASS or LICENSED METHODS by LICENSEE, its AFFILIATES, SUBLICENSEES or any other transferees; or (3) in connection with any statement, representation or warranty of LICENSEE, its AFFILIATES, SUBLICENSEES or any other transferees with respect to the LICENSED PRODUCTS or LICENSED METHODS. Each INDEMNIFIED PERSON shall notify LICENSEE promptly after such INDEMNIFIED PERSON learns of a CLAIM or threatened CLAIM for which indemnity may be sought under this Section 14.1. The LICENSEE shall have the right to assume the defense of any legal action for which indemnity may be sought under this Section 14.1. LICENSEE shall not be responsible for indemnity with regard to any CLAIM that is settled without LICENSEE's prior written consent. Notwithstanding any provision of this AGREEMENT to the contrary, no INDEMNIFIED PERSON shall be entitled to indemnity hereunder for any CLAIM arising out of or relating to such INDEMNIFIED PERSON's participation in any clinical trial involving any PRODUCT IN CLASS or such INDEMNIFIED PERSON's use of a PRODUCT IN CLASS as a patient.

- 14.2. LICENSEE shall purchase and maintain in effect and shall require its SUBLICENSEES to purchase and maintain in effect a policy of commercial, general liability insurance to protect YALE with respect to events described in Section 14.1. Such insurance shall:
  - (a) list "YALE, its trustees, directors, officers, employees and agents" as additional insureds under the policy;
  - (b) provide that such policy is primary and not excess or contributory with regard to other insurance YALE may have;
- (c) be endorsed to include product liability coverage in amounts no less than Five Million Dollars (\$5,000,000.00) per incident and Five Million Dollars (\$5,000,000.00) annual aggregate; and
  - (d) be endorsed to include contractual liability coverage for LICENSEE's indemnification under Section 14.1; and
- (e) by virtue of the minimum amount of insurance coverage required under Section 14.2(c), not be construed to create a limit of LICENSEE's liability with respect to its indemnification under Section 14.1.
- 14.3. By signing this AGREEMENT, LICENSEE certifies that the requirements of Section 14.2 will be met on or before the earlier of (a) the date of FIRST SALE of any PRODUCT IN CLASS or LICENSED METHOD or (b) the date any PRODUCT IN CLASS, or LICENSED METHOD is tested or used on humans, and will continue to be met thereafter. Upon YALE's request, LICENSEE shall furnish a Certificate of Insurance and a copy of the current Insurance Policy to YALE. LICENSEE shall give thirty (30) days' written notice to YALE prior to any cancellation of or material change to the policy.
- 14.4. (a) YALE MAKES NO, AND EXPRESSLY DISCLAIMS ALL, REPRESENTATIONS OR WARRANTIES THAT ANY CLAIMS OF THE LICENSED PATENTS, ISSUED OR PENDING, ARE VALID, OR THAT THE MANUFACTURE, USE, SALE OR OTHER DISPOSAL OF THE PRODUCTS IN CLASS, OR PRACTICE OF THE LICENSED METHODS, DOES NOT OR WILL NOT INFRINGE UPON ANY PATENT OR OTHER RIGHTS NOT VESTED IN YALE.
- (b) EXCEPT AS OTHER WISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, YALE MAKES NO, AND EXPRESSLY DISCLAIMS ALL, REPRESENTATIONS AND WARRANTIES WHATSOEVER WITH RESPECT TO THE LICENSED PATENTS, PRODUCTS IN CLASS AND LICENSED METHODS, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. LICENSEE SHALL MAKE NO STATEMENTS, REPRESENTATION OR WARRANTIES WHATSOEVER TO ANY THIRD PARTIES WHICH ARE INCONSISTENT WITH SUCH DISCLAIMER BY YALE. IN NO EVENT SHALL YALE, OR ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES, BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES OF ANY KIND. INCLUDING ECONOMIC

DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER YALE SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING. IN NO EVENT SHALL YALE, OR ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES, BE LIABLE FOR DAMAGES IN EXCESS OF AMOUNTS YALE HAS RECEIVED FROM LICENSEE UNDER THIS LICENSE.

#### ARTICLE 15 NOTICES, PAYMENTS

15.1. Any payment, notice or other communication required by this AGREEMENT (a) shall be in writing, (b) may be delivered personally or sent by reputable overnight courier with written verification of receipt or by registered or certified first class United States Mail, postage prepaid, return receipt requested, (c) shall be sent to the following addresses or to such other address as such party shall designate by written notice to the other party, and (d) shall be effective upon receipt:

FOR YALE: Managing Director YALE UNIVERSITY Office of Cooperative Research 433 Temple Street New Haven, Connecticut 06511 FOR LICENSEE: Chief Executive Officer Kolltan Pharmaceuticals, Inc. 300 George Street New Haven, Connecticut, 06511

With a copy to: General Counsel Kolltan Pharmaceuticals, Inc. 300 George Street New Haven, Connecticut, 06511

#### ARTICLE 16 LAWS, FORUM AND REGULATIONS

- 16.1. Any matter arising out of or related to this AGREEMENT shall be governed by and in accordance with the substantive laws of the State of Connecticut, without regard to its conflicts of law principles, except where the federal laws of the United States are applicable and have precedence. Any dispute arising out of or related to this AGREEMENT shall be brought in a court of competent jurisdiction in the State of Connecticut.
- 16.2. LICENSEE shall comply, and shall cause its AFFILIATES to comply and require its SUBLICENSEES to comply, with all foreign and United States federal, state, and local laws, regulations, rules and orders applicable to the testing, production, transportation, packaging, labeling, export, sale and use of the PRODUCTS IN CLASS and practice of the LICENSED METHODS. In particular, LICENSEE shall be responsible for assuring compliance with all United States export laws and regulations applicable to this LICENSE and LICENSEE's activities under this AGREEMENT.

#### ARTICLE 17 MISCELLANEOUS

- 17.1. This AGREEMENT shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.
- 17.2. This AGREEMENT constitutes the entire agreement of the parties relating to the LICENSED PATENTS, PRODUCTS IN CLASS and LICENSED METHODS, and all prior representations, agreements and understandings, written or oral, are merged into it and are superseded by this AGREEMENT. This AGREEMENT supersedes the SECOND AMENDED AND RESTATED LICENSE AGREEMENT in its entirety and, as of the THIRD AMENDMENT EFFECTIVE DATE, the SECOND AMENDED AND RESTATED LICENSE AGREEMENT shall be of no further force and effect; provided, however, that any obligations to either party accrued by the other party prior to the THIRD AMENDMENT EFFECTIVE DATE under the SECOND AMENDED AND RESTATED LICENSE AGREEMENT shall remain as such.
- 17.3. The provisions of this AGREEMENT shall be deemed separable. If any part of this AGREEMENT is rendered void, invalid, or unenforceable, such determination shall not affect the validity or enforceability of the remainder of this AGREEMENT unless the part or parts which are void, invalid or unenforceable shall substantially impair the value of the entire AGREEMENT as to either party.
  - 17.4. Articles, paragraph and section headings are inserted for convenience of reference only and do not form a part of this AGREEMENT.
- 17.5. No person not a party to this AGREEMENT, including any employee of any party to this AGREEMENT, shall have or acquire any rights by reason of this AGREEMENT. Nothing contained in this AGREEMENT shall be deemed to constitute the parties partners with each other or any third party.
- 17.6. This AGREEMENT may not be amended or modified except by written agreement executed by each of the parties. This AGREEMENT is personal to LICENSEE and shall not be assigned by LICENSEE without the prior written consent of YALE; provided, however, that no such consent of YALE shall be required in case of any assignment of this AGREEMENT by LICENSEE in connection with a merger, consolidation, sale or other transfer of all or substantially all of LICENSEE's assets or any similar business combination or reorganization so long as the assignee shall expressly assume in writing LICENSEE's obligations under this AGREEMENT; provided further, however, that in case of any such action or transaction described in the immediately preceding proviso, if the same constitutes a CHANGE OF CONTROL nothing in this Section 17.6 shall remove such transaction from Section 5.4 or 5.7. Sublicenses shall not be deemed a sale or other transfer of assets by LICENSEE governed by this Section 17.6, but instead shall be governed by Article 4 and, in respect of milestone royalties by Sections 5.5 and 5.8. Any attempted assignment in contravention of this Section 17.6 shall be null and void and shall constitute a material breach of this AGREEMENT.

- 17.7. LICENSEE, or any SUBLICENSEE or assignee, will not create, assume or permit to exist any lien, pledge, security interest or other encumbrance on this AGREEMENT or any sublicense.
- 17.8. The failure of any party hereto to enforce at any time, or for any period of time, any provision of this AGREEMENT shall not be construed as a waiver of either such provision or of the right of such party thereafter to enforce each and every provision of this AGREEMENT.
- 17.9. This AGREEMENT may be executed in any number of counterparts and any party may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument.
- 17.10. Neither YALE nor LICENSEE shall be liable to perform its obligations as required by this AGREEMENT, or shall be in default of its obligations under this AGREEMENT, to the extent such failure to perform or default is caused by any reason beyond such party's control, including, without limitation, any of the following: labor disturbances or disputes of any kind, accidents, failure of any required governmental approval, civil disorders, acts of aggression, acts of God, energy or other conservation measures, failure of utilities, delays or defaults by common carrier, mechanical breakdowns, material shortages, disease, or similar occurrences. In case of any such reason beyond a party's control, the time for performance of such party's obligations affected thereby shall be extended by the period of the event or circumstance constituting such reason and for a reasonable period of time thereafter.
- 17.11. YALE has provided LICENSEE with the Yale University Patent Policy in effect as of the EFFECTIVE DATE, a copy of which is attached hereto as Appendix E. As described in the recitals to this AGREEMENT, as of the EFFECTIVE DATE, SCHLESSINGER serves on the LICENSEE Board of Directors and the LICENSEE Scientific Advisory Board, and as a paid consultant to LICENSEE. LICENSEE agrees that, for so long as SCHLESSINGER is an employee of YALE, LICENSEE's rights to any INVENTIONS of SCHLESSINGER created other than in his capacity as a YALE employee shall be subject to the attached Yale University Patent Policy, and that any agreement, past or future, between SCHLESSINGER and LICENSEE regarding INVENTIONS of SCHLESSINGER shall be construed in accordance therewith.

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IN WITNESS to their agreement, the parties have caused this AGREEMENT to be executed in duplicate originals by their duly authorized representatives.

