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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016
or

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

For transition period from _____ to _____.
Commission File Number: 001-37841

Kadmon Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3576929**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
450 East 29th Street, New York, NY	**10016**
(Address of principal executive offices)	(Zip Code)

(212) 308-6000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, par value $0.001 per share	**The New York Stock Exchange**

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES ☒ NO ☐

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

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

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

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

As of June 30, 2016, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public market for the Registrant's common stock. The Registrant therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The Registrant's Common Stock began trading on The New York Stock Exchange on July 27, 2016.

The number of shares of the registrant's common stock outstanding as of March 15, 2017 was 51,846,521.

Kadmon Holdings, Inc.

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REFERENCES TO KADMON

In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires:

- references to the "Company," "Kadmon," "we," "us" and "our" following the date of the Corporate Conversion (July 26, 2016) refer to Kadmon Holdings, Inc. and its consolidated subsidiaries;
- references to the "Company," "Kadmon," "we," "us" and "our" prior to the date of the Corporate Conversion refer to Kadmon Holdings, LLC and its consolidated subsidiaries; and
- references to the "Corporate Conversion" or "corporate conversion" refer to all of the transactions related to the conversion of Kadmon Holdings, LLC into Kadmon Holdings, Inc., including the conversion of all of the outstanding membership units of Kadmon Holdings, LLC into shares of common stock of Kadmon Holdings, Inc. effected on July 26, 2016. See Note 1, "Organization and Basis of Presentation—Corporate Conversion, Initial Public Offering and Debt Conversion," of the notes to our audited consolidated financial statements included in this Annual Report on Form 10-K for more information.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K may be forward-looking statements. Statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, including, among others, statements regarding future capital expenditures and debt service obligations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, the following:

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our reliance on the success of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- our ability to expand our sales and marketing capabilities;
- the commercialization of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- cost associated with defending intellectual property infringement, product liability and other claims;
- regulatory developments in the United States, Europe and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding;
- the rate and degree of market acceptance of our product candidates;
- developments relating to our competitors and our industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- our ability to achieve cost savings and benefits from our efforts to streamline our operations and to not harm our business with such efforts;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;
- litigation, including costs associated with prosecuting or defending pending or threatened claims and any adverse outcomes or settlements, whether or not covered by insurance;
- our expected use of proceeds from our initial public offering (IPO), March 2017 private placement and other sources of liquidity;
- the future trading price of the shares of our common stock and impact of securities analysts’ reports on these prices; and/or
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

The forward-looking statements in this Annual Report on Form 10-K are only predictions, and we may not actually achieve the plans, intentions or expectations included in our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

PART 1

Item 1. Business

Overview

We are a fully integrated biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics within autoimmune and fibrotic diseases, oncology and genetic diseases. We leverage our research and clinical development team members, who prior to joining Kadmon brought more than 15 drugs to market, to identify and develop our novel product candidates, through in-licensing products and employing our small molecule and biologics platforms. By retaining global commercial rights to our clinical product candidates, we believe we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. Below is a brief description of our lead product candidates:

- ***KD025***. The most advanced candidate in our rho-associated coiled-coil kinase (ROCK) platform, KD025, is a potential first-in-class, oral, selective ROCK2 inhibitor. ROCK2 is a molecular target in autoimmune, fibrotic and neurodegenerative diseases. We established proof of concept for KD025 in autoimmune disease in an open-label, Phase 2 clinical trial in moderate to severe psoriasis. In this study, KD025 showed clinical activity after 12 weeks. We have three ongoing Phase 2 clinical studies of KD025: a randomized, placebo-controlled study in moderate to severe psoriasis; a randomized open-label study in idiopathic pulmonary fibrosis (IPF); and a dose-escalating open-label study in chronic graft-versus-host disease (cGVHD). We expect to report data from these ongoing studies by the end of 2017.

- ***Tesevatinib in Oncology***. Tesevatinib is an oral tyrosine kinase inhibitor (TKI) with demonstrated clinical activity against epidermal growth factor receptor (EGFR). Unlike currently marketed TKIs, tesevatinib is expected to be highly blood-brain barrier penetrant and to accumulate in the leptomeninges based on the results of preclinical trials and data from ongoing Phase 2 clinical studies. We are conducting a Phase 2 clinical study of tesevatinib in non-small cell lung cancer (NSCLC) with activating EGFR mutations in patients with brain metastases and/or leptomeningeal metastases. Data from the first 13 enrolled patients indicate that tesevatinib enters the central nervous system (CNS) and targets EGFR-driven intracranial tumors to achieve tumor shrinkage and/or clinically significant improvement of neurological symptoms. There are no effective approved therapies for NSCLC patients with activating EGFR mutations whose disease has spread to the brain or leptomeninges, making this an area of significant unmet medical need. We are also conducting an exploratory Phase 2 clinical trial of tesevatinib in glioblastoma.

- ***Tesevatinib in Polycystic Kidney Disease (PKD)***. Due to tesevatinib's demonstrated clinical activity against EGFR and Src family kinases, which are key molecular drivers of PKD, a genetic kidney disorder, and tesevatinib's accumulation in the kidneys, we are developing tesevatinib to treat autosomal dominant PKD (ADPKD) and autosomal recessive PKD (ARPKD). In PKD preclinical models, tesevatinib demonstrated statistically significant inhibition of the formation and growth of kidney cysts and prevented further loss of kidney function. In our ongoing, open-label, Phase 2a clinical trial in ADPKD, we have demonstrated that tesevatinib is well tolerated and have selected a dose for additional clinical development. We plan to initiate a randomized, placebo-controlled, Phase 2 clinical trial of tesevatinib in ADPKD in mid-2017. We obtained orphan drug designation status in the United States for tesevatinib for the treatment of patients with ARPKD in Q1 2016. We plan to initiate a Phase 1 clinical trial of tesevatinib in ARPKD in Q2 2017. There are currently no approved drug therapies for ADPKD or ARPKD in the United States.

- ***KD034***. We are developing a portfolio of generic formulations of trientine hydrochloride called KD034 for the treatment of Wilson's disease, a genetic liver disease characterized by an inability to excrete copper. In December 2016, we submitted an Abbreviated New Drug Application (ANDA) for our bottled generic capsule formulation of Syprine (trientine hydrochloride). In Q1 2017, we plan to submit a second ANDA for our generic form of Syprine in proprietary blister packaging that will offer room temperature stability, which we believe has the potential to address shortcomings of currently available trientine hydrochloride formulations. We intend to use Kadmon Pharmaceuticals, LLC (Kadmon Pharmaceuticals), our specialty-focused commercial organization, to market these formulations, if approved.

Kadmon Pharmaceuticals markets and distributes a portfolio of branded generic ribavirin products for chronic hepatitis C virus (HCV) infection. In addition, Kadmon Pharmaceuticals distributes products in a variety of therapeutic areas, including those indicated for the management of rare diseases.

We do not currently depend on commercial revenues from Kadmon Pharmaceuticals to support our non-commercial operations, including drug development efforts and debt obligations. Instead, we leverage our commercial infrastructure, including the regulatory, quality and chemistry, manufacturing and controls (CMC) teams of Kadmon Pharmaceuticals, to

support the development of our clinical-stage product candidates. We believe that our commercial infrastructure will be most advantageous to us in the future, in connection with potential commercial collaborations as well as the anticipated commercialization of our pipeline product candidates, if approved.

Our Strategy

Our goal is to develop first-in-class, innovative therapies for significant unmet medical needs, including autoimmune and fibrotic diseases, oncology and genetic diseases, for which we plan, in many cases, to seek breakthrough designation from the FDA. Our key strategies to achieve this goal are listed below:

- ***Develop KD025 and our ROCK inhibitor platform to produce novel treatments for autoimmune, fibrotic and neurodegenerative diseases.*** We are developing KD025 for the treatment of autoimmune and fibrotic diseases. We have three ongoing Phase 2 clinical studies of KD025: a randomized, placebo-controlled study in moderate to severe psoriasis, a randomized, open-label study in IPF and an open-label study in cGVHD. We plan to report data from these clinical trials by the end of 2017. We have also generated a portfolio of highly selective ROCK2 and pan-ROCK inhibitors with varying specificity, distribution and solubility characteristics to treat specific autoimmune, fibrotic and neurodegenerative diseases.

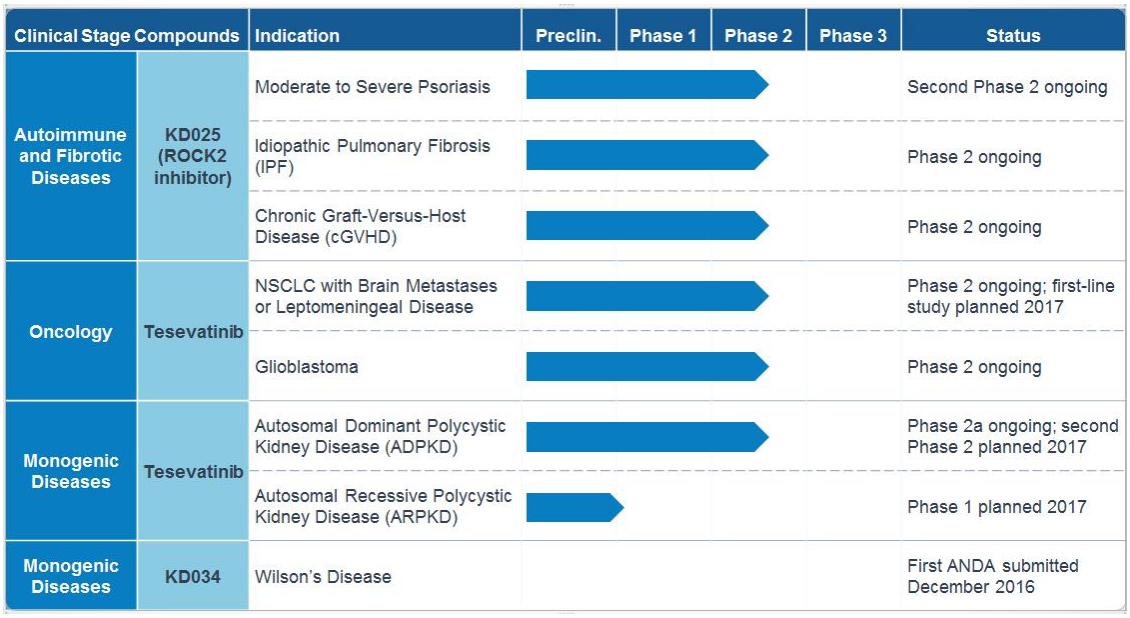
- ***Advance tesevatinib in NSCLC with brain metastases and/or leptomeningeal metastases.*** We are developing tesevatinib for NSCLC with activating EGFR mutations in patients with brain metastases and/or leptomeningeal metastases and have an ongoing Phase 2 clinical study in these indications. We plan to conduct a randomized Phase 2 clinical trial of tesevatinib as first-line treatment in NSCLC with activating EGFR mutations in patients who present with brain metastases. We believe that these indications represent the fastest potential path to FDA approval due to the lack of currently approved treatments for these patients.

- ***Advance tesevatinib for the treatment of ADPKD and ARPKD.*** We are evaluating the safety and tolerability of tesevatinib in ADPKD in an ongoing Phase 2a clinical study and in ARPKD in a planned Phase 1 clinical study. Due to tesevatinib's activity against EGFR and Src and its accumulation in the kidneys, we are investigating treatment at a significantly lower dosage compared to oncology indications, with the goal of minimizing dose-dependent side effects. PKD is a disease that requires lifelong treatment, and we believe that tesevatinib's tolerability profile makes it an attractive therapeutic product candidate for this indication. To address ARPKD, a pediatric disease closely related to ADPKD, we have developed a proprietary liquid formulation of tesevatinib for administration to children. We plan to initiate a Phase 2, randomized, placebo-controlled study of tesevatinib in ADPKD in mid-2017 and a Phase 1 clinical study in ARPKD in Q2 2017.

- ***Leverage our drug discovery platforms to identify and develop new product candidates for additional unmet medical needs.*** Our drug discovery platforms are focused on biologics as well as small molecule chemistry and support the future growth of our pipeline. Our most advanced preclinical product candidate, KD035, is an anti-angiogenic antibody targeting VEGFR2, which inhibits the formation of new blood vessels, blocking blood supply to tumors. We are also developing KD033, an anti-PD-L1/IL-15 fusion protein, which inhibits the PD-L1 pathway to reduce immune checkpoint blockade while simultaneously directing an IL-15-stimulated, specific immune response to the tumor microenvironment.

- ***Leverage our commercial infrastructure to market therapies for Wilson's disease and support our clinical development programs.*** We plan to seek approval for our proprietary formulation and packaging of trientine hydrochloride for the treatment of Wilson's disease under a Section 505(b)(2) New Drug Application (NDA) pathway. In addition, we are seeking approval for a generic formulation of trientine hydrochloride (in a bottled capsule and in blister packaging) for the treatment of Wilson's disease under an ANDA for a generic of Syprine (trientine hydrochloride). We intend to use Kadmon Pharmaceuticals to market these formulations, if approved, and support our development programs and commercialization of our clinical-stage product candidates.

Our Clinical-Stage Pipeline



ROCK2 Inhibitor Platform (Lead Compound: KD025)

The ROCK signaling pathway is a molecular target with substantial therapeutic potential in autoimmune, fibrotic and neurodegenerative disease. Two ROCK isoforms exist: ROCK1 and ROCK2. We have generated a portfolio of oral ROCK2 and pan-ROCK inhibitors that we believe have the greatest potential based on characteristics including potency, solubility, bioavailability and, in some cases, blood-brain barrier penetrance, to treat specific autoimmune, fibrotic and neurodegenerative diseases.

A central goal in the study of autoimmune disease is to develop therapies that down-regulate pro-inflammatory immune responses while potentially preserving the immune system's ability to fight infections and tumors. Through our studies, we have demonstrated that selective ROCK2 inhibition affects key cellular functions that control and restore balance to the immune system. ROCK2 inhibition with KD025 reduces the production of pro-inflammatory cytokines, IL-17, IL-21 and IL-22 by T helper 17 (Th17) cells through the down-regulation of STAT3, a key transcription factor and regulator of the inflammatory pathway. ROCK2 inhibition concurrently increases the suppressive function of regulatory T cells (Tregs) through activation of STAT5, a controller of regulatory cell function, helping to resolve inflammation with a minimal effect on the rest of the immune response.

In fibrotic diseases, ROCK signaling is up-regulated throughout the fibrotic process, effecting macrophage infiltration, endothelial cell activation and myofibroblast differentiation. These processes result in the deposition of excess collagen and creation of scar tissue. We believe that ROCK inhibition with KD025 has the potential to halt and reverse these processes to successfully treat fibrotic diseases.

It is now well understood that neurodegenerative diseases have a neuroinflammatory component. These observations, coupled with the effects of ROCK on neuronal cell behavior, indicate that ROCK inhibition may play an important role in the treatment of neurodegenerative diseases, including, among many others, multiple sclerosis, Alzheimer's disease and Huntington's disease.

KD025 for the Treatment of Moderate to Severe Psoriasis

KD025 has demonstrated clinical activity in a completed Phase 2 clinical trial in moderate to severe psoriasis, resulting in Psoriasis Area and Severity Index (PASI) score reductions in 85% of patients completing the study, with minimal side effects. PASI scoring is a widely used visual measure of psoriasis severity. In completed Phase 2 and Phase 2a clinical studies in moderate to severe psoriasis, KD025 resulted in the down-regulation of pro-inflammatory response with no evidence of any deleterious impact on the rest of the immune system. We believe this effect may potentially avoid toxicities and increased susceptibility to lymphomas and opportunistic infections associated with currently available biologic therapies. KD025 is orally administered, whereas most current psoriasis therapies are formulated as infused or injectable biologics. We

believe that KD025 is an ideal treatment candidate for moderate to severe psoriasis because it has demonstrated clinical activity, is orally delivered and lacks side effects such as headache, nausea and diarrhea.

Medical Need: Moderate to Severe Psoriasis

Psoriasis is a chronic, immune-mediated, inflammatory skin condition affecting as many as 7.5 million people in the United States. Most psoriasis patients (approximately 80% to 90%) have chronic plaque psoriasis, characterized by recurrent exacerbations and remissions of thickened, erythematous, scaly patches of skin that can occur anywhere on the body. Approximately 15% to 25% of these patients have moderate to severe disease requiring systemic therapy. This subset of patients is our targeted patient population.

Many approved therapies target the immune system to treat psoriasis, including recently introduced biologic agents. All of these therapies have significant limitations, including increased risk of serious infections and malignancies, such as tuberculosis, lymphoma, immunogenicity and neurological disorders. In addition, these therapies require regular injections, which is a deterrent to many patients and prescribers. More recently, Otezla (apremilast) was approved by the FDA to treat patients with moderate to severe psoriasis, although it has several clinical side effects. Novel oral agents for moderate to severe psoriasis that lack significant side effects are needed.

KD025 Clinical Program in Moderate to Severe Psoriasis

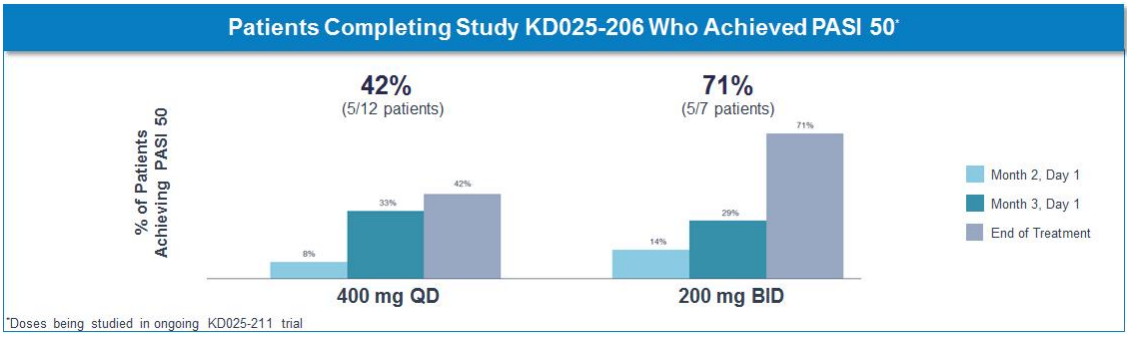
Ongoing Placebo-Controlled Phase 2 Clinical Study of KD025 in Moderate to Severe Psoriasis (KD025-211)

Based on clinical data from our recently completed Phase 2 clinical study of KD025, we are conducting a randomized, double-blind, placebo-controlled Phase 2 clinical study of KD025 in moderate to severe psoriasis in the United States. This dose-finding study is evaluating the safety, tolerability and efficacy of KD025 in up to 150 patients with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy. The 16-week study consists of five cohorts of 30 patients each: KD025 200 mg once daily (QD), KD025 200 mg twice daily (BID), KD025 400 mg QD, KD025 600 mg QD (administered as 400 mg in the morning and 200 mg in the evening) and matching placebo BID. The primary efficacy endpoint is the percentage of patients achieving a 75% reduction in PASI score at Week 16. The study was initiated in September 2016 and we expect to report data from this study in Q4 2017.

The FDA has also advised that we evaluate the potential of KD025 to induce carcinogenicity in two species, as recommended by current FDA guidelines for drug development. Carcinogenicity assessment planning will initiate in 2017 as KD025 progresses through development, and we will discuss the plan with the FDA Carcinogenicity Assessment Committee prior to initiating the studies, as recommended by the FDA.

Completed Open-Label Phase 2 Clinical Study of KD025 in Moderate to Severe Psoriasis (KD025-206)

We completed a Phase 2 clinical study of KD025 in the United States in patients with moderate to severe psoriasis who relapsed following a course of systemic therapy. KD025-206 was a twelve-week, dose-finding clinical study that consisted of three cohorts: KD025 400 mg QD, 200 mg BID and 400 mg BID. Of the 38 patients dosed, 26 completed the study. 85% of patients who completed the trial demonstrated a clinical benefit in moderate to severe psoriasis, defined as any decrease in PASI score. In the 400 mg QD cohort, 42% of patients (5 out of 12) achieved at least a 50% decrease in PASI score (PASI 50). In the 200 mg BID cohort, 71% of patients (5 out of 7) achieved PASI 50 (see figure below). In the 400 mg BID cohort, 29% of patients (2 out of 7) achieved PASI 50. Of the 38 patients in the trial, 12 discontinued, seven of whom had Grade 2-3 elevations in liver transaminases and were taken off therapy by the Kadmon medical monitor. Four patients voluntarily withdrew from the study and one patient was lost to follow-up.



Elevations in liver transaminases (alanine aminotransferase (ALT) and aspartate aminotransferase (AST)), enzymes that help metabolize amino acids and may be indicators of liver cell injury, were graded on a 0-4 scale based on the patient's laboratory results compared to the upper limit of normal (ULN) range, with Grade 4 reflecting the greatest elevation.

The grading of these liver-related laboratory abnormalities is distinct from the grading of other laboratory adverse events, which were graded on the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials, and the grading of clinical adverse events, which were graded on the Common Terminology Criteria for Adverse Events (CTCAE) Scale.

In the 400 mg QD cohort, no patients were discontinued for transaminase elevations. In the 200 mg BID cohort, two patients were discontinued for Grade 2 elevations in transaminases, and one patient was discontinued for a Grade 3 elevation in transaminases. In the 400 mg BID cohort, four patients were discontinued, one for a Grade 2 elevation in transaminases and three for Grade 3 elevations in transaminases.

All transaminase elevations returned to normal when drug was stopped and in three cases, transaminase elevations resolved while KD025 treatment was continued to end of therapy. One patient had elevated bilirubin levels at screening, prior to receiving study drug, which increased and then returned to the patient's baseline levels while on study drug. This bilirubin elevation was considered by the investigator to be unlikely related to study drug. There was one Grade 4 transaminase elevation that was observed nearly two months after the patient ended treatment. Approximately three months after the patient's end-of-treatment visit, this transaminase elevation was documented as resolved and was considered by the investigator to be unlikely related to study drug. No serious adverse events were reported in any of the three cohorts, whether based on laboratory abnormalities or clinical events. Liver abnormality grades (e.g., Grade 4) alone do not connote the same CTCAE adverse event grades. In addition to the laboratory adverse events noted, there were CTCAE Grade 1-2 clinical adverse events observed that did not result in any discontinuation of therapy. Due to the transaminase elevations observed in the 400 mg BID group, we are not studying this dose or higher doses in our ongoing Phase 2 placebo-controlled study of KD025 in moderate to severe psoriasis. Of note, only one Grade 3 transaminase elevation occurred in the doses being studied in the ongoing placebo-controlled trial (KD025-211).

Of patients who completed the study and for whom IL-17 measurements were available, 84% (21 out of 25) showed reduced levels of pro-inflammatory cytokine IL-17, the key driver in psoriasis, and a minimal effect on the rest of the immune system.

KD025 for the Treatment of Idiopathic Pulmonary Fibrosis

Medical Need: Idiopathic Pulmonary Fibrosis

IPF is a progressive fibrotic disease of the lungs, with a median survival of two to three years from the time of diagnosis. Approximately 128,000 people in the United States are living with IPF, with 48,000 new cases diagnosed annually. IPF is thought to be caused by repetitive environmental injury to the lining of the lung airways (epithelium) and the resulting abnormal wound-healing responses that lead to progressive buildup of stiff extracellular matrix, resulting in restrictive lung function, breathing difficulty and ultimately death. Novel therapeutic options have recently been approved for use; however, these treatments only slow decay in pulmonary function without significantly increasing survival. IPF patients are in need of new therapies designed to halt scarring of the lungs and meaningfully increase survival.

KD025 in Fibrotic Disease

In addition to ROCK2's potential role in autoimmunity, we believe ROCK2 plays an important role in the development of fibrotic disease. In our preclinical studies, ROCK2 inhibition with KD025 reduced Type 1 collagen secretion and stellate cell formation associated with scar tissue formation, improving organ function in models of fibrosis. Data from these preliminary studies suggest that treatment with KD025 may prevent the secretion of Type 1 collagen as well as the formation of myofibroblasts, cells primarily responsible for the secretion of collagen and the progression of fibrotic disease.

Ongoing Phase 2 Clinical Study of KD025 in Idiopathic Pulmonary Fibrosis (KD025-207)

We are conducting a randomized, open-label, Phase 2 clinical study to examine the safety, tolerability and activity of KD025 in IPF patients who have received or been offered anti-fibrotic drugs pirfenidone and/or nintedanib. We are enrolling up to 36 IPF patients randomized into two cohorts: one cohort of 24 patients treated with KD025 at 400 mg QD versus another cohort of 12 patients treated with standard of care. The primary efficacy endpoint is the percent change in forced vital capacity (FVC), from baseline to 24 weeks. The study was initiated in June 2016 and is being conducted in the United States. We expect to report data from this study no later than Q4 2017.

KD025 for the Treatment of Chronic Graft-Versus-Host Disease

Medical Need: Chronic Graft Versus Host Disease

Chronic GVHD is a common and often fatal graft-mediated complication following allogeneic stem cell transplantation in which transplanted immune cells attack recipient tissue, leading to fibrosis in the lung, gastrointestinal tract, liver and skin. It is estimated that greater than 50% of allogeneic hematopoietic stem cell transplant recipients develop cGVHD. Several studies have shown that IL-21 and IL-17, two pro-inflammatory cytokines regulated by the ROCK2 signaling pathway, play a key role in cGVHD pathogenesis. Currently, few therapeutic interventions exist for steroid-refractory cGVHD.

KD025 in Chronic Graft Versus Host Disease

In our preclinical research that was published in the journal *Blood* in March 2016, we demonstrated that ROCK2 inhibition with KD025 effectively decreased cGVHD manifestation in murine and human models. Specifically, KD025 treatment reversed the clinical and immunological symptoms of cGVHD in two murine models, in which mice showed improvements in pulmonary function and a significant decrease in the cGVHD pathology in the lung, liver and spleen compared to vehicle-treated animals. Data from human cells demonstrated that KD025 inhibited the production of pro-inflammatory cytokines. These findings suggest that KD025 may prevent the secretion of Type 1 collagen as well as the formation of myofibroblasts, cells primarily responsible for the secretion of collagen and the progression of fibrotic disease.