# YALE UNIVERSITY

# KOLLTAN PHARMACEUTICALS, INC.

By: /s/ E. Jonathan Soderstrom

E. Jonathan Soderstrom, Ph.D.
Managing Director
Office of Cooperative Research

Date: 17 May 2013

By: /s/ Gerald McMahon
President and Chief Executive Officer

Date: 3/14/13

# Appendix A

### LICENSED PATENTS

# (Shaded Rows = International (PCT) and Foreign Applications)

M&E Matter	Yale Reference				
Ňo.	No.	Serial No.	Title	Filing Date	Status
**]	[**]	[**]	[**]	[**]	[**]
onfidential Materials omitted	and filed separately with the Securities ar	nd Exchange Commi	ission. A total of 8 p	ages were omitted. [**	]
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	Securities and Exchange Comm		•	ons.	
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		THE PLAN			
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# Appendix C

# UNPATENTED VISITING SCIENTIST IP

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# THIRD PARTY RIGHTS

# **NONE**

#### Appendix E

#### YALE UNIVERSITY PATENT POLICY

Yale University Office of Cooperative Research

http://www.yale.edu/ocr/pfg/policies/patents.html

#### Yale University

Disclose an Invention Licensing Opportunities YEI FAQs Contact Us

#### Yale University Patent Policy

- 1. Encouragement or Patents. In the course of teaching, research, and other intellectual and administrative activity by faculty, staff fellows, students, and other individuals in the University community, discoveries or inventions both patentable and practical occur. Encouragement of such inventions in appropriate ways is both supportive of the public interest and consistent with the advancement or knowledge for its own sake, the primary purpose of teaching and research in a university. The University Patent Policy states the procedure to be followed in the administration of inventions which result from teaching, research, and other intellectual activity performed under University auspices except as further defined in paragraph 6.
- 2. Purpose of Patent Policy. The purposes of this University Patent Policy are (1) to help assure. In the public interest, that the patentability (or other means or explanation) and practicality of inventions will be evaluated by qualified persons, and that the income from inventions will be used to support further research or other desirable University activities; and (2) to define remuneration to the inventor or inventors (hereinafter the "Inventor") and the University as long as the invention is productive of royalties.
- 3. Procedure as to Inventions. The University has established a Committee on Cooperative Research, Patents, and Licensing (../../../provost/html/comm\_coopresearch.html) appointed from among members of the faculty and administration. One function of the Committee is to advise the University on matters of patents policy and administration. The University has also established an Office of Cooperative Research to facilitate transfer of its inventions/discoveries in the public interest.
  - a. Patent Applications. All inventions of the kind referred to in paragraph 1 shall be reported promptly in writing to the Provost through the Director of the Office of Cooperative Research. The Director, with the advice of the Committee on Cooperative Research, Patents, and Licensing, shall conduct an initial screening followed, when indicated, by a detailed evaluation of the invention. This may be done through an internal review, or by referral to an external organization that manages the evaluation. After the evaluation, the University may, alone or with the assistance of an external organization, make application for letters patent. At the request of the office of Cooperative Research, the Inventors shall execute assignments or other documents assigning to the University all their rights in the invention and any patent applications or resulting patents on the invention. Yale will retain title to all such patent applications and resulting patents. If the University decides that it does not wish, and has no legal obligation, to participate in the patenting or licensing of an invention, the University may release to the Inventor the University's interest in the invention, and the Inventor shall then be free to dispose of the invention as he or she wishes.

#### b. License Agreement.

- i. If the University decides to participate in the patenting or licensing or an invention, the Office of Cooperative Research will seek to enter into appropriate licensing arrangements to commercialize the invention. The objective of the University is to assure the development of its technology in furtherance of its own educational mission and for the benefit of society in general. Therefore, as a general policy, the University will set the terms or its licenses so as to further the achievement of this objective. Exclusive licenses will be granted if it appears to the Office of Cooperative Research that this is the most effective way of ensuring development to the point that the public will benefit. Any exclusive license agreement will be so drawn as to protect against failure of the licensee to carry out effective development and marketing within a specified time period.
- i. In research grants or contracts sponsored by industrial companies there will typically be a section covering patents on future inventions, if any, as in all government grants. When deemed appropriate, the sponsor may be granted a license to any inventions developed during the term of the grant or contract in accordance with the policies outlined in I) above.

#### 4. 4. Division of Royalties.

- a. Definition. For purposes of this policy, "royalties" shall include running royalties, advances against running royalties, up-front license fees, milestone payments, shares of stock or other securities issued by the licensee or another corporation ("equity"), and any other payments received by the University under a license agreement in consideration for licensing an invention, but shall not include amounts received from a licensee or others in sponsorship of research or under other agreements for other goods, services or rights.
- b. Recovery of Expenses. Royalties shall be used first to offset out-of-pocket expenses incurred by the University in applying for, obtaining, and defending a patent and in developing and negotiating license agreements during the

life of the patent. Expenses for this purpose will include fees paid be outside legal, consulting, and licensing organizations and any other out-of-pocket costs incurred by the University. The fees paid to the external individuals or organizations for such services may be of fixed dollar amount or may be in the form of an agreed-upon fraction or the gross royalty income, if any, or in any other form directly associated with commercialization/licensing of the invention. In addition, 10% or Royalties, after reduction as provided above for outof-pocket expenses, received in any year from an invention made on or after April 11, 1992 shall be retained by the University and applied toward the general support of the Office or Cooperative Research; provided, that if the total or such recoveries in any year exceeds the Office's approved budget, the excess shall be allocated in a pro rata basis among those inventions from which it was recovered and shall be distributed as part of Net Royalties in accordance with subparagraph (d).

- Net Royalties. Alter recovery of expenses by the University as provided in subparagraph (b), the remaining royalties will be designated Net Royalties.
- Distribution or Net Royalties. The Net Royalties as defined above shall be divided between the Inventor(s) (as defined under the patent law) and the University as follows:
  - The first \$100,000 of Net Royalties 50% to the Inventor(s) 50% allocated to the general support of University research, as described in paragraph 5.
  - Net Royalties between \$100,000 and \$200,000 40% to the Inventor(s) 60% allocated to the general support of University research, as described in paragraph 5.
  - Net Royalties exceeding \$200,000 30% to the Inventor(s)

70% allocated to the general support of University research, as described in paragraph 5.

For purposes of applying the above Net Royalty distribution formula (i.e., whether aggregate Net Royalties are \$100,000 or less, between \$100,000 and \$200,000, or more than \$200,000), equity shall be deemed to have the per-share value agreed upon in a goodfaith negotiation between the University and the licensee at the time the license agreement is executed, and the equity shall be deemed received after all cash Net Royalties received at or before the time the equity is issued. In the absence of such negotiated value, the Inventors shall receive 32% of the equity Net Royalties.

In its discretion, the University may either distribute equity to the Inventor(s) when it is received or arrange for the licensee to issue the Inventor's share of equity directly to the Inventor(s).

As used in this document, the term "Inventor" may represent two or more individuals. These individuals will be expected to agree among themselves on the fractional distribution of the "Inventor" share of any royalties. A written agreement must be signed by all the individuals involved, and deposited for the record in the Office of Cooperative Research. (Appropriate forms are available from the Office of Cooperative Research.) If no written agreement has been deposited at the time of a distribution of Net Royalties, the Inventors' share of such distribution shall be divided equally among the Inventors.

- Overriding Agreements with Third Parties. The foregoing provisions of this paragraph and the rest of this University Patent Policy are subject to the terms of applicable grants and contracts with third parties. See paragraph 7.
- 5. General Research Support from Net Royalties. The University's share or Net Royalties will be used in support of research, or if not specifically prohibited by the funding agency contract, will accrue to the Science Development Fund or other appropriate research fund, and will be allocated by the Provost. Before allocating funds, the Provost shall consult with the relevant subdivision of the University concerning the research to be supported.
- Inventions Not under University Auspices. Inventions by university employees usually result from teaching, research, or other intellectual activity involving University facilities or personnel. Accordingly, all inventions by University employees must be reported to the Office of Cooperative Research. When the University determines that an invention by a University employee is unrelated to the activities for which the individual is employed and has not involved the use of University facilities, then the University will make no claim to such an invention. All inventions made or conceived under circumstances involving University facilities or personnel are the property or the University.

An invention made by a faculty member in the course of a paid consulting engagement for a company may be assigned to the company only if it is unrelated to the activities for which the faculty member is employed by Yale and it was not made or conceived under circumstances involving University facilities or personnel. Such an invention will be considered unrelated to the activities for which the faculty member is employed by Yale if the invention arises directly out or consulting activity paid for by the company, and, for example, it is made in response to a problem posed by the company or is based on nonpublic information provided by the company to the faculty member for use in the consulting

engagement. It will be considered not to have involved the use of University facilities if no University facilities or resources (including but not limited to space, computers, laboratory equipment and supplies), no University-administered funds, and no University personnel other than the faculty member himself or herself, are involved in the conception or reduction to practice or the invention. All inventions made by Yale faculty members in the course of consulting, and any assignments of rights to such inventions, must be reported promptly to the Office of Cooperative Research. That Office will agree to abide by reasonable confidentiality restrictions for disclosures of inventions and assignments made in the course of consulting.

- 7. When Arrangements with Outside Organizations Override This Policy. Arrangements with outside organizations that propose terms which are exceptions to this Policy must be submitted to the President or Provost for review by the University with he advice of the Committee on Cooperative Research, Patents, and Licensing, If approved by the University the terms shall be binding upon all members or the faculty, staff, and employees of the University conducting such research or utilizing such facilities, and will supersede the provisions of the patent policy to the extent that the terms are inconsistent therewith.
- a. Inventions by Staff Resulting from Performance or the Responsibilities of Their Employment. Not infrequently, in the course of carrying out assigned responsibilities of their employment, staff employees may make commercially useful inventions or develop licensable property, (i.e., the employee received salary or wages for the specific function of developing the work which ultimately has commercial value). In such cases, there is no presumption that the University will share royalty (or other) revenues with the employee. Normally, the University does not share revenues with staff except in cases where it appears that the invention or commercially valuable property has not resulted from the performance of assigned duties. In these Instances, the invention (or other commercially valuable work) will be reviewed by the Committee on Cooperative Research, Patents, and Licensing and a recommendation will be made to the Provost. In these cases, the division of royalties as specified in paragraph 4(d) of this policy may not apply and the Provost may substitute different provisions after review of the recommendations of the Committee on Cooperative Research, Patents, and Licensing.
- 9. Governmental Rights in Certain Inventions. Current governmental regulations permit educational institutions to retain rights and title to patentable inventions which results from federally funded experimental, developmental and research work. Retention of rights by University is contingent upon the fulfilling of a number of obligations on the part of the University and of the Inventor(s) and these obligations must be discharged in order to protect the Interests of all parties. Though the University may retain rights and title to such patentable inventions, the federal government retains a royalty free license and places certain other restrictions upon the ultimate disposition or the patents(s). Details of the implementing regulations may be obtained from the Office or Cooperative Research. Incumbent upon members of the University community who apply for and receive federal finding to support research or who use federal monies in the conduct of their research is the requirement for written agreement that they will promptly disclose patentable inventions to the University and will execute all instruments necessary to protect the rights of the government and/or the University. Forms for this agreement will be provided to all faculty and will be available for other participants (i.e. collaborators, post-doctoral students, graduate students) from the appropriate departmental chairman or, at the Chairman's option, from the Departmental Business Office.
- 10. Revocation or Amendment. This patent policy is subject to revocation or amendment by the Corporation. In case of doubt as to the interpretation of this patent policy, a definitive interpretation will be provided by the President or Provost after receiving the advice of the Committee on Cooperative Research, Patents, and Licensing. This patent policy is effective as to all inventions/discoveries made on or after February 23, 1998.