Ongoing Phase 2 Clinical Study of KD025 in Chronic Graft-Versus-Host Disease (KD025-208)

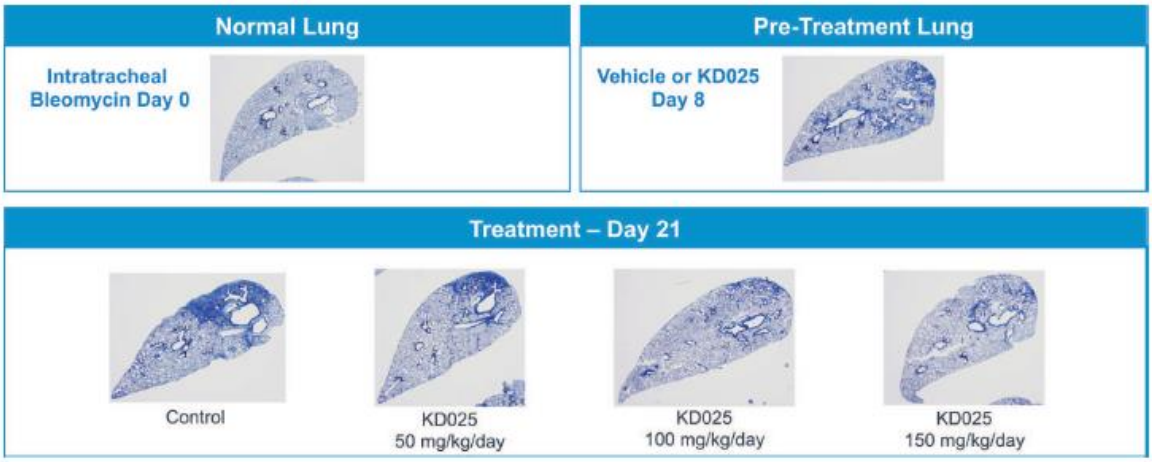
We are conducting an open-label, dose-escalating Phase 2 clinical study in the United States to evaluate the safety, tolerability and activity of KD025 in patients with steroid-dependent cGVHD and active disease. We are enrolling up to 48 cGVHD patients into three cohorts of 16 patients: KD025 200 mg QD, 200 mg BID and 400 mg QD for 24 weeks. The primary efficacy endpoint is to evaluate KD025 activity at 24 weeks in terms of complete response and partial response, as defined by the 2014 NIH Consensus Development Project on Clinical Trials in cGVHD. The study was initiated in September 2016 and we expect to report data from this study no later than Q4 2017.

KD025 Animal Models

KD025 has demonstrated activity in multiple rodent models of autoimmune, fibrotic and neurodegenerative diseases, including collagen-induced arthritis, inflammatory bowel disease, cGVHD, scleroderma, lupus, pulmonary fibrosis and multiple sclerosis. In each case, KD025 administration halted, and in certain cases reversed, disease progression.

Treatment with KD025 attenuated pulmonary fibrosis, significantly reducing fibrosis and inflammation in the lung in a dose-dependent manner in a bleomycin-induced mouse model. This model, induced by infusing the chemotherapy bleomycin into the lungs of mice, is believed to reproduce the tissue alterations found in human pulmonary fibrosis. KD025 dosed QD for 13 days at clinically relevant dose levels in bleomycin-treated mice significantly reduced lung fibrosis and inflammation and improved pulmonary function (see figure below). Importantly, this effect was demonstrated in mice in which pulmonary fibrosis was already established at the time KD025 treatment was initiated (Day 8), suggesting that KD025 potentially reverses pulmonary fibrosis.

KD025 Reduces Pulmonary Fibrosis in Mice



KD025 attenuated the progression of fibrosis (shown in dark blue) in a dose-dependent manner in mice with bleomycin-induced lung fibrosis.

Tesevatinib for NSCLC with Activating EGFR Mutations with Brain Metastases and/or Leptomeningeal Metastases

Tesevatinib (KD019) is an oral small molecule TKI with demonstrated clinical activity against activating mutations of EGFR, a cell surface receptor that is often overexpressed in lung cancer. In a completed Phase 2 study, response rates of tesevatinib (57%) in previously untreated NSCLC patients with activating EGFR mutations were similar to that of erlotinib (65%) in the same patient population. Unlike currently marketed treatments, tesevatinib is highly penetrant of the blood-brain barrier, which separates the circulating blood from the brain. In preclinical studies, tesevatinib reached equal concentration in the brain as in blood, compared to less than 0.15:1 brain/blood ratios of approved EGFR inhibitors erlotinib, afatinib and gefitinib, and reached levels in the choroid plexus (a network of blood vessels in each ventricle of the brain) and in the leptomeninges of more than 15 times the blood levels. Tesevatinib has shown clinical response for the treatment of brain metastases and leptomeningeal metastases in NSCLC patients with activating EGFR mutations, controlling tumor cell growth. QTc prolongation has been observed in previous tesevatinib studies without any arrhythmia observed. Detailed ECG studies are carried out in every tesevatinib clinical study and a composite report will be available for submission to the FDA in the future. Tesevatinib is also a reversible TKI, therefore limiting severe toxicities associated with other therapies. We believe that tesevatinib's anti-EGFR activity, pre-clinical blood-brain barrier penetrance and specific tissue accumulation present an important opportunity to treat CNS metastases and would offer a strong competitive advantage for tesevatinib over approved therapies that in particular do not have the same blood-brain barrier penetrance.

Medical Need: NSCLC with Activating EGFR Mutations with Brain Metastases and/or Leptomeningeal Metastases

Lung cancer is the most common type of cancer and is responsible for the greatest number of cancer deaths worldwide, killing approximately 1.4 million people globally each year. NSCLC is the most common form of lung cancer, accounting for approximately 85% of all cases.

Approximately 20% of NSCLC cases are driven by activating mutations to the EGFR gene. Approximately 50% of patients with NSCLC with activating EGFR mutations will develop CNS metastases, while approximately 10% of these patients will present with CNS metastases.

Despite the frequency of progression to the CNS, there are no effective approved therapies for brain metastases or leptomeningeal metastases in patients with NSCLC and activating EGFR mutations. Published data have demonstrated that currently approved TKIs have poor brain penetration and are thus unable to effectively treat these metastases. In patients with EGFR-mutant NSCLC, high doses of EGFR TKIs gefitinib or erlotinib have been used to treat brain metastases, with some degree of efficacy. However, in light of poor brain penetration of these agents, response rates are low and the time to disease progression is generally short. Other EGFR inhibitors with improved brain penetration are in development, but to date none have been approved that are being used to treat patients with EGFR-mutant NSCLC with CNS metastases at initial presentation. Brain metastases and leptomeningeal metastases result in significant morbidity, with median survival of three to four months. Therefore, CNS metastases represent a major unmet medical need.

Oncology Clinical Program

To date, more than 250 subjects have received at least one dose of tesevatinib for either solid tumor malignancies or as healthy volunteers in clinical pharmacology studies. In completed clinical studies, tesevatinib demonstrated activity through target kinase inhibition and was safe for chronic dosing in oncology patients at 300 mg QD.

Ongoing Phase 2 Clinical Study of Tesevatinib in NSCLC with Activating EGFR Mutations and Brain Metastases and/or Leptomeningeal Metastases (KD019-206)

In Q4 2015, we initiated a Phase 2 open-label clinical study in the United States of tesevatinib 300 mg QD in NSCLC in up to 60 patients with activating EGFR mutations whose disease has metastasized to the brain and/or the leptomeninges. Patients are divided into three cohorts: patients who have progressed with measurable brain metastases while on other EGFR therapy, patients who have symptomatically progressed with leptomeningeal metastases while on other EGFR therapy and patients with measurable brain metastases and no prior EGFR therapy. In patients with measurable brain metastases, the primary endpoint is the objective response rate within the brain. In patients with leptomeningeal metastases, the primary endpoint is improvement in symptoms compared to baseline.

Data from the first 13 enrolled patients demonstrated that tesevatinib enters the CNS and targets EGFR-driven intracranial tumors to achieve tumor shrinkage and/or clinically significant improvement of neurological symptoms. Of the first 13 patients enrolled, 12 had progressed while on prior treatment with erlotinib and radiation therapy to the brain, five of whom had also received other EGFR inhibitors and chemotherapy. One patient was treatment-naïve. Of the 12 patients who had

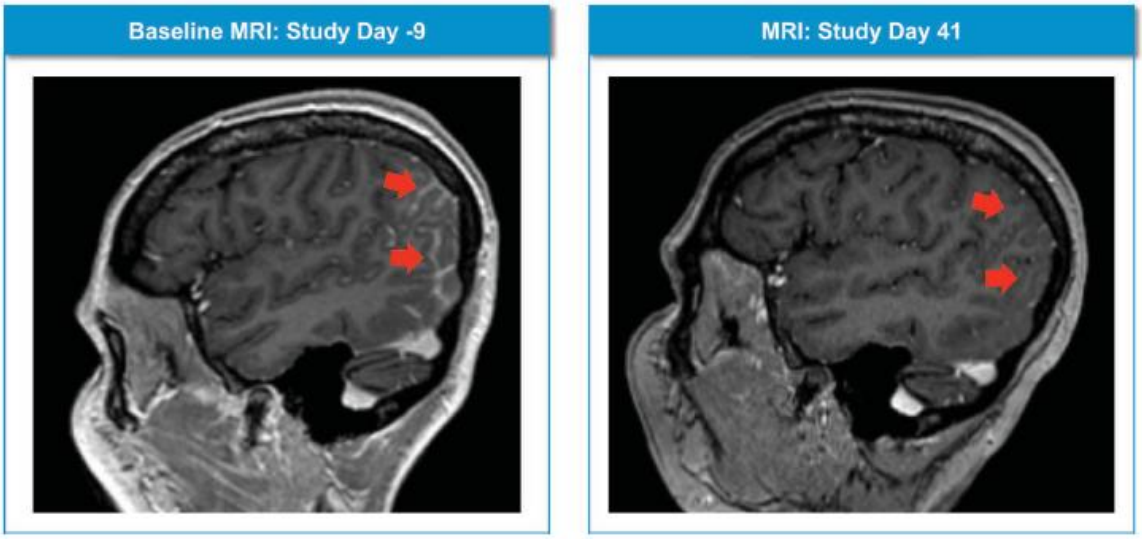
disease progression while on prior therapy, four patients enrolled with brain metastases, three of whom showed clinical benefit with tesevatinib, and eight patients enrolled with leptomeningeal metastases, seven of whom showed clinical benefit with tesevatinib. The treatment-naïve patient (Patient 045-005) showed a robust partial response in brain metastases in an MRI taken on Study Day 29 and showed a partial response in both brain metastases and peripheral disease at Study Day 57 and durability of over 100 days. In total, 11 of the first 13 enrolled patients had no CNS progression.

The observed improvements in neurological symptoms include, for some of the enrolled patients, improved strength and balance and reduced headache and fatigue. The observed tumor shrinkages were based on the differences in lesion diameter measurements conducted by a neuroradiologist at the study sites. Of note, one patient with brain metastases and leptomeningeal metastases (Patient 034-002) showed a 57% reduction in a measurable cerebral metastasis in MRI scans at Day 41 from the initial MRI scans. Additionally, one patient with brain metastases (Patient 045-003) showed an approximate 50% decrease in brain metastases mass overall, based on the cumulative measured and observed decreases in multiple brain lesions in MRI scans at Day 23 from the initial MRI scans. These decreases are shown in the figures below. One patient enrolled to date did not show improvement at any point: a 66-year old male, who died within 21 days of initiating tesevatinib therapy due to urosepsis. Any of the other current or future patients may have or could experience disease progression, deterioration or death, notwithstanding any observed improvements at earlier points in the study. To date, no formal interim analyses have been conducted.

The study was designed specifically to assess the efficacy of tesevatinib in CNS metastases, with full knowledge that these heavily pretreated patients had extensive exposure to other EGFR inhibitors and that tesevatinib therefore may not control peripheral disease well due to the previous development of EGFR inhibitor resistance mechanisms. Thus, as expected, five of the 12 pretreated patients had peripheral disease progression, while in four of those five patients, tesevatinib controlled CNS lesions.

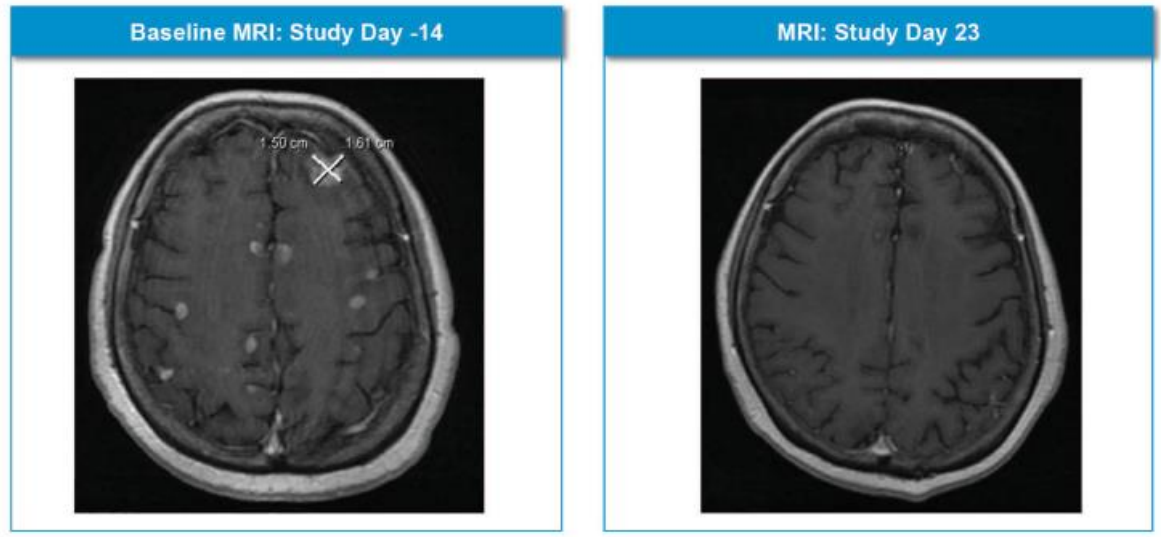
Although these are initial observations of study investigators in a limited number of patients, we believe these responses observed in a high proportion of these NSCLC patients with CNS metastases support our continued development of tesevatinib for metastatic NSCLC.

Ongoing NSCLC Study: Patient with Brain Metastases and Leptomeningeal Metastases (034-002)
Sees Improved Right Parieto-Occipital Leptomeningeal Enhancement



Ongoing NSCLC Study: Patient with Brain Metastases (045-003)

Sees ~50% Decrease in Brain Metastases Mass Overall



Planned Randomized Phase 2 Clinical Study of Tesevatinib in NSCLC with Activating EGFR Mutations and Brain Metastases at Presentation (KD019-209)

Based on encouraging clinical data from our ongoing Phase 2 study in EGFR-mutant NSCLC with CNS metastases, we believe that tesevatinib as first-line therapy may treat existing CNS metastases as well as potentially prevent the development of new lesions in EGFR-mutant NSCLC in patients who present with brain metastases. We plan to initiate a randomized, controlled Phase 2 clinical study of tesevatinib as front-line therapy versus treatment with erlotinib or gefitinib in NSCLC patients with activating EGFR mutations who present with brain metastases. We plan to commence enrollment in this study in Q2 2017 in approximately 145 patients in the United States, Asia and potentially additional locations. The primary endpoint of the trial will be to compare the median progression-free survival in the CNS and peripherally in patients who receive initial treatment with tesevatinib versus initial treatment with erlotinib or gefitinib. We expect to report data from this study in Q4 2018.

Ongoing Phase 2 Clinical Study of Tesevatinib in Glioblastoma (KD019-208)

EGFR protein overexpression and gene amplification is present in approximately 50% of gliomas, which are malignant tumors of the glial tissue of the brain. Data show that 25% of gliomas have a mutant EGFR receptor, called vIII. However, clinical studies of EGFR inhibitors in patients with gliomas have produced disappointing results, primarily due to poor blood-brain barrier penetration. Based on our research, we began enrolling a Phase 2 clinical study of tesevatinib for the treatment of glioblastoma in August 2016. This open-label, exploratory Phase 2 clinical study examines the safety, tolerability and activity of tesevatinib 300 mg QD in up to 40 patients with recurrent glioblastoma, including patients with EGFR overexpression or mutations.

Completed Clinical Studies of Tesevatinib

Prior to our acquisition of tesevatinib, previously called XL647, the following clinical studies were conducted.

Study Number	Phase	Study Design (including primary endpoints)	Study Population Characteristics	Tesevatinib Doses	Number of Patients Dosed
XL647-201	2	Nonrandomized, open-label, Simon two-stage (response rate, safety and tolerability)	NSCLC, no prior systemic treatment for advanced cancer	Intermittent 5&9 dosing (a) at 350 mg (tablet) 300 mg QD (tablet)	Tesevatinib: 41 Tesevatinib: 14
XL647-203	2	Nonrandomized, open-label and Simon two-stage (best confirmed response rate)	Patients with NSCLC who have progressed after benefit from treatment with erlotinib or gefitinib	300 mg QD (tablet)	Tesevatinib: 41

XL647-001	1	Dose-escalation (safety, tolerability and PK)	Advanced solid tumors	Intermittent 5&9 dosing at 0.06-7 mg/kg (PIB); MTD was 4.68 mg/kg (PIB), which was converted to 350 mg (tablet)	Tesevatinib: 41
XL647-002	1	Dose-escalation (safety, tolerability, PK and maximum tolerated dose)	Advanced solid tumors	QD dosing at 75, 150, 200, 300, and 350 mg (tablet)	Tesevatinib: 31
XL647-004	1	Randomized 2-way crossover between fed and fasting states (food effect on bioavailability)	Healthy volunteers	Single 300-mg oral dose in fed and fasted states	Tesevatinib: 24
XL647-005	1	Open-label; non-randomized (absorption, metabolism, excretion, and mass balance)	Healthy volunteers	Single 300-mg oral dose of 14C-tesevatinib	Tesevatinib: 8

(a) QD dosing on the first five days of repeated 14-day cycles.

Completed Phase 2 Clinical Studies of Tesevatinib

The first Phase 2 clinical study of tesevatinib, XL647-201, enrolled treatment-naïve NSCLC patients. This clinical study was conducted in the United States. In this study, tesevatinib demonstrated a 57% overall response rate in NSCLC patients with EGFR activating mutations, based on Response Evaluation Criteria In Solid Tumors (RECIST) assessment, achieving progression-free survival of 9.3 months and overall survival of 22.5 months.

The second Phase 2 clinical study, XL647-203, enrolled patients with relapsed or recurrent NSCLC and a known EGFR resistance mutation (T790M) or progression following treatment with single agent erlotinib or gefitinib. This clinical study was conducted in the United States. This study demonstrated that tesevatinib has limited efficacy against NSCLC with EGFR resistance mutations. Based on RECIST assessment, the majority of evaluable patients had a best response of stable disease (21/33 patients, 63.6%) and one patient (1/33, 3%) achieved a confirmed partial response which lasted for 7.4 months. Once achieved, stable disease for patients dosed with tesevatinib was maintained for 1.7 to 15.2 months.

Tesevatinib for Polycystic Kidney Disease

We are also developing tesevatinib for the treatment of PKD, an inherited kidney disorder. Tesevatinib inhibits the molecular pathways central to the progression of ADPKD and ARPKD, namely EGFR and Src family kinases. In addition, tesevatinib accumulates in the kidneys, 15-fold greater than in the blood. In rodent PKD models, tesevatinib-treated animals have dramatically fewer and smaller renal cysts than vehicle treated controls. We believe the inhibition of EGFR and Src family kinases by tesevatinib and its accumulation in the kidneys make it an excellent potential therapeutic product candidate for PKD. These characteristics allow for lower dosage in patients, making it potentially suitable for long-term use. We believe that tesevatinib, if approved, could be a first-line therapy for both ADPKD and ARPKD.

Tesevatinib is currently in a Phase 2a clinical study in the United States in ADPKD. We plan to begin enrolling a randomized, placebo-controlled Phase 2 study in ADPKD in the United States in mid-2017 and a Phase 1 study in ARPKD in the United States in Q2 2017.

Medical Need: Polycystic Kidney Disease

PKD is the most prevalent monogenic disease, with approximately 600,000 patients in the United States and 12.5 million patients worldwide, affecting more individuals than all other monogenic diseases combined. There are two forms of the disease: ADPKD, which presents in adulthood, and ARPKD, a rare autosomal recessive form affecting infants. ADPKD and ARPKD demonstrate significant elevation in molecular signaling cascades frequently implicated in cancer cell growth, including EGFR and Src family kinases. A key characteristic of PKD is the formation of enlarged, fluid-filled cysts, which compromise kidney function and lead to rapid progression to end-stage renal disease. EGFR in particular is implicated in the expansion of renal cysts in PKD. The growth of large cysts over decades in ADPKD compromises kidney function and eventually results in the need for dialysis and kidney transplant. ADPKD is one of the leading causes of end-stage renal disease, with approximately 50% of patients requiring dialysis by the age of 60.

ARPKD affects approximately one in 20,000 children born in the United States and is a more severe disease than ADPKD, causing cyst formation in multiple organs, leading to significant morbidity and mortality in childhood, with those surviving typically requiring dialysis by the age of 10.

There are no FDA-approved therapies for either form of PKD and, to our knowledge, there are no candidates in clinical studies for ARPKD. While the role of EGFR is well known in disease causation and progression, other molecules have not been tested in PKD because the blood/serum concentrations required to impact the kidney would be very high and would likely have an intolerable toxicity profile. Current standard of care for end-stage PKD is limited to dialysis and kidney transplant. Therefore, PKD represents a significant unmet medical need and a substantial commercial opportunity as patients with PKD need therapies that can slow disease progression and increase survival.

PKD Clinical Program

Ongoing Phase 2a Study of Tesevatinib in Autosomal Dominant Polycystic Kidney Disease (KD019-101)

Kadmon is conducting an ongoing, single-agent Phase 2a study of tesevatinib in ADPKD. Findings from this study have demonstrated that tesevatinib is well tolerated and have also identified tesevatinib 50 mg QD as the optimal dose to treat ADPKD.

KD019-101 was initiated as a dose-finding Phase 1b/2a study of tesevatinib. The study enrolled 61 patients with a Total Kidney Volume (TKV) at entry of 1,333.5 mL (normal kidney volume is approximately 400 mL). The Phase 1b portion of the study demonstrated that tesevatinib was generally well tolerated at 50, 100 and 150 mg QD and 150 mg dosed twice or three times weekly, with rashes occurring in the 150 mg dose cohorts. No serious adverse events have occurred, and the 50 mg QD dose was associated with mild rashes in less than 20% of patients. Patients from Study KD019-101 may continue on tesevatinib therapy in Study KD019-207, an extension study to collect long-term safety data.

Recent findings from the study further demonstrated the safety of tesevatinib in ADPKD. The data indicated that tesevatinib is a MATE 1/2-K transporter inhibitor, which mildly increases levels of serum creatinine. Normally, an increase in serum creatinine may indicate kidney damage, but in the case of MATE 1/2-K inhibitors, these increases occur without clinically meaningful alterations in kidney function. In the ongoing trial, serum creatinine levels increased by 10% to 14% during the first 28 days of tesevatinib treatment and reversed upon treatment discontinuation. Importantly, levels of cystatin C, another measure of renal function, were relatively unchanged during the same period.

We received guidance from the FDA on our development plan for tesevatinib in ADPKD at our End-of-Phase 2 meeting on March 21, 2016. The FDA recommended that we gather, and we are gathering, further safety data from additional patients enrolling in our ongoing Phase 2a study prior to initiating our randomized, placebo-controlled study in this indication.

Planned Phase 2 Placebo-Controlled Study of Tesevatinib in Autosomal Dominant Polycystic Kidney Disease (KD019-211)

We plan to initiate a Phase 2, randomized, double-blind, placebo-controlled trial of tesevatinib in ADPKD in the United States in mid-2017. The study will evaluate the efficacy and safety of tesevatinib in up to 100 patients divided evenly into two cohorts of tesevatinib 50 mg QD versus matched placebo. The primary endpoint of the study will be reduction in height-adjusted TKV in the treatment arm versus placebo. The secondary endpoint of the study will be the comparison of estimated glomerular filtration rate (eGFR) in the treatment arm versus placebo. The randomized study design is intended to provide data to enable subsequent registration trials and attract potential partners for co-development of advanced clinical trials. We expect to report data from this study by Q4 2018.

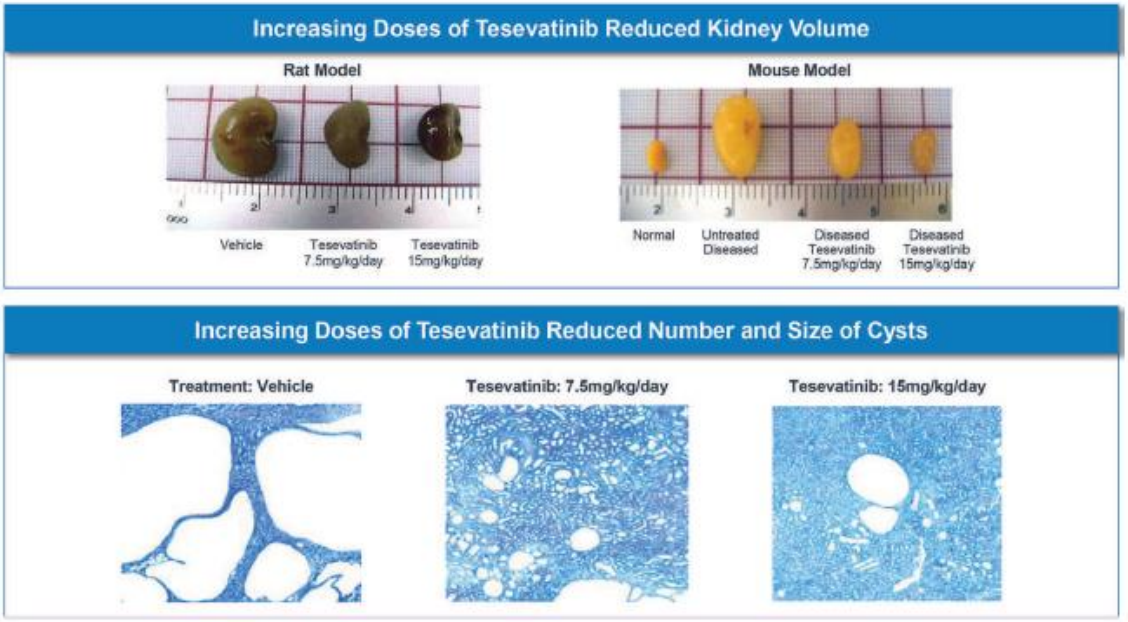
Planned Phase 1 Study of Tesevatinib in Autosomal Recessive Polycystic Kidney Disease (KD019-103)

We obtained orphan drug designation status in the United States for tesevatinib for the treatment of patients with ARPKD in Q1 2016. Following the FDA's acceptance of our Investigational New Drug (IND) application in December 2016, we plan to begin enrolling a Phase 1 dose-finding clinical trial of tesevatinib for the treatment of ARPKD in Q2 2017. In order to accommodate the ARPKD population, we developed a taste-masking liquid formulation of tesevatinib for dosing to children, which is designed to enable titration, the process of gradually adjusting the dose of medication by body weight to reach the appropriate dose. Developmental toxicology studies in animals, which are required for this pediatric patient population, indicated that tesevatinib is generally well tolerated, with data supportive of clinical trial initiation. The Phase 1 study will be an ascending single-dose safety study in ARPKD patients ages five to 12. The study will consist of three cohorts: tesevatinib 0.25 mg/kg, 0.50 mg/kg and 1.0 mg/kg, and we expect to enroll six to 18 subjects. We expect to report data from this study in Q4 2017.