Revised February, 1998

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### Appendix F

# **KOLLTAN PATENTS**

(Shaded Rows = International (PCT) and Foreign Applications)

Jones Day	Kolltan Reference				
Matter No.	No.	Serial No.	Title	Filing Date	Status
[**]		[**]	[**]	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [\*\*]

#### AMENDMENT NUMBER ONE TO THIRD AMENDED AND RESTATED LICENSE AGREEMENT

YALE UNIVERSITY, a corporation organized and existing under and by virtue of a charter granted by the general assembly of the Colony and State of Connecticut and located in New Haven, Connecticut ("YALE"), and KOLLTAN PHARMACEUTICALS, INC., a corporation organized and existing under the laws of the State of Delaware, and with principal offices located at 300 George Street, New Haven, CT 06511 ("LICENSEE"), have entered into that certain Third Amended and Restated License Agreement, dated March 14, 2013, as amended and/or restated from time to time (the "Agreement"), an exclusive license to YALE's receptor tyrosine kinases (RTKs) intellectual property, which agreement YALE internally designates as contract number [\*\*]. As set forth herein, the parties now wish to amend the Agreement. This Amendment Number One to Third Amended and Restated License Agreement ("Amendment No. 1"), which YALE will internally designate as [\*\*], shall be effective as of March 21, 2014 ("Effective Date").

WHEREAS, an invention [\*\*] was originally jointly owned by YALE and The Governing Council of the University of Toronto, an institution of higher education having offices located at the Innovations & Partnerships Office, 100 College Street, Toronto, ON, Canada M5G 1L5 ("TORONTO");

WHEREAS, YALE has prepared a provisional patent application [\*\*] from the invention disclosed as [\*\*] naming inventors from YALE and from TORONTO (the "PATENT APPLICATION"), a copy of which has been provided by YALE to LICENSEE and which as of the EFFECTIVE DATE has been filed with the United States Patent and Trademark Office;

WHEREAS, LICENSEE and TORONTO have entered into an agreement, effective as of December 5, 2013, pursuant to which TORONTO has assigned to LICENSEE all of TORONTO's interests in [\*\*] and the [\*\*] PATENTS (defined below) (the "ASSIGNMENT"); and

WHEREAS, [\*\*] is, as of the effective date of the ASSIGNMENT, jointly owned by YALE and LICENSEE;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants set forth herein, the parties agree as follows:

#### I. <u>Memorandum of Understanding</u>

- 1. Filing. LICENSEE hereby agrees to pay the invoiced expenses for the [\*\*] PATENTS pursuant to the terms of the Agreement (as amended by Amendment No. 1); provided that, upon assumption of prosecution of the [\*\*] PATENTS pursuant to Section I.3. below, such section will govern all expenses associated with the [\*\*] PATENTS incurred thereafter.
- 2. <u>Schlessinger Involvement</u>. The parties acknowledge that the [\*\*] PATENTS being included as "LICENSED PATENTS" under the Agreement (as amended by Amendment No. 1) were made, created, developed, discovered, conceived or first reduced to practice while

SCHLESSINGER was MEANINGFULLY INVOLVED AT KOLLTAN and MEANINGFULLY INVOLVED AT YALE as defined in Section 2.26(b) under the Agreement (as amended by Amendment No. 1).

3. <u>Prosecution.</u> Notwithstanding Article 10 of the Agreement (as amended by Amendment No. 1), LICENSEE shall be entitled, at its sole expense, to assume prosecution of the PATENT APPLICATION and any other United States or foreign patents or patent applications claiming [\*\*], including any continuations, divisionals, and continuations-in-part, and continued prosecution application(s), any reissues, re-examinations, renewals, or extensions, substitutes, and the relevant international equivalents (collectively, the "[\*\*] PATENT(S)"). Any additional patent applications claiming, using, derived from, or arising from [\*\*] or an [\*\*] PATENT shall be an [\*\*] PATENT.

Upon request from LICENSEE, YALE will timely transfer to LICENSEE responsibility for prosecution of the [\*\*] PATENTS. All [\*\*] PATENTS shall be prepared, prosecuted, filed and maintained by independent patent counsel chosen by LICENSEE and reasonably acceptable to YALE. Said independent patent counsel shall be ultimately responsible to LICENSEE, but YALE shall also be the client of said patent counsel. YALE shall have the right to retain, at its own expense, separate patent counsel to advise YALE regarding such patent matters. LICENSEE shall instruct patent counsel to keep LICENSEE, YALE and YALE's patent counsel, if such counsel should be engaged by YALE, fully informed of the progress of all [\*\*] PATENTS, and to give both LICENSEE and YALE reasonable opportunity to comment on the type and scope of useful claims and the nature of supporting disclosures and other matters in the course of patent prosecution and maintenance.

In making its decisions regarding patent matters related to [\*\*] PATENTS, LICENSEE shall (a) give due regard to the advice of its patent counsel, (b) instruct its patent counsel to consider any advice offered by YALE and YALE's patent counsel, if such counsel should be engaged by YALE, and (c) conduct such preparation, prosecution and maintenance of [\*\*] PATENTS in a manner that is commercially reasonable in order to commercialize PRODUCTS IN CLASS and/or LICENSED METHODS for which royalties will be payable by LICENSEE to YALE pursuant to the Agreement. In the event of a disagreement concerning the prosecution of the [\*\*] PATENTS, LICENSEE shall have the right to make the final decision concerning such the prosecution. LICENSEE shall have no liability to YALE for damages, whether direct, indirect or incidental, consequential or otherwise, allegedly arising from its good faith decisions, actions and omissions taken in compliance with the Agreement in connection with such patent prosecution.

If LICENSEE desires to abandon any [\*\*] PATENT, LICENSEE will provide YALE with sufficient prior written notice, and YALE may then assume prosecution of such patent; and, thereafter, (i) if the [\*\*] PATENT remains a "LICENSED PATENT" under the Agreement,

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

then the provisions in the Agreement governing prosecution costs will apply; and (ii) if the [\*\*] PATENT ceases to be a "LICENSED PATENT" under the Agreement, YALE's prosecution of such patent will be at YALE's expense, and, in the case of this clause (ii), LICENSEE will timely assign LICENSEE's joint ownership interests in such [\*\*] PATENTS that are being abandoned by LICENSEE to YALE.

4. <u>Joint Ownership.</u> YALE represents that it has not entered into any agreement with TORONTO directly relating to [\*\*] or the [\*\*] PATENTS. To the extent that YALE's consent, as a joint owner of [\*\*] or the [\*\*] PATENTS with TORONTO, was needed for TORONTO's assignment of [\*\*] or the [\*\*] PATENTS to LICENSEE, YALE hereby consents to TORONTO's assignment of [\*\*] and the [\*\*] PATENTS to LICENSEE.

As a result of the assignment of rights from TORONTO to LICENSEE making YALE and LICENSEE joint owners of [\*\*] and the [\*\*] PATENTS, YALE and LICENSEE agree that each of LICENSEE and YALE will have the right to practice and exploit [\*\*] and any [\*\*] PATENTS without the duty of accounting to the other party or seeking consent (for licensing, assigning, or otherwise exploiting [\*\*] or any [\*\*] PATENTS) from the other party by reason of the joint ownership thereof but subject to compliance with the terms and conditions of the Agreement (as amended by Amendment No. 1) or, if the Agreement has expired or terminated (entirely or with respect to [\*\*] or a particular [\*\*] PATENT(S)), any surviving terms of the Agreement applicable to [\*\*] and such [\*\*] PATENTS, as applicable; and each party hereby waives any right it may have under the laws of any jurisdiction to require any such approval or accounting, and, to the extent there are any applicable laws that prohibit such a waiver, each party will be deemed to so consent.

The parties acknowledge that LICENSEE has a separate ownership interest in [\*\*] and the [\*\*] PATENTS obtained through LICENSEE's assignment from TORONTO, and the inclusion of [\*\*] and the [\*\*] PATENTS under the Agreement (as amended by Amendment No. 1) only relates to YALE's interest in them; as such, Licensee will continue to have the right to practice and exploit [\*\*] and [\*\*] PATENTS even if [\*\*] and [\*\*] PATENTS cease to be "LICENSED PATENTS" under the Agreement (as amended by Amendment No. 1) or the Agreement (as amended by Amendment No. 1) expires or terminates.

### II. Amendments

1. <u>Definitions</u>. All capitalized terms used herein shall have the meaning given to such terms in the Agreement, unless otherwise specifically defined in Amendment No. 1.

### 2. Additional LICENSED PATENTS.

The parties agree that the [\*\*] PATENTS are "LICENSED PATENTS" under the Agreement (as amended by Amendment No. 1).

3. Addition of the [\*\*] PATENTS to Appendix A LICENSED PATENTS. Appendix A of the Agreement is hereby amended to add the PATENT APPLICATION as follows:

M&E	Yale				
Matter	Reference	Serial No./		Filing Date/	
No.	No.	Patent No.	Title	Issue Date	Status
[**]	[**]	[**]	[**]	[**]	[**]

4. Entire Agreement. Except as explicitly amended by Amendment No. 1, all other terms and conditions of the Agreement shall remain in full force and effect and apply fully to the terms of Amendment No. 1 as if part of the Agreement.

Signature Page Follows

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment No. 1 (including the associated Memorandum of Understanding herein).

YALE UNIVERSITY		KOLLTAN PHARMACEUTICALS, INC.		
By:	/s/ E. Jonathan Soderstrom	By:	/s/ Gerald McMahon	
	E. Jonathan Soderstrom, Ph.D. Managing Director Office of Cooperative Research		Gerald McMahon President and Chief Executive Officer	
Date:	10 April 2014	Date:	3-24-2014	

# AMENDMENT NUMBER TWO TO THIRD AMENDED AND RESTATED LICENSE AGREEMENT

YALE UNIVERSITY, a corporation organized and existing under and by virtue of a charter granted by the general assembly of the Colony and State of Connecticut and located in New Haven, Connecticut ("YALE"), and KOLLTAN PHARMACEUTICALS, INC., a corporation organized and existing under the laws of the State of Delaware, and with principal offices located at 300 George Street, New Haven, CT 06511 ("LICENSEE"), have entered into that certain Third Amended and Restated License Agreement, dated March 14, 2013, as amended by that certain Amendment Number One to Third Amended and Restated License Agreement, effective March 21,2014, and as amended and/or restated from time to time (the "Agreement"), an exclusive license to YALE's receptor tyrosine kinases (RTKs) intellectual property, which agreement YALE internally designates as contract number [\*\*]. As set forth herein, the parties now wish to amend the AGREEMENT. This Amendment Number Two to Third Amended and Restated License Agreement ("AMENDMENT NO. 2"), which YALE will internally designate as [\*\*], shall be effective as of December 1, 2014 ("AMENDMENT NO. 2 EFFECTIVE DATE").

WHEREAS, an invention titled [\*\*] was developed pursuant to the RESEARCH AGREEMENT and is a "Joint Invention" under the RESEARCH AGREEMENT;

WHEREAS, LICENSEE has prepared a provisional patent application titled "[\*\*]" from the invention disclosed as [\*\*] naming inventors from YALE and LICENSEE (the "[\*\*] PATENT APPLICATION," described in the table II(3) below), which as of the AMENDMENT NO. 2 EFFECTIVE DATE has been filed with the United States Patent and Trademark Office;

WHEREAS, an invention titled "[\*\*]" ("[\*\*]") was developed pursuant to the RESEARCH AGREEMENT and is a "Joint Invention" under the RESEARCH AGREEMENT:

WHEREAS, LICENSEE has prepared a provisional patent application titled "[\*\*]" from the invention disclosed as [\*\*] naming inventors from YALE and LICENSEE (the "[\*\*] PATENT APPLICATION," described in the table II(3) below), which as of the AMENDMENT NO. 2 EFFECTIVE DATE has been filed with the United States Patent and Trademark Office; and

WHEREAS, YALE and LICENSEE desire to confirm the [\*\*] PATENT APPLICATION and the [\*\*] PATENT APPLICATION as LICENSED PATENTS under the AGREEMENT;

NOW, THEREFORE, in consideration of the promises and of the mutual covenants set forth herein, the parties agree as follows:

- I. Memorandum of Understanding
- 1. <u>Schlessinger Involvement</u>. The parties acknowledge that the [\*\*] PATENT APPLICATION and the [\*\*] PATENT APPLICATION being included as "LICENSED PATENTS" under the AGREEMENT (as amended by AMENDMENT NO. 2) claim RTK TECHNOLOGY that was made, created, developed, discovered, conceived or first reduced to practice by or on behalf of SCHLESSINGER, LAX the SCHLESSINGER LAB, or LAX LAB while

SCHLESSINGER was MEANINGFULLY INVOLVED AT YALE as defined in Section 2.26(b) under the AGREEMENT (as amended by AMENDMENT NO. 2)

2. <u>Prosecution</u>. Notwithstanding Article 10 of the Agreement (as amended by AMENDMENT No. 2), the following prosecution provisions will govern the prosecution of the [\*\*] PATENT APPLICATION and the [\*\*] PATENT APPLICATION, including any continuations, divisionals, and continuations-in-part, and continued prosecution application(s), any reissues, reexaminations, renewals, or extensions, substitutes, and the relevant international equivalents of each thereof (collectively, the "AMENDMENT NO. 2 PATENT(S)").

LICENSEE shall have the right to prepare, file and prosecute patent applications jointly in the name of LICENSEE and in the name of YALE claiming AMENDMENT NO. 2 PATENTS. LICENSEE will provide YALE with a copy of any such patent applications, in a timely manner, for LAX's and YALE's review and comment prior to the first filing thereof and YALE and LAX shall review the same and respond to LICENSEE in a timely manner. LICENSEE will further provide YALE with a copy of all material correspondence between the applicable patent office and LICENSEE's patent counsel, if said counsel is not shared by the parties, concerning the prosecution of such patent application(s) in a timely manner to:

Yale University
Office of Cooperative Research
Attn: Director of Intellectual Property
433 Temple Street
New Haven, CT 06511
P: 203-436-4675
F: 203-436-8086
E: diane.k.morrissey@yale.edu

or to such other address as YALE may specify for such purpose by notice to LICENSEE, and shall reference the RESEARCH AGREEMENT ([\*\*]). LAX and YALE will cooperate with and provide assistance to LICENSEE in connection with such activities, including, without limitation, execution of all documents, and performance of all acts reasonably necessary, to prepare, file and prosecute such patent applications, and maintain, enforce and defend such patents. LICENSEE shall bear all of its own expenses, including, without limitation, the fees of LICENSEE's legal counsel, and any out-of-pocket expenses of YALE associated with the preparation, filing and prosecution of such patent applications, and the maintenance of any patents issued therefrom.

If LICENSEE elects not to file or thereafter prosecute specific claims and/or applications of an AMENDMENT NO.2 PATENT in any country, LICENSEE will promptly notify YALE at the address listed above, or to such other address as YALE may specify for such purpose by notice to LICENSEE, and shall reference the RESEARCH AGREEMENT ([\*\*]). In such event, YALE, at its expense, will have the right to file and prosecute such application, and/or maintain such patent in such country, jointly in its and LICENSEE's names

3. <u>Joint Ownership</u>. As joint owners of each of [\*\*],[\*\*] and the AMENDMENT NO. 2 PATENTS, YALE and LICENSEE agree that each of LICENSEE and YALE will have the right to practice and exploit each of [\*\*],[\*\*] and the AMENDMENT NO. 2 PATENTS without the duty of accounting to the other party or seeking consent (for licensing, assigning, or otherwise exploiting [\*\*],[\*\*], or any AMENDMENT NO. 2 PATENT) from the other party by reason of the joint ownership thereof, but subject to compliance with the terms and conditions of the AGREEMENT (as amended by AMENDMENT NO. 2) or, if the AGREEMENT has expired or terminated (entirely or with respect to any of [\*\*],[\*\*], or the AMENDMENT NO. 2 PATENTS), any surviving terms of the AGREEMENT applicable to [\*\*],[\*\*] or such AMENDMENT NO. 2 PATENT, as applicable; and each party hereby waives any right it may have under the laws of any jurisdiction to require any such approval or accounting, and, to the extent there are any applicable laws that prohibit such a waiver, each party will be deemed to so consent. For clarity, each of YALE and LICENSEE will continue to have the right to practice and exploit each of [\*\*],[\*\*] and the AMENDMENT NO. 2 PATENTS even if [\*\*],[\*\*] or the AMENDMENT NO. 2 PATENTS cease to be "LICENSED PATENTS" under the AGREEMENT (as amended by AMENDMENT NO. 2).

This Space Intentionally Left Blank: Amendments Follow

# II. Amendments

1. <u>Definitions</u>. All capitalized terms used herein shall have the meaning given to such terms in the AGREEMENT, unless otherwise specifically defined in AMENDMENT NO. 2.

## 2. Additional LICENSED PATENTS.

Subject to Section I(2) herein, the parties agree that the AMENDMENT NO. 2 PATENTS are "LICENSED PATENTS" under the AGREEMENT (as amended by AMENDMENT NO. 2).

3. Addition of the [\*\*] PATENT APPLICATION and the [\*\*] PATENT APPLICATION to Appendix A LICENSED PATENTS. Appendix A of the AGREEMENT is hereby amended to add the [\*\*] PATENT APPLICATION and the [\*\*] PATENT APPLICATION as follows:

	Y a le					
JD	Reference	Serial No./		Filing Date/		
Matter No.	No.	Patent No.	Title	Issue Date	Status	
[**]	[**]	[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	

4. <u>Entire Agreement</u>. Except as explicitly amended by AMENDMENT NO. 2, all other terms and conditions of the Agreement shall remain in full force and effect and apply fully to the terms of Amendment No. 2 as if part of the Agreement.

#### Signature Page Follows

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this AMENDMENT NO. 2 (including the associated Memorandum of Understanding herein).

YALE UNIVERSITY	KOLLTAN PHARMACEUTICALS, INC.
By: /s/ E. Jonathan Soderstrom, Ph.D.  E. Jonathan Soderstrom, Ph.D.  Managing Director  Office of Cooperative Research	By: /s/ Gerald McMahon Gerald McMahon President and Chief Executive Officer

Date:

Date:

December 1, 2014

December 5, 2014

#### CELLDEX THERAPEUTICS, INC.

#### 2008 STOCK OPTION AND INCENTIVE PLAN

#### as amended and restated, effective as of June 15, 2017

#### Section 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Celldex Therapeutics, Inc. 2008 Stock Option and Incentive Plan (the "Plan"). The purpose of the Plan is to encourage and enable the officers, employees, Non-Employee Directors and other key persons (including consultants and prospective employees) of Celldex Therapeutics, Inc. (the "Company") and its Subsidiaries upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its business to acquire a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

The following terms shall be defined as set forth below:

"Act" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the compensation committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"Award" or "Awards," except where referring to a particular category of grant under the Plan, shall include Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Deferred Stock Awards, Restricted Stock Awards, Unrestricted Stock Awards, Cash-Based Awards, Performance Share Awards and Dividend Equivalent Rights.

"Award Agreement" means a written or electronic agreement setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Agreement is subject to the terms and conditions of the Plan.

"Board" means the Board of Directors of the Company.

"Cash-Based Award" means an Award entitling the recipient to receive a cash-denominated payment. "Change of Control" is defined in Section 20.

"Code" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

- "Covered Employee" means an employee who is a "Covered Employee" within the meaning of Section 162(m) of the Code.
- "Date of Grant" means the date on which an Award under the Plan is granted by the Administrator, or such later date as the Administrator may specify to be the effective date of an Award.
  - "Deferred Stock Award" means an Award of phantom stock units to a grantee.
- "Disability" means a grantee being considered "disabled" within the meaning of Section 409A and Treasury Regulation 1.409A-3(i)(4), as well as any successor regulation or interpretation.
- "Dividend Equivalent Right" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.
  - "Effective Date" means the date on which the amended and restated Plan is approved by stockholders as set forth in Section 22.
  - "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.
- "Fair Market Value" of a share of Stock shall be, as applied to a specific date (i) the closing price of a share of Stock as of the date of determination on the principal established stock exchange or national market system on which the Stock is then traded (or, if there is no trading in the Stock as of such date, the closing price of a share of Stock on the most recent date preceding the date of determination on which trades of the Stock were recorded), or (ii) if the shares of Stock are not then traded on an established stock exchange or national market system but are then traded in an over-the-counter market, the average of the closing bid and asked prices for the shares of Stock in such over-the-counter market as of the date of determination (or, if there are no closing bid and asked prices for the shares of Stock as of such date, the average of the closing bid and the asked prices for the shares of Stock on the most recent date preceding such date on which such closing bid and asked prices are available on such over-the-counter market), or (iii) if the shares of Stock are not then listed on a national securities exchange or national market system or traded in an over-the-counter market, the price of a share of Stock as determined by the Administrator in its discretion in a manner consistent with Section 409A of the Code and Treasury Regulation 1.409A-1(b)(5)(iv), as well as any successor regulation or interpretation.
  - "Incentive Stock Option" means any Stock Option designated and qualified as an "incentive stock option" as defined in Section 422 of the Code.
- "Non-Employee Director" means a member of the Board who is not also an employee of the Company or any Subsidiary. "Non-Qualified Stock Option" means any Stock Option that is not an Incentive Stock Option.