Polycystic Kidney Disease Preclinical Data

In a dose-dependent manner, tesevatinib significantly slowed the progression of PKD in rat and mouse models. Tesevatinib reduced of the formation and growth of renal cystic lesions, reduced kidney volume and weight, and reduced kidney/body weight ratio (see figure below). Treatment with tesevatinib was also associated with reductions in serum creatinine and blood urea nitrogen, indicative of improved kidney function.

Tesevatinib is Effective in Rat and Mouse Models of Polycystic Kidney Disease



KD034

KD034 represents our portfolio of formulations of trientine hydrochloride for second-line treatment of Wilson's disease, a genetic liver disease.

Medical Need: Wilson's disease

Wilson's disease is a genetic disorder characterized by an inability to excrete copper, leading to severe hepatic, neurologic, psychiatric and/or ophthalmic abnormalities. Wilson's disease is categorized by the FDA as an orphan disease with approximately 10,000 people diagnosed in the United States. Diagnosis of Wilson's disease can be challenging due to its varied symptoms and multi-organ impact. As such, there is a need to identify and treat patients early to prevent severe hepatic and neurologic complications associated with disease progression.

Currently approved Wilson's disease therapies include chelating agents such as penicillamine or trientine hydrochloride. Penicillamine has a high rate of serious and sometimes fatal adverse events including blood disorders, kidney damage, lung problems, nervous system problems and skin diseases. Severe adverse effects requiring drug discontinuation occur in approximately 30% of patients. Trientine hydrochloride, currently marketed under the brand name Syprine, is used as second-line therapy for patients intolerant of penicillamine. Trientine hydrochloride is well tolerated and effective. The currently marketed formulation of trientine hydrochloride has multiple drawbacks, including necessity for cold storage, a lack of a liquid formulation, high pill burden and inconvenient dosing schedules, potentially impacting patient compliance. Since Wilson's disease requires lifelong management and as the consequences of discontinuing therapy can be fatal, well-tolerated, effective and convenient therapies are needed.

Key Differentiating Attributes of KD034

For broad market access purposes, we are developing a bottled generic 250 mg capsule formulation of trientine hydrochloride that is identical to Syprine. We are also developing a generic 250 mg capsule formulation in a blister packaging that offers room temperature stability, which we believe has the potential to address shortcomings of currently available

trientine hydrochloride formulations. We are also developing a proprietary liquid formulation of trientine hydrochloride for children and other populations who have difficulty swallowing solid pills.

KD034 Development Program for Wilson's disease

We conducted an open-label bioequivalence clinical study in the United States, which showed that our generic capsule formulation was equivalent to Syprine in healthy volunteers. We are also assessing stability of our generic capsule in blister packaging.

Regulatory Strategy

In December 2016, we submitted an ANDA for our bottled generic formulation of trientine hydrochloride. In Q1 2017, we plan to submit a second ANDA for our generic form of trientine hydrochloride in blister packaging that offers room temperature stability. We intend to use Kadmon Pharmaceuticals, our specialty-focused commercial organization, to market these formulations, if approved. In addition, we plan to seek approval for our proprietary liquid formulation of trientine hydrochloride, for which we plan to pursue a Section 505(b)(2) New Drug Application (NDA) pathway.

We believe that stability, bioavailability and bioequivalence studies will be needed for the 505(b)(2) submission. Based on the history of the compound (i.e., it is not a new chemical entity) and the nature of the studies planned, we do not plan to conduct these studies under a new IND as we believe we meet the exemption criteria under which bioavailability and bioequivalence studies using unapproved versions of approved drug products can be conducted without submission of an IND.

Our Drug Discovery Platforms and Preclinical Molecules

Drug Discovery Platforms

We have two drug discovery platforms that support our pipeline of clinical-stage product candidates: biologics and small molecule chemistry. We leverage our team of scientific experts and our advanced understanding of the molecular mechanisms of disease to establish development paths for disease areas where significant unmet medical needs exist.

Kadmon Preclinical Compounds in Development (pre-IND)

Platform	Compound	Potential Indication(s)
Biologics	Anti-VEGFR2 monoclonal antibody (KD035)	Anti-angiogenesis
	Anti-PD-L1 monoclonal antibody (KD036)	Immuno-oncology
	Bi-functional anti-PD-L1/IL-15 fusion protein (KD033)	Immuno-oncology
Small Molecule Chemistry	ROCK2 and pan-ROCK inhibitors (KD025 follow-on molecules)	Autoimmune and fibrotic diseases
	Brain-penetrant ROCK2 inhibitors	Neurodegenerative diseases
Metabolomics/Small Molecule Chemistry	GLUT inhibitors	Autoimmune diseases

Biologics

We have a fully human monoclonal antibody platform run by an experienced group of scientists. This team has developed multiple commercially successful antibodies prior to joining Kadmon, including Erbitux (cetuximab) and Cyramza (ramucirumab). Our scientists are developing monoclonal antibodies as well as fusion proteins and bispecific antibodies that we believe represent the next generation of cancer therapeutics.

Our most advanced candidate from our biologics platform, KD035, is a proprietary anti-angiogenic antibody targeting VEGFR2, which inhibits the formation of new blood vessels, blocking blood supply to tumors. New research has demonstrated that inhibition of the VEGF/VEGFR2 pathway also reduces the expression of PD-1, activating the immune system to attack tumors and potentially augmenting the efficacy of immune checkpoint therapies.

We are also developing KD033, a novel anti-PD-L1/IL-15 fusion protein. KD033 inhibits the PD-L1 pathway to reduce immune checkpoint blockade while simultaneously directing an IL-15-stimulated, specific immune response to the tumor microenvironment. KD033 potentially offers greater efficacy than immuno-oncology monotherapy while avoiding toxicities associated with systemic administration of cytokine therapy.

Treatment with KD033 significantly prolonged the survival of colon-tumor bearing mice, especially compared to treatment with IL-15 or anti-PD-L1 as single agents. In a separate mouse model, KD033 stimulated long-lasting memory $CD8^+$ T cells to achieve persistent antitumor efficacy without additional treatment. KD033 has demonstrated significant tumor inhibition in murine models that are resistant to PD-L1, PD-1 or CTLA-4 antibodies, suggesting that KD033 may deliver promising clinical outcomes in cancer patients resistant or refractory to immuno-oncology monotherapy. We have presented encouraging preclinical data on KD033 at scientific conferences.

We entered into a collaboration and licensing agreement with Jinghua Pharmaceutical Group Co., Ltd. (Jinghua) in November 2015 to develop anti-VEGFR2 and anti-PD-L1 monoclonal antibodies, KD035 and KD036, exclusively for Greater China.

Small Molecule Chemistry

In addition to conducting traditional medicinal chemistry, we have licensed a proprietary chemical library (the "Chiromics" library) created through an innovative process of enzymatic catalysis. This new method of creating molecules permits the isolation of product candidates with novel chemical scaffolds that we believe will be able to hit targets that were previously difficult to address with traditional small molecule therapies.

We are leveraging our small molecule chemistry team's expertise to build and expand our ROCK inhibitor platform. We have identified and are developing ROCK2 and pan-ROCK inhibitor compounds with varying specificity, distribution and solubility characteristics to treat specific autoimmune and fibrotic diseases, as well as blood-brain barrier penetrant ROCK2 inhibitors to treat neurodegenerative diseases.

In addition, our small molecule chemistry team develops inhibitors to glucose transport 1 (GLUT-1), a molecular target of the metabolic pathway that is associated with autoimmune diseases.

Research and Development

Research and development expenses consist primarily of costs incurred for the development of our product candidates. For the years ended December 31, 2016, 2015 and 2014, we recognized $35.8 million, $33.6 million and $32.9 million, respectively, in research and development expenses. For further detail about our research and development activities, refer to the research and development sections in "Management's Discussion and Analysis" in this Annual Report on Form 10-K.

Sales and Marketing

Kadmon Pharmaceuticals is our marketing and sales organization focused on specialty pharmaceuticals. Kadmon Pharmaceuticals markets a portfolio of branded and generic ribavirin products used as part of a combination treatment for chronic HCV infection (Ribasphere RibaPak and Ribasphere). In addition, Kadmon Pharmaceuticals distributes products in a variety of therapeutic areas, including tetrabenazine for the treatment of chorea associated with Huntington's disease; valganciclovir for the treatment of cytomegalovirus (CMV) retinitis; abacavir, lamivudine, and a lamivudine and zidovudine combination tablet for the treatment of human immunodeficiency virus type 1 (HIV-1) infection; and entecavir and lamivudine for the treatment of chronic hepatitis B virus (HBV) infection.

Kadmon Pharmaceuticals is a fully integrated commercial organization encompassing managed care and specialty pharmacy account directors, experienced regulatory, quality, compliance and CMC teams, marketing experts and sales specialists. Kadmon Pharmaceuticals has long-standing relationships with specialty pharmacies. The specialty pharmacies through which we distribute our products are fully independent of Kadmon. We do not have any ownership interest in or affiliations with any specialty pharmacy, nor do we consolidate the financial results of any specialty pharmacies with our own.

We do not currently place significant value on our commercial operations from a revenue-generation standpoint, as revenues from such operations do not currently support our research and development efforts. Product revenues from our commercial operations are primarily derived from sales of RibaPak and Ribasphere. Kadmon Pharmaceuticals' sales of these drugs have significantly declined, from $63.5 million for the year ended December 31, 2014, to $29.3 million and $17.0 million for the years ended December 31, 2015 and 2016, respectively, as the treatment of chronic HCV infection has significantly changed with multiple ribavirin-free therapies having entered the market. We leverage our commercial infrastructure to support the development of our clinical-stage product candidates by providing quality assurance, compliance, regulatory and pharmacovigilance among other capabilities. We believe our commercial infrastructure will be most advantageous to us in the future, in connection with the anticipated commercialization of our pipeline product candidates, if approved.

Strategic Collaborations and License Agreements

Symphony Evolution, Inc.

In August 2010, we entered into a license agreement with Symphony Evolution, Inc. (Symphony), under which Symphony granted to us an exclusive, worldwide, royalty-bearing, sublicensable license under certain Symphony patents, copyrights and technology to develop, make, use, sell, import and export XL647 and the related technology in the field of oncology and non-oncology.

We are the licensee of granted patents in Australia, Canada, Europe, Japan and the United States. The patents claim tesevatinib as a composition-of-matter, as well as use of tesevatinib to treat certain cancers. A pending U.S. application supports additional composition-of-matter claims and methods of synthesis. The last to expire U.S. patent in this family has a term that ends in May 2026 based on a calculated Patent Term Adjustment (PTA) and without regard to any potential Patent Term Extension (PTE), which could further extend the term by an additional five years.

We are the licensee of a second family of granted patents in China and Europe, as well as applications in Canada, Eurasia, Japan, Taiwan and the United States. These patents and applications disclose the use of tesevatinib to treat PKD. The last to expire U.S. patent in this family would have a term that ends in 2031, though this term could be extended by obtaining a PTA and/or PTE.

The license agreement includes a series of acquisition and worldwide development milestone payments totaling up to $218.4 million, and $14.1 million of these payments and other fees have been paid as of December 31, 2016. Additionally, the license agreement includes commercial milestone payments totaling up to $175.0 million, none of which have been paid as of December 31, 2016, contingent upon the achievement of various sales milestones, as well as single-digit sales royalties. The royalty term expires with the last to expire patent.

Our agreement with Symphony will expire upon the expiration of the last to expire patent within the licensed patents. We may terminate the agreement at any time upon six months written notice to Symphony. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. Symphony may terminate the agreement if we challenge the licensed patents. Either party may terminate the agreement upon the bankruptcy or insolvency of the other party.

On June 11, 2014 we and Symphony executed an additional amendment to the amended and restated agreement, whereby the $1.1 million payment due on June 1, 2014 was extended to September 30, 2014. This amendment increased the payment to $1.2 million to include fees for deferral of the payment. We expensed $200,000 to research and development expense for these additional fees during 2014.

On September 30, 2014 we and Symphony executed an additional amendment to the amended and restated agreement, whereby the $1.2 million payment due on September 30, 2014 was extended to November 30, 2014. This amendment increased the payment to $1.4 million to include fees for deferral of the payment. We expensed $200,000 to research and development expense for these additional fees during 2014. In November 2014, we made payment to Symphony for $1.4 million in settlement of this obligation.