"Option" or "Stock Option" means any option to purchase shares of Stock granted pursuant to Section 5.

"Performance-Based Award" means any Restricted Stock Award, Deferred Stock Award, Performance Share Award or Cash-Based Award granted to a Covered Employee that is intended to qualify as "performance-based compensation" under Section 162(m) of the Code and the regulations promulgated thereunder.

"Performance Criteria" means the performance criteria used in performance goals governing Performance-based Awards granted to Covered Employees which may include any or all of the following: (i) the Company's return on equity, assets, capital or investment, (ii) pre-tax or after-tax profit levels of the Company or any Subsidiary, a division, an operating unit or a business segment of the Company, or any combination of the foregoing; (iii) cash flow, funds from operations, year-end cash and equivalents balance or similar measure; (iv) total shareholder return; (v) changes in the market price of the Stock; (vi) sales or market share; (vii) earnings per share; (viii) partnerships, collaborations, joint ventures, alliances and similar arrangements involving the Company; (ix) mergers, acquisitions and business combinations of or by the Company; or (x) the Company's rights to intellectual property and scientific discoveries.

"Performance Cycle" means one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Criteria will be measured for the purpose of determining a grantee's right to and the payment of a Restricted Stock Award, Deferred Stock Award, Performance Share Award or Cash-Based Award.

"Performance Goals" means, for a Performance Cycle, the specific goals established in writing by the Administrator for a Performance Cycle based upon the Performance Criteria.

"Performance Share Award" means an Award entitling the recipient to acquire shares of Stock upon the attainment of specified Performance Goals.

"Restricted Stock Award" means an Award entitling the recipient to acquire, at such purchase price (which may be zero) as determined by the Administrator, shares of Stock subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation in which the outstanding shares of Stock are converted into or exchanged for securities of the successor entity and the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the successor entity immediately upon completion of such transaction, or (iii) the sale of all of the Stock of the Company to an unrelated person or entity.

"Sale Price" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

"Section 409A" means Section 409A of the Code and the regulations and other guidance promulgated thereunder. "Stock" means the Common Stock, par value \$.01 per share, of the Company, subject to adjustments pursuant to Section 3.

"Stock Appreciation Right" means an Award entitling the recipient to receive shares of Stock having a value equal to the excess of the Fair Market Value of the Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

"Subsidiary" means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

"Ten Percent Owner" means an employee who owns or is deemed to own (by reason of the attribution rules of Section 424(d) of the Code) more than 10 percent of the combined voting power of all classes of stock of the Company or any parent or subsidiary corporation.

"Unrestricted Stock Award" means an Award of shares of Stock free of any restrictions.

## Section 2. ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

- (a) Administration of Plan. The Plan shall be administered by the Administrator. To the extent advisable or otherwise required by applicable law, regulation or rule, it is intended that each member of the Administrator shall qualify as (i) a "non-employee director" under Rule 16b-3, (ii) an "outside director" under Section 162(m) of the Code and the regulations thereunder and (iii) an "independent director" under the rules of any national securities exchange on which the shares of Stock are then listed. If it is later determined that one or more members of the Administrator do not so qualify, actions taken by the Administrator shall be valid despite such failure to qualify.
- (b) Powers of Administrator. The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:
  - (i) to select the individuals to whom Awards may from time to time be granted;
  - (ii) to determine the time or times of grant, and the extent, if any, of Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Deferred Stock Awards, Unrestricted Stock Awards, Cash-Based Awards, Performance Share Awards and Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;
    - (iii) to determine the number of shares of Stock to be covered by any Award;
  - (iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the form of written instruments evidencing the Awards;

- (v) to accelerate the exercisability or vesting of all or any portion of any Award upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event:
  - (vi) subject to the provisions of Section 5(b), to extend at any time the period in which Stock Options may be exercised; and
- (vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

- (c) Delegation of Authority to Grant Options. Subject to applicable law, the Administrator, in its discretion, may delegate to the Chief Executive Officer of the Company all or part of the Administrator's authority and duties with respect to the granting of Options, to individuals who are (i) not subject to the reporting and other provisions of Section 16 of the Exchange Act and (ii) not Covered Employees. Any such delegation by the Administrator shall include a limitation as to the amount of Options that may be granted during the period of the delegation and shall contain guidelines as to the determination of the exercise price and the vesting criteria. The Administrator may revoke or amend the terms of a delegation at any time but such action shall not invalidate any prior actions of the Administrator's delegate or delegates that were consistent with the terms of the Plan.
- (d) Award Agreement. Awards under the Plan shall be evidenced by Award Agreements that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award, the provisions applicable in the event employment or service terminates, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award.
- (e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

#### Section 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 20,000,000 shares, subject to adjustment as provided in

Section 3(b) (the "Share Reserve"); provided that not more than 500,000 shares shall be issued in the form of Unrestricted Stock Awards, Restricted Stock Awards, Deferred Stock Awards or Performance Share Awards. For purposes of this limitation, the shares of Stock underlying the Awards granted under the Plan that are forfeited, canceled or otherwise terminated (other than by exercise) shall be added back to the shares of Stock available for issuance under the Plan. Shares (i) tendered or withheld in payment of an Option, (ii) tendered or withheld to satisfy any tax withholding obligation or (iii) repurchased by the Company with Option proceeds, shall not revert to or be added back to the Share Reserve. Further, shares of Stock covered by a Stock Appreciation Right, to the extent that it is exercised and settled in shares of Stock, and whether or not shares of Stock are actually issued to the grantee upon the exercise of the Stock Appreciation Right, shall be considered issued or transferred pursuant to the Plan. Subject to such overall limitations, shares of Stock may be issued up to such maximum number pursuant to any type or types of Award; provided, however, that Stock Options or Stock Appreciation Rights with respect to no more than 2,000,000 shares of Stock may be granted to any one individual grantee during any one calendar year period. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

- Changes in Stock. Subject to Section 3(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, including the maximum number of shares that may be issued in the form of Unrestricted Stock Awards, Restricted Stock Awards, Deferred Stock Awards or Performance Share Awards, (ii) the number of Stock Options or Stock Appreciation Rights that can be granted to any one individual grantee in one calendar year and the maximum number of shares that may be granted under a Performance-Based Award, (iii) the number and kind of shares or other securities subject to any then outstanding Awards under the Plan, (iv) the repurchase price, if any, per share subject to each outstanding Restricted Stock Award, and (v) the price for each share subject to any then outstanding Stock Options and Stock Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Stock Options and Stock Appreciation Rights) as to which such Stock Options and Stock Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.
- (c) Mergers and Other Transactions. Upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate, unless provision is made in

connection with the Sale Event in the sole discretion of the parties thereto for the assumption or continuation by the successor entity of Awards theretofore granted, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree (after taking into account any acceleration hereunder). In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a cash payment to the grantees holding Options and Stock Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Options and Stock Appreciation Rights (to the extent then exercisable (after taking into account any acceleration hereunder) at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Stock Appreciation Rights; or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Stock Appreciation Rights held by such grantee.

(d) Substitute Awards. The Administrator may grant Awards under the Plan in substitution for stock and stock based awards held by employees, directors or other key persons of another corporation in connection with the merger or consolidation of the employing corporation with the Company or a Subsidiary or the acquisition by the Company or a Subsidiary of property or stock of the employing corporation. The Administrator may direct that the substitute awards be granted on such terms and conditions as the Administrator considers appropriate in the circumstances. Any substitute Awards granted under the Plan shall not count against the share limitation set forth in Section 3(a).

#### Section 4. ELIGIBILITY

Grantees under the Plan will be such full or part-time officers and other employees, Non-Employee Directors and key persons (including consultants and prospective employees) of the Company and its Subsidiaries as are selected from time to time by the Administrator in its sole discretion.

#### Section 5. STOCK OPTIONS

Any Stock Option granted under the Plan shall be in such form as the Administrator may from time to time approve. Stock Options granted under the Plan may be either Incentive Stock Options or Non-Qualified Stock Options. Incentive Stock Options may be granted only to employees of the Company or any Subsidiary that is a "subsidiary corporation" within the meaning of Section 424(f) of the Code. To the extent that any Option does not qualify as an Incentive Stock Option, it shall be deemed a Non-Qualified Stock Option.

Stock Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable.

(a) Exercise Price. The exercise price per share for the Stock covered by a Stock Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of

grant but shall not be less than 100 percent of the Fair Market Value on the Date of Grant. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the option price of such Incentive Stock Option shall be not less than 110 percent of the Fair Market Value on the Date of Grant.

- (b) Option Term. The term of each Stock Option shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the term of such Stock Option shall be no more than five years from the Date of Grant.
- (c) Exercisability; Rights of a Stockholder. Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may accelerate the exercisability of all or any portion of any Stock Option upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event. An optionee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options.
- (d) Method of Exercise. Stock Options may be exercised in whole or in part, by giving written notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods to the extent provided in the Option Award Agreement:
  - (i) In cash, by certified or bank check or other instrument acceptable to the Administrator;
  - (ii) Through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the optionee on the open market or that are beneficially owned by the optionee and are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date. To the extent required to avoid variable accounting treatment under applicable accounting rules, such surrendered shares shall have been owned by the optionee for at least six months; or
  - (iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Stock Option will be contingent upon receipt from the optionee (or a purchaser acting in his stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Award Agreement or

applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the optionee upon the exercise of the Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Stock Options may be permitted through the use of such an automated system.

(iv) Annual Limit on Incentive Stock Options. To the extent required for "incentive stock option" treatment under Section 422 of the Code, the aggregate Fair Market Value (determined as of the time of grant) of the shares of Stock with respect to which Incentive Stock Options granted under this Plan and any other plan of the Company or its parent and subsidiary corporations become exercisable for the first time by an optionee during any calendar year shall not exceed \$100,000. To the extent that any Stock Option exceeds this limit, it shall constitute a Non-Qualified Stock Option.

#### Section 6. STOCK APPRECIATION RIGHTS

- (a) Exercise Price of Stock Appreciation Rights. The exercise price of a Stock Appreciation Right shall not be less than 100 percent of the Fair Market Value of the Stock on the Date of Grant.
- (b) Grant and Exercise of Stock Appreciation Rights. Stock Appreciation Rights may be granted by the Administrator independently of any Stock Option granted pursuant to Section 5 of the Plan.
- (c) Terms and Conditions of Stock Appreciation Rights. Stock Appreciation Rights shall be subject to such terms and conditions as shall be determined from time to time by the Administrator.

#### Section 7. RESTRICTED STOCK AWARDS

- (a) Nature of Restricted Stock Awards. The Administrator shall determine the restrictions and conditions applicable to each Restricted Stock Award at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established performance goals and objectives. The grant of a Restricted Stock Award is contingent on the grantee executing the Restricted Stock Award Agreement. The terms and conditions of each such Award Agreement shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.
- (b) Rights as a Stockholder. Upon execution of the Restricted Stock Award Agreement and payment of any applicable purchase price, a grantee shall have the rights of a stockholder with respect to the voting of the Restricted Stock, subject to such conditions contained in the Restricted Stock Award Agreement. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Stock shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such

Restricted Stock are vested as provided in Section 7(d) below, and (ii) certificated Restricted Stock shall remain in the possession of the Company until such Restricted Stock is vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

- (c) Restrictions. Restricted Stock may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Stock Award Agreement. Except as may otherwise be provided by the Administrator either in the Award Agreement or, subject to Section 18 below, in writing after the Award Agreement is issued if a grantee's employment (or other service relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Stock that has not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other service relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a stockholder. Following such deemed reacquisition of unvested Restricted Stock that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.
- (d) Vesting of Restricted Stock. The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Stock and the Company's right of repurchase or forfeiture shall lapse. Notwithstanding the foregoing, in the event that any such Restricted Stock granted to employees shall have a performance-based goal, the restriction period with respect to such shares shall not be less than one year, and in the event any such Restricted Stock granted to employees shall have a time-based restriction, the total restriction period with respect to such shares shall not be less than three years; provided, however, that Restricted Stock with a time-based restriction may become vested incrementally over such three-year period. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the shares on which all restrictions have lapsed shall no longer be Restricted Stock and shall be deemed "vested." Except as may otherwise be provided by the Administrator either in the Award Agreement or, subject to Section 18 below, in writing after the Award Agreement is issued (but in such case only with respect to acceleration of vesting upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event), a grantee's rights in any shares of Restricted Stock that have not vested shall automatically terminate upon the grantee's termination of employment (or other service relationship) with the Company and its Subsidiaries and such shares shall be subject to the provisions of Section 7(c) above.

#### Section 8. DEFERRED STOCK AWARDS

(a) Nature of Deferred Stock Awards. The Administrator shall determine the restrictions and conditions applicable to each Deferred Stock Award at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established performance goals and objectives. The grant of a Deferred Stock Award is contingent on the grantee executing the Deferred Stock Award Agreement. The terms

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and conditions of each such Award Agreement shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees. Notwithstanding the foregoing, in the event that any such Deferred Stock Award granted to employees shall have a performance-based goal, the restriction period with respect to such Award shall not be less than one year, and in the event any such Deferred Stock Award granted to employees shall have a time-based restriction, the total restriction period with respect to such Award shall not be less than three years; provided, however, that any Deferred Stock Award with a time-based restriction may become vested incrementally over such three-year period. At the end of the deferral period, the Deferred Stock Award, to the extent vested, shall be settled in the form of shares of Stock. To the extent that a Deferred Stock Award is subject to Section 409A, it may contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order for such Award to comply with the requirements of Section 409A.

- (b) Election to Receive Deferred Stock Awards in Lieu of Compensation. The Administrator may, in its sole discretion, permit a grantee to elect to receive a portion of future cash compensation otherwise due to such grantee in the form of a Deferred Stock Award. Any such election shall be made in writing and shall be delivered to the Company no later than the date specified by the Administrator and in accordance with Section 409A and such other rules and procedures established by the Administrator. Any such future cash compensation that the grantee elects to defer shall be converted to a fixed number of phantom stock units based on the Fair Market Value of Stock on the date the compensation would otherwise have been paid to the grantee if such payment had not been deferred as provided herein. The Administrator shall have the sole right to determine whether and under what circumstances to permit such elections and to impose such limitations and other terms and conditions thereon as the Administrator deems appropriate.
- (c) Rights as a Stockholder. A grantee shall have the rights as a stockholder only as to shares of Stock acquired by the grantee upon settlement of a Deferred Stock Award; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the phantom stock units underlying his Deferred Stock Award, subject to such terms and conditions as the Administrator may determine.
- (d) Termination. Except as may otherwise be provided by the Administrator either in the Award Agreement or, subject to Section 18 below, in writing after the Award Agreement is issued (but in such case only with respect to acceleration of vesting upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event), a grantee's right in all Deferred Stock Awards that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

# Section 9. UNRESTRICTED STOCK AWARDS

Grant or Sale of Unrestricted Stock. The Administrator may, in its sole discretion, grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Stock Award under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

#### Section 10. CASH-BASED AWARDS

Grant of Cash-Based Awards. The Administrator may, in its sole discretion, grant Cash-Based Awards to any grantee in such number or amount and upon such terms, and subject to such conditions, as the Administrator shall determine at the time of grant. The Administrator shall determine the maximum duration of the Cash-Based Award, the amount of cash to which the Cash-Based Award pertains, the conditions upon which the Cash-Based Award shall become vested or payable, and such other provisions as the Administrator shall determine. Each Cash-Based Award shall specify a cash-denominated payment amount, formula or payment ranges as determined by the Administrator. Payment, if any, with respect to a Cash-Based Award shall be made in accordance with the terms of the Award and may be made in cash or in shares of Stock, as the Administrator determines.

#### Section 11. PERFORMANCE SHARE AWARDS

- (a) Nature of Performance Share Awards. The Administrator may, in its sole discretion, grant Performance Share Awards independent of, or in connection with, the granting of any other Award under the Plan. The Administrator shall determine whether and to whom Performance Share Awards shall be granted, the Performance Goals, the periods during which performance is to be measured, and such other limitations and conditions as the Administrator shall determine.
- (b) Rights as a Stockholder. A grantee receiving a Performance Share Award shall have the rights of a stockholder only as to shares actually received by the grantee under the Plan and not with respect to shares subject to the Award but not actually received by the grantee. A grantee shall be entitled to receive shares of Stock under a Performance Share Award only upon satisfaction of all conditions specified in the Performance Share Award agreement (or in a performance plan adopted by the Administrator).
- (c) Termination. Except as may otherwise be provided by the Administrator either in the Award agreement or, subject to Section 18 below, in writing after the Award agreement is issued (but in such case only with respect to acceleration of vesting upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event), a grantee's rights in all Performance Share Awards shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

#### Section 12. PERFORMANCE-BASED AWARDS TO COVERED EMPLOYEES

(a) Performance-Based Awards. Any employee or other key person providing services to the Company and who is selected by the Administrator may be granted one or more Performance-Based Awards in the form of a Restricted Stock Award, Deferred Stock Award, Performance Share Awards or Cash-Based Award payable upon the attainment of Performance Goals that are established by the Administrator and relate to one or more of the Performance Criteria, in each case on a specified date or dates or over any period or periods determined by the Administrator. The Administrator shall define in an objective fashion the manner of calculating the Performance Criteria it selects to use for any Performance Period. Depending on the

Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a division, business unit, or an individual. The Administrator, in its discretion, may adjust or modify the calculation of Performance Goals for such Performance Period in order to prevent the dilution or enlargement of the rights of an individual (i) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event or development, (ii) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting the Company, or the financial statements of the Company, or (iii) in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions provided however, that the Administrator may not exercise such discretion in a manner that would increase the Performance-Based Award granted to a Covered Employee. Each Performance-Based Award shall comply with the provisions set forth below.

- (b) Grant of Performance-Based Awards. With respect to each Performance-Based Award granted to a Covered Employee, the Administrator shall select, within the first 90 days of a Performance Cycle (or, if shorter, within the maximum period allowed under Section 162(m) of the Code) the Performance Criteria for such grant, and the Performance Goals with respect to each Performance Criterion (including a threshold level of performance below which no amount will become payable with respect to such Award). Each Performance-Based Award will specify the amount payable, or the formula for determining the amount payable, upon achievement of the various applicable performance targets. The Performance Criteria established by the Administrator may be (but need not be) different for each Performance Cycle and different Performance Goals may be applicable to Performance-Based Awards to different Covered Employees.
- (c) Payment of Performance-Based Awards. Following the completion of a Performance Cycle, the Administrator shall meet to review and certify in writing whether, and to what extent, the Performance Goals for the Performance Cycle have been achieved and, if so, to also calculate and certify in writing the amount of the Performance-Based Awards earned for the Performance Cycle. The Administrator shall then determine the actual size of each Covered Employee's Performance-Based Award, and, in doing so, may reduce or eliminate the amount of the Performance-Based Award for a Covered Employee if, in its sole judgment, such reduction or elimination is appropriate.
- (d) Maximum Award Payable. The maximum Performance-Based Award payable to any one Covered Employee under the Plan in respect of any calendar year is (i) 250,000 shares of Stock (subject to adjustment as provided in Section 3(b) hereof) for a Performance-Based Award that is a Restricted Stock Award, Deferred Stock Award or Performance Share Award and (ii) \$1,000,000 in value for a Performance-Based Award that is a Cash-Based Award. In the case of Performance Goals based on Performance Cycles beginning and ending in different calendar years, the number of shares of Stock or cash amount which is paid in respect of each calendar year during the Performance Cycle shall be determined by multiplying the total number of shares of Stock or cash amount, as applicable, paid for the Performance Cycle by a fraction, of which (i) the numerator is the number of days during the Performance Cycle in that particular calendar year, and (ii) the denominator is the total number of days during the Performance Cycle. The limitations in this Section 12(d) shall be interpreted and applied in a manner consistent with Section 162(m) of the Code and the regulations thereunder.

#### Section 13. DIVIDEND EQUIVALENT RIGHTS

- (a) Dividend Equivalent Rights. A Dividend Equivalent Right may be granted hereunder to any grantee as a component of a Deferred Stock Award, Restricted Stock Award or Performance Share Award or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Agreement. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional shares of Stock, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of a Deferred Stock Award, Restricted Stock Award or Performance Share Award may provide that such Dividend Equivalent Right shall be settled upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award. A Dividend Equivalent Right granted as a component of a Deferred Stock Award, Restricted Stock Award or Performance Share Award may also contain terms and conditions different from such other Award.
- (b) Interest Equivalents. Any Award under this Plan that is settled in whole or in part in cash on a deferred basis may provide in the grant for interest equivalents to be credited with respect to such cash payment. Interest equivalents may be compounded and shall be paid upon such terms and conditions as may be specified by the grant.
- (c) Termination. Except as may otherwise be provided by the Administrator either in the Award Agreement or, subject to Section 18 below, in writing after the Award Agreement is issued (but in such case only with respect to acceleration of vesting upon (1) a grantee's death, (2) a grantee's Disability, or (3) a Change of Control or Sale Event), a grantee's rights in all Dividend Equivalent Rights or interest equivalents granted as a component of a Deferred Stock Award, Restricted Stock Award or Performance Share Award that has not vested shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

#### Section 14. TRANSFERABILITY OF AWARDS

- (a) Transferability. Except as provided in Section 14(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.
- (b) Administrator Action. Notwithstanding Section 14(a), the Administrator, in its discretion, may provide either in the Award Agreement regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or

her Awards (other than any Incentive Stock Options) to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award.