Nano Terra, Inc.

In April 2011, our subsidiary Kadmon Corporation entered into a joint venture with Surface Logix, Inc. (SLx) through the formation of NT Life Sciences, LLC (NT Life), whereby Kadmon Corporation contributed $0.9 million at the date of formation in exchange for a 50.0% interest in NT Life. Contemporaneously with our entry into the joint venture, we entered into an exclusive sub-license agreement with NT Life under which NT Life granted us rights to certain patents and know-how it licensed from SLx relating to the compound SLx-2119 (KD025). Under this agreement, NT Life granted to us an exclusive, worldwide, royalty-bearing, sublicensable license to make, have made, use, sell, offer for sale, import and export the product candidates. NT Life also granted to us a worldwide, non-exclusive, non-transferable, sublicensable license under certain SLx platform technology to make, have made, use, sell, offer for sale, import and export the product candidates. The initial purpose of the joint venture with SLx was to develop assets licensed to us from SLx and to define the royalty obligations with respect to certain products not exclusively licensed to us. The joint venture is, however, currently inactive. We expect that the joint venture will become active and develop certain intellectual property in the future.

Regarding KD025, we are the licensee of granted patents in the United States, as well as applications in Australia, Canada, Europe, Japan and the United States, which claim KD025 as a composition-of-matter, as well as use of KD025 to treat certain diseases. The last to expire U.S. patent in this family has a term that ends in October 2029 based on a calculated PTA and without regard to any potential PTE, which could further extend the term by an additional five years.

In consideration for the rights granted to us by NT Life, we agreed to assume certain of Nano Terra, Inc.'s (Nano Terra) payment obligations, which are limited to the royalty percentages discussed in this paragraph, under the Agreement and Plan of Merger dated April 8, 2011, by and among Nano Terra, NT Acquisition, Inc., SLx, and Dion Madsen, as the Stockholder Representative (Merger Agreement). Pursuant to these obligations, we are required to pay to the Stockholder Representative a royalty based on a percentage of net sales of licensed program products in the mid-single digits, subject to specified deductions and adjustments. We are also required to pay to NT Life a 10.0% royalty on the net sales remaining after giving effect to the royalty payment to the Stockholder Representative. Pursuant to the assumption of payment obligations, we are also required to pay to the Stockholder Representative a portion of any sublicensing revenue relating to the licensed program products ranging from the low twenty percents to the low forty percents, subject to specified deductions and adjustments. We are also required to pay to NT Life any remaining sublicensing revenue.

Our agreement with NT Life will, with respect to a licensed program product, end on a country-by-country and licensed program product-by-licensed program product basis upon the latest of (a) the expiration or invalidation of the last valid claim of a patent right covering such licensed program product in such country and (b) the expiration or termination of payment obligations with respect to such licensed program product. The agreement will, with respect to the SLx platform technology, end on a country-by-country basis upon expiration or invalidation of the last valid claim of a patent right covering such SLx platform technology.

We may terminate the agreement at any time upon six months written notice to NT Life. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. NT Life may terminate the agreement if we challenge the licensed patents. Either party may terminate the agreement upon the bankruptcy or insolvency of the other party. The agreement shall terminate in the event we are dissolved. The agreement shall terminate on a licensed program product-by-licensed program product basis in the event such licensed program product reverts to the Stockholder Representative because of a failure to satisfy the diligence requirements as set forth in the Merger Agreement.

Dyax Corp.

In July 2011 we entered into a license agreement with Dyax Corp. ("Dyax") for the rights to use the Dyax Antibody Libraries, Dyax Materials and Dyax Know-How (collectively "Dyax Property"). Unless otherwise terminated, the agreement is for a term of four years. The agreement includes the world-wide, non-exclusive, royalty-free, non-transferable licenses to be used in the research field, without the right to sublicense. Additionally, we have the option to obtain a sublicense for use in the commercial field if any research target is obtained. We were required to pay Dyax $600,000 upon entering into the agreement and $300,000 annually to maintain the agreement. The initial payment was deferred and recorded as prepaid expense; $300,000 of which will be amortized over the term of the agreement, and $300,000 of which was amortized in a manner consistent with that of the annual payments. All subsequent annual payments will be and have been recorded as prepaid expense and amortized over the applicable term of one year.

On September 13, 2012 we entered into a separate license agreement with Dyax whereby we obtained from Dyax the exclusive, worldwide license to use research, develop, manufacture and commercialize DX-2400 in exchange for payment of $500,000. All payments associated with this agreement were recorded as research and development expense at the time the agreement was executed.

The DX-2400 license requires us to make additional payments contingent on the achievement of certain development milestones (such as receiving certain regulatory approvals and commencing certain clinical trials) and sales targets. None of these targets have been achieved and, as such, no assets or liabilities associated with the milestones have been recorded in the accompanying consolidated financial statements for the year ended December 31, 2016. The DX-2400 license also includes royalty payments commencing on the first commercial sale of any licensed product, which had not occurred as of December 31, 2016 and 2015.

Chiromics, LLC

In November 2011, we entered into a non-exclusive license and compound library sale agreement with Chiromics, LLC (Chiromics) under which Chiromics granted to us a non-exclusive, royalty-free license to use certain compound libraries and related know-how for the research, discovery and development of biological and/or pharmaceutical products. No patents were licensed to us under this agreement. The Chiromics library is a collection of more than one million compounds used as a discovery platform. The library was invented using a pioneering technology, which allows access to diverse molecules previously unattainable with traditional synthetic methods. The molecular leads in the library are novel and have complex drug-like properties enabling the identification of biologically active molecular scaffolds.

We paid Chiromics $200,000 upon execution of the agreement and a total of $300,000 upon the delivery of the compound libraries. We were also required to make quarterly payments of $200,000 for the eight quarters following delivery of the compound libraries. The agreement with Chiromics has no expiration date. Either party may terminate the agreement for

any material breach by the other party that is not cured within a specified time period or upon the bankruptcy or insolvency of the other party.

VIVUS, Inc.

In June 2015, we entered into a co-promotion agreement with VIVUS, Inc. for the co-promotion of Qsymia, a treatment for chronic weight management in obese and overweight adults. In November 2016, we notified Vivus that we will not renew this agreement and therefore the agreement terminated on December 31, 2016. No meaningful revenue was generated from this agreement as of December 31, 2016 and 2015.

MeiraGTx Limited

In April 2015, we executed several agreements which transferred our ownership of Kadmon Gene Therapy, LLC to MeiraGTx Limited ("MeiraGTx"), a then wholly-owned subsidiary of Kadmon. As part of these agreements, we also transferred various property rights, employees and management tied to the intellectual property and contracts identified in the agreements to MeiraGTx. At a later date, MeiraGTx ratified its shareholder agreement and accepted the pending equity subscription agreements, which provided equity ownership to various parties. The execution of these agreements resulted in a 48% ownership in MeiraGTx by us. After MeiraGTx was deconsolidated or derecognized, the retained ownership interest was initially recognized at fair value and a gain of $24.0 million was recorded based on the fair value of this equity investment. Our investment is being accounted for under the equity method at zero cost with an estimated fair value at the time of the transaction of $24.0 million. This value was determined based upon the implied value established by the cash raised by MeiraGTx in exchange for equity interests by third parties.

We assessed the applicability of ASC 810 to the aforementioned agreements and based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, determined that MeiraGTx is a variable interest entity, however consolidation is not required as we are not the primary beneficiary based upon the voting and managerial structure of the entity.

MeiraGTx, a limited company organized under the laws of England and Wales, was established to focus on the development of novel gene therapy treatments for a range of inherited and acquired disorders. MeiraGTx is developing therapies for ocular diseases, including rare inherited blindness, as well as xerostomia following radiation treatment for head and neck cancer. MeiraGTx is also developing an innovative gene regulation platform that has the potential to expand the way that gene therapy can be applied, creating a new paradigm for biologic therapeutics in the biopharmaceutical industry.

As part of a transition services agreement with MeiraGTx, we recognized $1.0 million of service revenue to license and other revenue during each of the years ended December 31, 2016 and 2015. During April 2016, we received 230,000 shares of MeiraGTx's convertible preferred Class C shares as a settlement for $1.2 million in receivables from MeiraGTx. Under ASC 323, the Class C shares of MeiraGTx do not qualify as common stock or in-substance common stock and the $1.2 million was recorded as a cost method investment. We also received cash payments of $0.2 million for service revenue earned during 2016.

We assessed the recoverability of both the cost method and equity method investment in MeiraGTx at December 31, 2016 and 2015 and identified no events or changes in circumstances that may have a significant adverse impact on the fair value of this investment. For the years ended December 31, 2016 and 2015, we recorded our share of MeiraGTx's net loss of $13.6 million and $2.8 million, respectively, inclusive of adjustments related to MeiraGTx's 2015 financial statements that resulted in us recording a loss on equity method investment of $3.9 million for the year ended December 31, 2016. We maintain a 38.7% ownership in MeiraGTx at December 31, 2016. Our maximum exposure associated with MeiraGTx is limited to our initial investment of $24.0 million.

AbbVie Inc.

In June 2013, we entered into a series of agreements with AbbVie Inc. (AbbVie) related to our ribavirin product. Pursuant to an asset purchase agreement, as amended, we sold marketing authorizations and related assets for ribavirin in certain countries outside the United States for a cash purchase price of $20.0 million, and we subsequently received an additional cash payment of $19.0 million as consideration for certain future regulatory approvals and clinical milestones. Pursuant to a license agreement, as amended, we licensed certain rights to develop, manufacture and market our proprietary, high-dose formulation of ribavirin in the United States for an upfront cash payment of $49.0 million, and we subsequently received a cash payment of $1 million as consideration for the achievement of a certain milestone. Pursuant to a supply agreement, as amended, we agreed to supply AbbVie with ribavirin tablets. Under the license agreement and asset purchase agreement, each as amended, we received aggregate upfront payments totaling $69.0 million. Under the asset purchase agreement, as amended, AbbVie is required to pay royalty payments equal to a low single-digit percentage of annual net sales of the compound. Under the license agreement, as amended, for calendar year 2016, AbbVie paid us a royalty based on the

number of prescriptions dispensed by AbbVie. Under the license agreement, in the event that AbbVie commercialized a product co-packaged with ribavirin in the United States, beginning in 2017, AbbVie would be required to pay royalty payments equal to a high double digit percentage of the reference selling point of ribavirin with respect to such co-packaged product. There are no royalty payments under the supply agreement. The license agreement, as amended, will remain in effect unless it is terminated pursuant to the terms of the agreement. AbbVie may terminate the license agreement, as amended, at any time upon prior written notice. There were no patents licensed to us in this series of agreements.

Zydus Pharmaceuticals USA, Inc.

In June 2008, we entered into an asset purchase agreement with Zydus Pharmaceuticals USA, Inc. (Zydus) where we purchased all of Zydus' rights, title and interest to high dosages of ribavirin. Under the terms of the agreement, we made paid a one-time purchase price of $1.1 million. We are required to pay a royalty based on net sales of products in the mid-teen percents, subject to specified reductions and offsets. No patents were licensed to us under this agreement. In April 2013, we entered into an amendment to the asset purchase agreement with Zydus which reduced the royalty payable on net sales of products from the low twenty percents to the mid-teen percents.

In June 2008, we also entered into a non-exclusive patent license agreement with Zydus, under which we granted Zydus a non-exclusive, royalty free, fully paid up, non-transferable license under certain of our patent rights related to ribavirin. This agreement will expire upon the expiration or termination of a specific licensed patent. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period or upon the bankruptcy or insolvency of the other party.

We recorded royalty expenses of $1.2 million, $2.7 million and $6.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Jinghua Pharmaceutical Group Co., Ltd.

In November 2015, we entered into a collaboration and license agreement with Jinghua. Under this agreement, we granted to Jinghua an exclusive, royalty-bearing, sublicensable license under certain of our intellectual property and know-how to use, develop, manufacture, and commercialize certain monoclonal antibodies in China, Hong Kong, Macau and Taiwan.

In partial consideration for the rights granted to Jinghua under the agreement, we received an upfront payment of $10.0 million in the form of an investment in our Class E redeemable convertible membership units. We are eligible to receive from Jinghua a royalty equal to a low double-digit percentage of net sales of product in the territory. In addition to such payments, we are eligible to receive milestone payments for the achievement of certain development milestones, totaling up to $40.0 million. We earned a $2.0 million milestone payment in March 2016, which was recorded as license and other revenue during the year ended December 31, 2016. No revenue was recognized for the years ended December 31, 2015 and 2014. We earned another $2.0 million milestone payment in January 2017, which was received in February 2017 and will be recorded as license and other revenue. We are also eligible to receive a portion of sublicensing revenue from Jinghua ranging from a percentage in the low double-digits to the low thirties based on the development stage of a product.

Our agreement with Jinghua will continue on a product-by-product and country-by-country basis until the later of 10 years after the first commercial sale of the product in such country or the date on which there is no longer a valid claim covering the licensed antibody contained in the product in such country. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period or upon the bankruptcy or insolvency of the other party. No patents were licensed to us under this agreement.

Camber Pharmaceuticals, Inc.