- (c) Family Member. For purposes of Section 14(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.
- (d) Designation of Beneficiary. Each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

## Section 15. TAX WITHHOLDING

- (a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for Federal income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.
- (b) Payment in Stock. Subject to approval by the Administrator, a grantee may elect to have the Company's minimum required tax withholding obligation satisfied, in whole or in part, by authorizing the Company to withhold from shares of Stock to be issued pursuant to any Award a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due.

#### Section 16. SECTION 409A AWARDS.

To the extent applicable, it is intended that the Plan and all Awards hereunder comply with the requirements of Section 409A or an exemption thereto, and the Plan and all Award Agreements shall be interpreted and applied by the Administrator in a manner consistent with this intent in order to avoid the imposition of any additional tax under Section 409A.

Notwithstanding anything in the Plan or an Award Agreement to the contrary, in the event that any provision of the Plan or an Award Agreement is determined by the Administrator, in its sole discretion, to not comply with the requirements of Section 409A or an exemption thereto, the Administrator shall, in its sole discretion, have the authority to take such actions and to make such interpretations or changes to the Plan or an Award Agreement as the Administrator deems necessary, regardless of whether such actions, interpretations, or changes shall adversely affect a grantee, subject to the limitations, if any, of applicable law. To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any such Award may not be accelerated except to the extent permitted by Section 409A. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on any grantee by Section 409A or any damages for failing to comply with Section 409A.

#### Section 17. TRANSFER, LEAVE OF ABSENCE, ETC.

For purposes of the Plan, the following events shall not be deemed a termination of employment:

- (a) a transfer to the employment of the Company from a Subsidiary or from the Company to a Subsidiary, or from one Subsidiary to another; or
- (b) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

#### Section 18. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall

(a) adversely affect rights under any outstanding Award without the holder's consent or (b) except as provided in Section 3(b) or 3(c), without the prior approval of the Company's stockholders, (1) reduce the exercise price of or otherwise reprice, including through replacement grants, any outstanding Stock Option or Stock Appreciation Right or (2) cancel in exchange for, or otherwise exchange for, cash or other securities any outstanding Stock Option or Stock Appreciation Right with an exercise price at or above the then-current Fair Market Value of the Stock. To the extent required under the rules of any securities exchange or market

system on which the Stock is listed, to the extent determined by the Administrator to be required by the Code to ensure that Incentive Stock Options granted under the Plan are qualified under Section 422 of the Code or to ensure that compensation earned under Awards qualifies as performance-based compensation under Section 162(m) of the Code, Plan amendments shall be subject to approval by the Company stockholders entitled to vote at a meeting of stockholders. Nothing in this Section 18 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(c).

#### Section 19. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

#### Section 20. CHANGE OF CONTROL PROVISIONS

Upon the occurrence of a Change of Control as defined in this Section 20:

- (a) Unless provision is made in connection with the Change of Control for the assumption or continuation by the successor entity of Awards theretofore granted, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree, each outstanding Stock Option, Stock Appreciation Right and Dividend Equivalent Right shall automatically become fully exercisable.
- (b) Unless provision is made in connection with the Change of Control for the assumption or continuation by the successor entity of Awards theretofore granted, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares as such parties shall agree, (i) conditions and restrictions on each outstanding Restricted Stock Award, Deferred Stock Award and Performance Share Award which relate solely to the passage of time and continued employment will be removed. Performance or other conditions (other than conditions and restrictions relating solely to the passage of time and continued employment) will continue to apply unless otherwise provided in the applicable Award Agreement.
  - (c) "Change of Control" shall mean the occurrence of any one of the following events:
  - (i) any "Person," as such term is used in Sections 13(d) and 14(d) of the Act (other than the Company, any of its Subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its Subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities

of the Company representing 25 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Company's Board of Directors ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

- (ii) persons who, as of the Effective Date, constitute the Company's Board of Directors (the "Incumbent Directors") cease for any reason, including, without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority of the Board, provided that any person becoming a director of the Company subsequent to the Effective Date shall be considered an Incumbent Director if such person's election was approved by or such person was nominated for election by either (A) a vote of at least a majority of the Incumbent Directors or (B) a vote of at least a majority of the Incumbent Directors who are members of a nominating committee comprised, in the majority, of Incumbent Directors; but provided further, that any such person whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of members of the Board of Directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board, including by reason of agreement intended to avoid or settle any such actual or threatened contest or solicitation, shall not be considered an Incumbent Director; or
- (iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), (B) any sale, lease, exchange or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company; or
  - (iv) the stockholders of the Company shall approve any plan or proposal for the liquidation or dissolution of the Company.

Notwithstanding the foregoing, a "Change of Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of shares of Voting Securities beneficially owned by any person to 25 percent or more of the combined voting power of all then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company), then a "Change of Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

#### Section 21. GENERAL PROVISIONS

- (a) No Distribution. The Administrator may require each person acquiring Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.
- Delivery of Stock. Notwithstanding any provision of the Plan to the contrary, unless otherwise determined by the Administrator or required by any applicable law, rule or regulation, any obligation set forth in the Plan pertaining to the delivery or issuance of stock certificates evidencing shares of Stock may be satisfied by having issuance and/or ownership of such shares recorded on the books and records of the Company (or, as applicable, its transfer agent or stock plan administrator). Stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any shares of Stock pursuant to the exercise of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery of such shares is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. All shares of Stock delivered pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.
- (c) Stockholder Rights. Until Stock is deemed delivered in accordance with Section 21(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with an Award, notwithstanding the exercise of a Stock Option or any other action by the grantee with respect to an Award.
- (d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not

confer upon any employee any right to continued employment with the Company or any Subsidiary.

- (e) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to such Company's insider trading policy and procedures, as in effect from time to time.
- (f) Forfeiture of Awards under Sarbanes-Oxley Act. If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company, as a result of misconduct, with any financial reporting requirement under the securities laws, then any grantee who is one of the individuals subject to automatic forfeiture under Section 304 of the Sarbanes-Oxley Act of 2002 shall reimburse the Company for the amount of any Award received by such individual under the Plan during the 12-month period following the first public issuance or filing with the United States Securities and Exchange Commission, as the case may be, of the financial document embodying such financial reporting requirement.

#### Section 22. EFFECTIVE DATE OF PLAN

This amended and restated Plan shall become effective upon approval by the holders of a majority of the votes cast at a meeting of stockholders at which a quorum is present. No grants of Stock Options and other Awards may be made hereunder after the tenth anniversary of the Effective Date and no grants of Incentive Stock Options may be made hereunder after the tenth anniversary of the date the amended and restated Plan is approved by the Board.

#### Section 23. GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.

## ADOPTION AND APPROVAL OF PLAN (AS AMENDED AND RESTATED):

Date Amended and Restated Plan Adopted by Board: April 17, 2015

Date Amended and Restated Plan Adopted by Stockholders/Effective Date: June 10, 2015

Date Amendment Adopted by Board: March 1, 2017

Date Amendment Adopted by Stockholders/Effective Date: June 15, 2017

# CELLDEX THERAPEUTICS, INC. 2004 EMPLOYEE STOCK PURCHASE PLAN As amended effective as of June 15, 2017

- 1. *Purpose*. The purpose of the Celldex Therapeutics, Inc. 2004 Employee Stock Purchase Plan (the "Plan") is to provide eligible employees of Celldex Therapeutics, Inc. (the "Company") and certain of its subsidiaries with opportunities to purchase shares of the Company's common stock, par value \$.01 per share (the "Common Stock"). Four Hundred Thousand (400,000) shares of Common Stock in the aggregate have been approved and reserved for this purpose. The Plan is intended to constitute an "employee stock purchase plan" within the meaning of Section 423(b) of the Internal Revenue Code of 1986, as amended (the "Code"), and shall be interpreted in accordance with that intent.
- 2. Administration. The Plan will be administered by the person or persons (the "Administrator") appointed by the Company's Board of Directors (the "Board") for such purpose. The Administrator has authority to make rules and regulations for the administration of the Plan, and its interpretations and decisions with regard thereto shall be final and conclusive. No member of the Board or individual exercising administrative authority with respect to the Plan shall be liable for any action or determination made in good faith with respect to the Plan or any option granted hereunder.
- 3. Offerings. The Company will make one or more offerings to eligible employees to purchase Common Stock under the Plan ("Offerings"). Unless otherwise determined by the Administrator, each Offering will begin on the first business day occurring on or after each January 1 and July 1 and will end on the last business day occurring on or before the following June 30 and December 31, respectively. The Administrator may, in its discretion, designate a different period for any Offering, provided that no Offering shall exceed 27 months in duration or overlap any other Offering.
- 4. Eligibility. Each individual classified as an employee (within the meaning of Section 3401(c) of the Code and the regulations thereunder) by the Company or a Designated Subsidiary (as defined in Section 12) on the Company's or the Designated Subsidiary's payroll records during the relevant participation period are eligible to participate in any one or more of the Offerings under the Plan, provided that as of the first day of the applicable Offering (the "Offering Date") they are customarily employed by the Company or a Designated Subsidiary for more than 20 hours a week and more than five months in the calendar year during which the Offering Date occurs or in the calendar year immediately preceding such year, and have completed at least 30 days of employment.
- 5. Participation. An employee eligible on any Offering Date may participate in such Offering by submitting an enrollment form to his appropriate payroll location at least 15 business days before the Offering Date (or by such other deadline as shall be established for the Offering). The form will (a) state a whole percentage to be deducted from his Compensation (as defined in Section 12) per pay period, (b) authorize the purchase of Common Stock for him in each Offering in accordance with the terms of the Plan and (c) specify the exact name or names in which shares of Common Stock purchased for him are to be issued pursuant to Section 11. An employee who does not enroll in accordance with these procedures will be deemed to have waived his right to participate. Unless an employee files a new enrollment form or withdraws from the Plan, his deductions and purchases will continue at the same percentage of Compensation for future Offerings, provided he remains eligible. Notwithstanding the foregoing, participation in the Plan will neither be permitted nor be denied contrary to the requirements of the Code.
- 6. Employee Contributions. Each eligible employee may authorize payroll deductions at a minimum of one percent (1%) up to a maximum of fifteen percent (15%) of his Compensation for each pay period. The Company will maintain book accounts showing the amount of payroll deductions

made by each participating employee for each Offering. No interest will accrue or be paid on payroll deductions.