Tetrabenazine

In February 2016, we entered into a supply and distribution agreement with Camber Pharmaceuticals, Inc. (Camber) for the purposes of marketing, selling and distributing tetrabenazine, a medicine that is used to treat the involuntary movements (chorea) of Huntington's disease. The initial term of the agreement is twelve months. Under the agreement, we will obtain commercial supplies of tetrabenazine and will distribute tetrabenazine through our existing sales force and commercial network. We will pay Camber a contracted price for supply of tetrabenazine and will retain 100% of the revenue generated from the sale of tetrabenazine. We recognized revenue of $0.6 million during the year ended December 31, 2016. No revenue was generated from sales of tetrabenazine in 2015 and 2014.

Valganciclovir

In May 2016, we amended our agreement with Camber to include the marketing, selling and distributing of valganciclovir, a medicine that is used for the treatment of CMV retinitis, a viral inflammation of the retina of the eye, in

patients with acquired immunodeficiency syndrome (AIDS) and for the prevention of CMV disease, a common viral infection complicating solid organ transplants, in kidney, heart and kidney pancreas transplant patients. We will pay Camber a contracted price for supply of valganciclovir and will retain 100% of the revenue generated from the sale of valganciclovir. We recognized revenue of $0.9 million during the year ended December 31, 2016. No revenue was generated from sales of valganciclovir in 2015 and 2014.

Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine.

In August 2016, we amended our agreement with Camber to include the marketing, selling and distributing of Abacavir tablets, USP, a medicine that is used in combination with other antiretroviral agents for the treatment of HIV-1 infection; Entecavir, a medicine that is used for the treatment of chronic HBV infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease; Lamivudine tablets, a nucleoside analogue medicine used in combination with other antiretroviral agents for the treatment of HIV-1 infection; Lamivudine tablets (HBV), a medicine that is used for the treatment of chronic HBV infection associated with evidence of hepatitis B viral replication and active liver inflammation; and Lamivudine and Zidovudine tablets, USP, a combination of two nucleoside analogue medicines, used in combination with other antiretrovirals for the treatment of HIV-1 infection. We will pay Camber a contracted price for supply of these products and will retain 100% of the revenue generated from the sale of these products. No meaningful revenue was generated from sales of these products for the year ended December 31, 2016, 2015 and 2014.

In February 2017, we entered into a third amendment to the supply and distribution agreement with Camber extending the initial term of the agreement by an additional twelve months.

Our Intellectual Property

The proprietary nature of, and protection for, our product candidates, their methods of use, and our technologies are an important part of our strategy to discover and develop small molecules and biologics that address areas of significant unmet medical needs in autoimmune, fibrotic and neurodegenerative diseases, oncology, genetic diseases, and in the area of immuno-oncology. We are the owner or exclusive licensee of patents and applications relating to certain of our product candidates, and are pursuing additional patent protection for them and for our other product candidates and technologies. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Additionally, we maintain copyrights and trademarks, both registered and unregistered.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important products, product candidates, technologies, inventions and know-how related to our business and our ability to defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our development programs. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants, advisors and partners to enter into confidentiality agreements and other arrangements upon the commencement of their employment or engagement. The chart below identifies which of our product candidates are covered by patents and patent applications that we own or license, the relevant expiration periods and the major jurisdictions. Additional patent applications have been filed to extend the patent life on some of these products, but there can be no assurance that these will issue as filed.

Product Candidate	Description/ Indications	US Patent Numbers	Patent Expiration(0)	Patent Type	Major Jurisdictions	Claim Type
KD014	Monoclonal Antibody/Bone Growth	7,745,587	2026+	Utility	AU, CA, EP, US	Composition of Matter/ Method of Use
Tesevatinib	Multi-kinase Inhibitor/Oncology	7,576,074 8,658,654	2026+	Utility	AU, CA, EP, JP, US	Composition of Matter/ Method of Use
Tesevatinib	Multi-kinase Inhibitor/Polycystic Kidney Disease	Pending	2031*	Utility	CA, CN, EA, EP, TW, US	Composition of Matter/ Method of Use
KD025	ROCK2 Inhibitor/Psoriasis, Fibrosis	8,357,693 8,916,576	2029+	Utility	CA, CN, EA, EP, JP, US	Composition of Matter/ Method of Use
KD033	Monoclonal Antibody, Immunoconjugate/Oncology	Pending	2035*	Utility	CN, TBD	Composition of Matter/ Method of Use
KD034	Chelating Agent/Wilson's Disease	Pending	2036*	Provisional	US, TBD	Formulation
KD035	VEGFR2 Monoclonal Antibody/Oncology, Angiogenesis	Pending	2033*	Utility	CN, EA, EP, JP, US	Composition of Matter/ Method of Use
Ribavirin	Nucleoside Inhibitor/Hepatitis	6,720,000 7,538,094 7,723,310	2028+	Utility	US	Composition of Matter
Metabolic Inhibitors	Metabolic Inhibitors/Viral Infection	9,029,413	2028*	Utility	CA, EP, JP, US	Method of Use
GLUT Inhibitors	Glucose Uptake Inhibitors/Immunological and Infectious Diseases	Pending	2036*	Provisional	US, TBD	Method of Use
PDGFRβ Antibody	Monoclonal Antibody/Oncology	Pending	2037*	Provisional	US, TBD	Composition of Matter/ Method of Use
PD-L1/VEGFR Antibody	Bispecific Antibody/Oncology	Pending	2037*	Provisional	US, TBD	Composition of Matter/ Method of Use

(0) Indicates the expiration date of a main patent within a patent family.

\+ Indicates the expiration date of a granted patent for which a Patent Term Adjustment (PTA) has been fixed by the United States Patent and Trademark Office. The date may be lengthened by a Patent Term Extension (PTE) upon regulatory approval.

* Indicates the calculated expiration date of a pending patent application based solely on a twenty-year term from the international filing date, without regard to the outcome of patent prosecution or obtaining a PTA and/or PTE.

Manufacturing and Supply

We currently do not own or operate manufacturing facilities for the production of our product candidates. We currently outsource to a limited number of external service providers the production of all active pharmaceutical ingredients (API), drug substances and drug products, and we expect to continue to do so to meet the preclinical and clinical requirements of our product candidates. We do not have long-term agreements with these third parties. We have framework agreements with most of our external service providers, under which they generally provide services to us on a short-term, project-by-project basis. We have long-term relationships with our manufacturing and supply chain partners for our commercial products.

Currently, our drug substance or API raw materials for our product candidates can be supplied by multiple source suppliers. Our API drug raw material for our ribavirin portfolio of products is approved to be supplied by a single source, which we believe has the capacity and quality control to meet ongoing demands. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. The contract manufacturing organizations that we use to manufacture our product candidates and our ribavirin portfolio are obligated to operate under current Good Manufacturing Practice regulations (cGMP) conditions.

Competition

We compete directly with companies that focus on psoriasis, IPF, cGVHD, NSCLC with brain metastases and/or leptomeningeal metastases and PKD, and companies dedicating their resources to novel forms of therapies for these indications. We also face competition from academic research institutions, governmental agencies and other various public and private research institutions. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Branded and generic therapies in our commercial operation, particularly RibaPak and Ribasphere, face significant direct competition from other generic high-dose ribavirin offerings, as well as competition from lower dose and lower cost generic versions of ribavirin. Additionally, the chronic HCV treatment landscape has significantly changed as multiple new therapies have entered, such as Viekira Pak (AbbVie), Epclusa (Gilead Sciences, Inc.), Harvoni (Gilead Sciences, Inc.), Olysio (Janssen Pharmaceuticals, Inc.) and Zepatier (Merck & Co.), and will continue to enter the market that (either now or in the future) may not require the use of ribavirin as part of the treatment protocol.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe effects than any products that we may develop. Our competitors also may obtain FDA, European Medicines Agency (EMA) or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

There are a number of currently marketed therapies and products in late-stage clinical development to treat psoriasis, IPF, cGVHD, NSCLC with brain metastases and/or leptomeningeal metastases and PKD, including:

Psoriasis	IPF	cGVHD	NSCLC with Brain Metastases and/or Leptomeningeal Metastases	PKD
• Systemic treatments • Soriatane (acitretin) • Cyclosporine • Methotrexate • Otezla (apremilast) • Biologics • Taltz (ixekizumab) • Enbrel (etanercept) • Humira (adalimumab) • Cosentyx (secukinumab) • Remicade (infliximab)	• Esbriet (pirfenidone) • Ofev (nintedanib)	• Corticosteroids • Calcineurin inhibitors	While there are no approved treatments in the United States for these indications, we understand that there are certain off-label uses for Tarceva (erlotinib) and Avastin (bevacizumab).	While there are no approved treatments in the United States for this indication, we understand that there are certain off-label uses for tolvaptan.

Certain products in development may provide efficacy, safety, dosing convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval.

Government Regulation

Government Regulation and Product Approval

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture (including manufacturing changes), quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA), and in the case of biologics, also the Public Health Service Act (PHS Act), and various implementing regulations. Most biological products meet the FDCA's definition of "drug" and are subject to FDA drug requirements, supplemented by biologics requirements.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies according to "good clinical practices" (GCP) regulations, to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- preparation and submission to the FDA of an NDA or Biologics License Application (BLA);
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP 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.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical or biological product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. When a sponsor wants to proceed to test the product candidate in humans, it must submit an IND in order to conduct clinical trials.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing

before their participation in any clinical study. Further, an institutional review board (IRB) must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH), for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.

- *Phase 2.* Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, or a BLA for a biological drug product, requesting approval to market the product.

The submission of an NDA or BLA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees. For FDA fiscal year 2016 the application fee for an application with clinical data was $2,374,200. Sponsors are also subject to the product and establishment fees. For fiscal 2016, the product fee was $114,450, and the establishment fee was $585,200.

In addition, under the Pediatric Research Equity Act of 2003 (PREA), an NDA or BLA applications (or supplements to applications) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data that are adequate to assess the safety and effectiveness of the drug 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, unless the applicant has obtained a waiver or deferral.

In 2012, the FDASIA amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP), within sixty days of an End-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies, and/or other clinical development programs.

The FDA also may require submission of a REMS to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is 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 reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. For biologics, the applicant must demonstrate that the product is safe, pure, and potent (interpreted to include effectiveness), and that the facilities designed for its production meet standards to ensure the product will consistently be safe, pure, and potent.

The FDA may approve an NDA or BLA only if the methods used in, and the facilities and controls used for, the manufacture processing, packing, and testing of the product are adequate to ensure and preserve its identity, strength, quality, and purity. Drug cGMPs are established in 21 C.F.R. Parts 210 and 211, and biologic drug products must meet the drug standards as well as the supplemental requirements in 21 C.F.R. Part 600 et seq.

Before approving an NDA or BLA, the FDA often will inspect the facility or facilities where the product is or will be manufactured.

The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to ensure that clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied, or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter, or, in some cases, a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

ANDAs and Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or BLA (described above) for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. For some drugs (e.g., locally acting drugs like topical anti-fungals), other means of demonstrating bioequivalence may be required by the FDA, especially where rate and/or extent of absorption are difficult or impossible to measure. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

The third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below. Thus approval of a Section 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a

Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant.

Expedited Programs

Fast Track Designation

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs (including biological drug products) are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request.

The FDA may initiate review of sections of a Fast Track drug's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of each portion of the NDA or BLA and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the application is submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical study process.

Accelerated Approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that fills an unmet medical need, providing a meaningful therapeutic benefit to patients over existing treatments, based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical studies, a surrogate endpoint is a marker, such as a measurement of laboratory or clinical signs of a disease or condition that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical studies sometimes referred to as Phase 4 studies to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated approval regulations are subject to prior review by the FDA.

Breakthrough Designation

The Food and Drug Administration Safety and Innovation Act (FDASIA), amended the FDCA to require the FDA to expedite the development and review of a breakthrough therapy. A drug or biologic product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug or biologic product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical studies is as efficient as practicable.

Priority Review

Priority review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after the FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Post-Approval Requirements

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations, and other problems 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. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

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 the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. 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.

The FDA may withdraw a product approval if compliance with regulatory requirements 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, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required 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 REMS 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;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

In addition, the distribution of prescription drugs and biologics is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of the products and product samples at the federal level, and sets minimum standards

for the registration and regulation of distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidances and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term effectively lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA/BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension. Extensions are not granted as a matter of right and the extension must be applied for prior to expiration of the patent and within a 60-day period from the date the product is first approved for commercial marketing. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for Patent Term Extensions, defined as the length of the regulatory review of products covered by our granted patents, for some of our currently owned or licensed applications and patents to add patent life beyond their current expiration dates. Such extensions will depend on the length of the regulatory review; however, there can be no assurance that any such extension will be granted to us.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The specific scope varies, but fundamentally the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving applications for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to the term of any existing regulatory exclusivity, including the non-patent exclusivity periods described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric clinical study in accordance with an FDA-issued "Written Request" for such a clinical study.

With respect to biologics, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (collectively, the PPACA) signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated licensure pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, only one biosimilar has been licensed under the BPCIA in the United States (in September 2015), with many more well into the process for approval. Numerous biosimilars have already been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars, although there has been significant litigation and questions over interpretation of such guidelines.

Biosimilarity, which requires that the product be "highly similar" and there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the

reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA is subject to significant uncertainty.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs (including biological drug products) intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA or BLA.

After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first applicant to receive FDA approval for a particular active ingredient to treat a particular disease or condition with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA/BLA application user fee.