- 7. Deduction Changes. Except as may be determined by the Administrator in advance of an Offering, an employee may not increase or decrease his payroll deduction during any Offering, but may increase or decrease his payroll deduction with respect to the next Offering (subject to the limitations of Section 6) by filing a new enrollment form at least 15 business days before the next Offering Date (or by such other deadline as shall be established for the Offering). The Administrator may, in advance of any Offering, establish rules permitting an employee to increase, decrease or terminate his payroll deduction during an Offering.
- 8. Withdrawal. An employee may withdraw from participation in the Plan by delivering a written notice of withdrawal to his appropriate payroll location. The employee's withdrawal will be effective as of the next business day. Following an employee's withdrawal, the Company will promptly refund to him his entire account balance under the Plan (after payment for any Common Stock purchased before the effective date of withdrawal). Partial withdrawals are not permitted. The employee may not begin participation again during the remainder of the Offering, but may enroll in a subsequent Offering in accordance with Section 5.
- 9. Grant of Options. On each Offering Date, the Company will grant to each eligible employee who is then a participant in the Plan an option ("Option") to purchase on the last day of such Offering (the "Exercise Date"), at the Option Price hereinafter provided for, (a) a number of shares of Common Stock determined by dividing such employee's accumulated payroll deductions on such Exercise Date by the lower of (i) 85% of the Fair Market Value of the Common Stock on the Offering Date, or (ii) 85% of the Fair Market Value of the Common Stock on the Exercise Date, or (b) such other lesser maximum number of shares as shall have been established by the Administrator in advance of the Offering; provided, however, that such Option shall be subject to the limitations set forth below. Each employee's Option shall be exercisable only to the extent of such employee's accumulated payroll deductions on the Exercise Date. The purchase price for each share purchased under each Option (the "Option Price") will be 85% of the Fair Market Value of the Common Stock on the Offering Date or the Exercise Date, whichever is less.

Notwithstanding the foregoing, no employee may be granted an option hereunder if such employee, immediately after the option was granted, would be treated as owning stock possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary (as defined in Section 12). For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of an employee, and all stock which the employee has a contractual right to purchase shall be treated as stock owned by the employee. In addition, no employee may be granted an Option which permits his rights to purchase stock under the Plan, and any other employee stock purchase plan of the Company and its Parents and Subsidiaries, to accrue at a rate which exceeds \$25,000 of the fair market value of such stock (determined on the option grant date or dates) for each calendar year in which the Option is outstanding at any time. The purpose of the limitation in the preceding sentence is to comply with Section 423(b)(8) of the Code and shall be applied taking Options into account in the order in which they were granted.

10. Exercise of Option and Purchase of Shares. Each employee who continues to be a participant in the Plan on the Exercise Date shall be deemed to have exercised his Option on such date and shall acquire from the Company such number of whole shares of Common Stock reserved for the purpose of the Plan as his accumulated payroll deductions on such date will purchase at the Option Price, subject to any other limitations contained in the Plan. Any amount remaining in an employee's account at the end of an Offering will be refunded to the employee promptly.

11. Issuance of Certificates. Certificates representing shares of Common Stock purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or in the name of a broker authorized by the employee to be his, or their, nominee for such purpose.

#### 12. Definitions.

- (a) The term "Compensation" means the amount of base pay, prior to salary reduction pursuant to either Sections 125, 132(f) or 401(k) of the Code, but excluding overtime, commissions, incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances or travel expenses, income or gains on the exercise of Company stock options, and similar items.
- (b) The term "Designated Subsidiary" means any present or future Subsidiary (as defined below) that has been designated by the Board to participate in the Plan. The Board may so designate any Subsidiary, or revoke any such designation, at any time and from time to time, either before or after the Plan is approved by stockholders.
- (c) The term "Fair Market Value of the Common Stock" as of any date of determination shall be (i) the closing price of a share of Common Stock as of such date on the principal established stock exchange or national market system on which the Common Stock is then traded (or, if there is no trading in the Common Stock as of such date, the closing price of a share of Common Stock on the most recent date preceding such date on which trades of the Common Stock were recorded), or (ii) if the shares of Common Stock are not then traded on an established stock exchange or national market system but are then traded in an over-the-counter market, the average of the closing bid and asked prices for the shares of Common Stock in such over-the-counter market as such date (or, if there are no closing bid and asked prices for the shares of Stock as of such date, the average of the closing bid and the asked prices for the shares of Common Stock on the most recent date preceding such date on which such closing bid and asked prices are available on such over-the-counter market), or (iii) if the shares of Common Stock are not then listed on a national securities exchange or national market system or traded in an over-the-counter market, the price of a share of Common Stock as determined by the Administrator in its discretion in a manner consistent with Section 409A of the Code and Treasury Regulation 1.409A-1(b)(5)(iv), as well as any successor regulation or interpretation.
  - (d) The term "Parent" means a "parent corporation" with respect to the Company, as defined in Section 424(e) of the Code.
  - (e) The term "Subsidiary" means a "subsidiary corporation" with respect to the Company, as defined in Section 424(f) of the Code.
- 13. Rights on Termination of Employment. If a participating employee's employment terminates for any reason before the Exercise Date for any Offering, no payroll deduction will be taken from any pay due and owing to the employee and the balance in his account will be paid to him or, in the case of his death, to his designated beneficiary as if he had withdrawn from the Plan under Section 8. An employee will be deemed to have terminated employment, for this purpose, if the corporation that employs him, having been a Designated Subsidiary, ceases to be a Subsidiary, or if the employee is transferred to any corporation other than the Company or a Designated Subsidiary. An employee will not be deemed to have terminated employment, for this purpose, if the employee is on an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to reemployment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise provides in writing.

- 14. Special Rules. Notwithstanding anything herein to the contrary, the Administrator may adopt special rules applicable to the employees of a particular Designated Subsidiary, whenever the Administrator determines that such rules are necessary or appropriate for the implementation of the Plan in a jurisdiction where such Designated Subsidiary has employees; provided that such rules are consistent with the requirements of Section 423(b) of the Code. Such special rules may include (by way of example, but not by way of limitation) the establishment of a method for employees of a given Designated Subsidiary to fund the purchase of shares other than by payroll deduction, if the payroll deduction method is prohibited by local law or is otherwise impracticable. Any special rules established pursuant to this Section 14 shall, to the extent possible, result in the employees subject to such rules having substantially the same rights as other participants in the Plan.
- 15. Optionees Not Stockholders. Neither the granting of an Option to an employee nor the deductions from his pay shall constitute such employee a holder of the shares of Common Stock covered by an Option under the Plan until such shares have been purchased by and issued to him.
- 16. Rights Not Transferable. Rights under the Plan are not transferable by a participating employee other than by will or the laws of descent and distribution, and are exercisable during the employee's lifetime only by the employee.
- 17. Application of Funds. All funds received or held by the Company under the Plan may be combined with other corporate funds and may be used for any corporate purpose.
- 18. Adjustment in Case of Changes Affecting Common Stock. In the event of a subdivision of outstanding shares of Common Stock, or the payment of a dividend in Common Stock, the number of shares approved for the Plan, and the share limitation set forth in Section 9, shall be increased proportionately, and such other adjustment shall be made as may be deemed equitable by the Administrator. In the event of any other change affecting the Common Stock, such adjustment shall be made as may be deemed equitable by the Administrator to give proper effect to such event.
- 19. Amendment of the Plan. The Board may at any time, and from time to time, amend the Plan in any respect, except that without the approval, within 12 months of such Board action, by the stockholders, no amendment shall be made increasing the number of shares approved for the Plan or making any other change that would require stockholder approval in order for the Plan, as amended, to qualify as an "employee stock purchase plan" under Section 423(b) of the Code.
- 20. Insufficient Shares. If the total number of shares of Common Stock that would otherwise be purchased on any Exercise Date plus the number of shares purchased under previous Offerings under the Plan exceeds the maximum number of shares issuable under the Plan, the shares then available shall be apportioned among participants in proportion to the amount of payroll deductions accumulated on behalf of each participant that would otherwise be used to purchase Common Stock on such Exercise Date.
- 21. Termination of the Plan. The Plan may be terminated at any time by the Board. Upon termination of the Plan, all amounts in the accounts of participating employees shall be promptly refunded.
- 22. Governmental Regulations. The Company's obligation to sell and deliver Common Stock under the Plan is subject to obtaining all governmental approvals required in connection with the authorization, issuance, or sale of such stock.

The Plan shall be governed by Massachusetts law except to the extent that such law is preempted by federal law.

23. *Issuance of Shares*. Shares may be issued upon exercise of an Option from authorized but unissued Common Stock, from shares held in the treasury of the Company, or from any other proper source.

- 24. *Tax Withholding*. Participation in the Plan is subject to any minimum required tax withholding on income of the participant in connection with the Plan. Each employee agrees, by entering the Plan, that the Company and its Subsidiaries shall have the right to deduct any such taxes from any payment of any kind otherwise due to the employee, including shares issuable under the Plan.
- 25. Notification Upon Sale of Shares. Each employee agrees, by entering the Plan, to give the Company prompt notice of any disposition of shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such shares were purchased.
- 26. Effective Date and Approval of Shareholders. The Plan was adopted by the Board of Directors on March 31, 2004 and was effective upon approval by the stockholders of the Company on May 13, 2004.

Exhibit 21.1

# ${\bf SUBSIDIARIES\ OF\ CELLDEX\ THE RAPEUTICS, INC.}$

	Jurisaiction of	Ownersnip
Name	Organization	Percentage
Celldex Australia PTY LTD	Australia	100%

# QuickLinks

Exhibit 21.1

SUBSIDIARIES OF CELLDEX THERAPEUTICS, INC.

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. 333-219867, 333-219869, 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 7, 2018 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 7, 2018

# QuickLinks

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

#### 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 7, 2018 By /s/ ANTHONY S. MARUCCI

Name: Anthony S. Marucci

Title: President and Chief Executive Officer

QuickLinks

Exhibit 31.1

**CERTIFICATION** 

#### CERTIFICATION

#### I, Sam Martin, 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 7, 2018 By /s/ SAM MARTIN

Name: Sam Martin

Title: Senior Vice President and Chief Financial

Officer

QuickLinks

Exhibit 31.2

**CERTIFICATION** 

### 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, 2017 (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 780(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 7, 2018 By: /s/ ANTHONY S. MARUCCI

Name: Anthony S. Marucci

Title: President and Chief Executive Officer

Date: March 7, 2018 By: /s/ SAM MARTIN

Name: Sam Martin

Title: Senior Vice President and Chief Financial

Officer

This certification shall 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.

# QuickLinks

Exhibit 32

 $\underline{\text{CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18~U.S.C.} SECTION~1350, AS~ADOPTED~\underline{PURSUANT~TO~SECTION~906~OF~THE~SARBANES-OXLEY~ACT~OF~2002}$