During the exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease or condition, except in limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product to the product with orphan drug exclusivity through a demonstration of superior safety, superior efficacy, or a major contribution to patient care, or if the manufacturer of the product with orphan exclusivity is not able to assure sufficient quantities of the product. "Same drug" means a drug that contains the same identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules and is intended for the same use as a previously approved drug, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug. Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, sales of Ribasphere RibaPak and any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. The process for determining whether a payor will provide coverage for a biologic or drug may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific biologics and drugs on an approved list, or formulary, which might not include all of the FDA-approved biologics or drugs for a particular indication, or place biologics and drugs at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an

appropriate return on our investment in product development. Further, one payor's determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement may differ significantly from payor to payor.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs and product candidates from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

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 following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities including pharmaceutical manufacturers from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, waivers of payment, ownership interest and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular applicable statutory exception or safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

- The False Claims Act, which imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an

obligation to pay money to the federal government. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or (as noted above) paying a kickback that results in a claim for items or services). In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, federal anti-kickback statute violations and certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, (as further adjusted to account for inflation), the potential for exclusion from participation in federal healthcare programs, and, although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

- The Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires applicable pharmaceutical manufacturers of covered drugs to engage in extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program (with certain exceptions) must report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members. Pharmaceutical manufacturers were required to begin such tracking on August 1, 2013, and to make their first report to the Centers for Medicare & Medicaid Services (CMS) by March 31, 2014 and annually thereafter. CMS posts manufacturer disclosures on a searchable public website. Failure to comply with the reporting obligations may result in civil monetary penalties.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information and the use of prescriber-identifiable data in certain circumstances, many of which

differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts 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.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. By way of example, in March 2010, the PPACA as amended was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP, establishing new methodologies by which AMP is calculated and rebates owed by manufacturers under the Medicaid Drug Rebate Program are collected for drugs that are inhaled, infused, instilled, implanted or injected, adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, expanding the universe of Medicaid utilization subject to drug rebates to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations and expanding the population potentially eligible for Medicaid drug benefits.

- In order for a pharmaceutical 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 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Recent proposed guidance from the U.S. Department of Health and Human Services Health Resources and Services Administration, if adopted in its current form, may affect manufacturers' rights and liabilities in conducting audits and resolving disputes under the 340B program.

- Effective in 2011, the PPACA imposed a requirement on manufacturers of branded drugs to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the donut hole).

- Effective in 2011, the PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

- The PPACA required pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers were required to begin tracking this information in 2013 and to report this information to CMS beginning in 2014. The reported information was made publicly available in a searchable format on a CMS website beginning in September 2014.

- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products by influencing decisions relating to coverage and reimbursement rates.

- The PPACA created the Independent Payment Advisory Board (IPAB), which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. The PPACA provided that under certain circumstances, IPAB's recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.

- The PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

- The PPACA established a licensure framework for follow-on biologic products.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from our products and product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Foreign Regulation of Drugs and Biologics

In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding development, approval, commercial sales and distribution of our products, and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products, if approved. Whether or not we obtain FDA approval for a product, we must 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 between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Employees

As of December 31, 2016, we employed 118 people, including 67 in research and development, 18 in commercial operations and 33 in a general and administrative capacity, including executive officers. We also engage a number of temporary employees and consultants. None of our employees is represented by a labor union with respect to his or her employment with us. We have not experienced any work stoppages, and we consider our relations with our employees to be good.

Facilities

Our corporate headquarters are located in New York, New York, and consist of approximately 48,892 square feet of space under a lease that expires in October, 2024. In addition, we also have locations in Warrendale, Pennsylvania; Cambridge,

Massachusetts and Monmouth Junction, New Jersey. We believe that our facilities are adequate for our current needs and for the foreseeable future.

Corporate Information

We were established in September 2010 as a Delaware limited liability company under the name Kadmon Holdings, LLC. In July 2016, we converted to a Delaware corporation pursuant to a statutory conversion and changed our name to Kadmon Holdings, Inc. We completed our IPO in August 2016. Our common stock is currently listed on The New York Stock Exchange under the symbol “KDMN.” We are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, and therefore we are subject to reduced public company reporting requirements. Our principal executive offices are located at 450 East 29th Street, New York, New York 10016, and our telephone number is (212) 308-6000. Our website address is www.kadmon.com. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the U.S. Securities and Exchange Commission (SEC).

Available Information

We make available on or through our website certain reports and amendments to those reports that we file with, or furnish to, the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. Our website address is www.kadmon.com. Copies of this information may be obtained at the SEC’s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Financial Position

We have incurred substantial losses since our inception, anticipate that we will continue to incur losses for the foreseeable future and may not achieve or sustain profitability. We expect to continue to incur significant expenses related to the development of our clinical product candidates for at least the next several years, and we anticipate that our expenses will increase substantially as a result of multiple initiatives.

Since inception, we have incurred substantial operating losses. Our consolidated net loss was $208.8 million, $147.1 million and 64.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our accumulated deficit was $155.7 million and $643.8 million at December 31, 2016 and 2015, respectively.

To date, we have financed our clinical development operations primarily through issuance of common stock in our IPO, a private placement of our common stock and warrants to purchase common stock, private placements of our membership units, debt financing and, to a lesser extent, through equipment lease financings. We expect to continue to incur significant expenses related to the development of our clinical product candidates for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue our clinical trials related to our most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates;
- incur expenses associated with operating as a public company;
- scale up our sales, marketing and distribution infrastructure and product sourcing capabilities to commercialize additional products we may acquire or license from others or for which we may develop and obtain regulatory approval; and/or
- scale up our operational, financial and management information systems and personnel, including personnel to support our product development and planned additional commercialization efforts.

In the absence of substantial revenue from the sale of products in our ribavirin portfolio, tetrabenazine, valganciclovir, Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine, which we distribute with Camber, or from other sources (the amount, timing, nature or source of which cannot be predicted), we expect our substantial losses to continue and we may need to discontinue operations. Our ability to generate sufficient revenues from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flow is uncertain. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

Our level of indebtedness could adversely affect our business and limit our ability to plan for, or respond to, changes in our business.

Since our inception, we have incurred substantial indebtedness in order to fund acquisitions, research and development activities and the operations of our commercial pharmaceutical business. At December 31, 2016, we had approximately $34.6 million outstanding under our senior secured non-convertible term loan (the 2015 Credit Agreement), which has a maturity date of June 17, 2018. We also had approximately $0.2 million of other funded debt. In addition, we have incurred recurring losses from operations and have an accumulated deficit of $155.7 million at December 31, 2016.

Our level of indebtedness could adversely affect our business by, among other things:

- requiring us to dedicate a substantial portion of our cash from operations and from financings to payments on our indebtedness, thereby reducing the availability of our cash for other purposes, including research and development, investment in our commercial operations and business development efforts;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a disadvantage to our competitors that may have less debt;
- limiting our flexibility in consolidating our corporate operations due to certain covenants that require us to maintain minimum liquidity in our business; and/or
- increasing our vulnerability to adverse economic and industry conditions.

We may not be able to generate sufficient cash to pay our indebtedness, and we may be forced to take other actions to satisfy our payment obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on, or to refinance, our debt obligations depends on our future performance, which will be affected by financial, business and economic conditions and other factors. We will not be able to control many of these factors, such as economic conditions in the industry in which we operate and competitive pressures. Our cash flow and cash on hand may not be sufficient to allow us to pay principal and interest on our debt and to meet our other obligations. If our cash flow and other capital resources are insufficient to timely fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, or to sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. In addition, the terms of existing or future debt agreements may restrict our ability to pursue any of these alternatives.

Our 2015 Credit Agreement matures on June 17, 2018. We may not be able to comply with the covenants under the 2015 Credit Agreement or refinance our debt under this facility before the maturity date, in which event our ability to continue our operations would be materially and adversely impacted.

Our 2015 Credit Agreement matures on June 17, 2018. Pursuant to a second amendment to the 2015 Credit Agreement that we entered into in November 2016, we are required to satisfy certain clinical development milestones, as well as to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. A failure to comply with these covenants is an event of default, which, if not cured or waived, could result in the acceleration of the debt under our 2015 Credit Agreement. No assurances can be given that we will be able to comply with these covenants or that we will be able to refinance this debt on or before the maturity date. Subsequent debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to comply with our covenants under these facilities, refinance our debt under these facilities or negotiate an extension of such facilities prior to their maturity dates, the lenders thereunder may accelerate our indebtedness and exercise the remedies available to them as secured creditors, including foreclosure on our tangible and intangible property that we have pledged as security. In that event, our ability to continue our operations may be materially and adversely impacted. If we raise additional funds through marketing and distribution arrangements or collaborations, strategic alliances or licensing arrangements with third parties, we may be required to pledge certain assets, grant licenses on terms that may not be favorable to us or relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We will need additional funding in the future, which may not be available to us, and this may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development and commercialization of our marketed products, including costs associated with:

- clinical trials for our product candidates;
- discovery of additional product candidates;
- life-cycle management of our marketed products;
- the continued commercialization of our commercial products; and/or

- preparing for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of that (those) product(s).

We do not expect that the net proceeds from our IPO, the $22.7 million of gross proceeds raised in March 2017 and our existing cash, cash equivalents and restricted cash will be sufficient to enable us to fund the completion of development and commercialization of any of our product candidates. We do not have any additional committed external source of funds. Additionally, our revenues may fall short of our projections or be delayed, or our expenses may increase, which could result in our capital being consumed significantly faster than anticipated. Our expenses may increase for many reasons, including:

- clinical trial-related expenses for our product candidates;
- the potential launch and marketing of our late-stage product candidates; and/or
- manufacturing scale-up for commercialization of our late-stage product candidates.

To the extent that we need to raise additional capital through the sale of equity or convertible debt securities, investors in our common stock will be diluted, and the terms of any newly issued securities may include liquidation or other preferences that adversely affect the value of our common stock.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern.

Based on our recurring losses from operations, the deficiency in stockholders' capital and a contractual obligation to raise $40.0 million of additional equity capital by the end of the second quarter of 2017 pursuant to the second amendment to the 2015 Credit Agreement we entered into in November 2016, our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2016 expressing substantial doubt about our ability to continue as a going concern. We expect to incur further losses over the next several years as we develop our business, and we will require significant additional funding to continue operations. If we are unable to continue as a going concern, we may be unable to meet our debt obligations, which could result in an acceleration of our obligation to repay such amounts, and we may be forced to liquidate our assets. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We are party to certain litigation, which could adversely affect our business, results of operations and financial condition.

We are party to various litigation claims and legal proceedings. We believe that the plaintiff's claims in each of the litigations in which we are currently involved have no merit and intend to vigorously defend each action. However, litigation is inherently uncertain, and any adverse outcome(s) could negatively affect our business, results of operations and financial condition. In addition, litigation can involve significant management time and attention and be expensive, regardless of outcome. During the course of litigation, there may be announcements of the results of hearings and motions and other interim developments related to the litigation. If securities analysts or investors regard these announcements as negative, the trading price of our shares of common stock may decline. In addition, we evaluate these litigation claims and legal proceedings to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, we establish reserves or disclose the relevant litigation claims or legal proceedings, as appropriate. These assessments and estimates are based on the information available to management at the time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from our current assessments and estimates. See Note 17, "Contingencies" of the notes to our audited consolidated financial statements included in this Annual Report on Form 10-K for more information.

Our ability to utilize our net operating loss carry-forwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and may never achieve profitability. To the extent that we continue to generate losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, 2016, we had unused federal and state net operating loss ("NOL") carry-forwards of approximately $432.8 million and $362.9 million, respectively, that may be applied against future taxable income. At December 31, 2016, we have fully reserved the deferred tax asset related to our NOL carry-forwards as reflected in our audited consolidated financial statements. These carry-forwards expire at various dates through December 31, 2036. Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership by one or more 5-percent stockholders (or certain groups of non-5-percent stockholders) over a three-year period), the corporation's ability to use its pre-change NOL carry-forwards and other pre-change tax attributes to offset its post-change income would be limited. We experienced ownership changes under Section 382 of the Code in 2010, 2011 and 2016, which may limit our ability to utilize NOL carry-forwards. We did not reduce the gross deferred tax assets related to the NOL carry-forwards, however, because the limitations do not hinder our ability to potentially utilize all of the NOL carry-forwards. We may experience ownership changes in the future as a result of future shifts in our stock ownership. As a result, if we earn net

taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us.

Risks Related to Our Clinical Development Pipeline

Clinical development is a lengthy and expensive process with a potentially uncertain outcome. Our long-term success depends upon the successful development and commercialization of our product candidates. To obtain regulatory approval to market our products, preclinical studies and costly and lengthy clinical trials are required. The conduct of preclinical studies and clinical trials is subject to numerous risks and results of the studies and trials are highly uncertain.

We currently have no internally clinically-developed products approved for sale and we cannot guarantee that we will ever develop such products. To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our long-term success depends upon the successful development, regulatory approval and commercialization of these product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased. Two of our product candidates, KD025 and tesevatinib, are in clinical trials and we have additional product candidates in preclinical development. Our business depends significantly on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase 3) be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves drugs or biologics on the basis of a single well-controlled clinical trial establishing effectiveness. However, if the FDA or the EMA determines that our Phase 3 clinical trial results do not demonstrate a statistically significant, clinically meaningful benefit with an acceptable safety profile, or if the FDA or EMA requires us to conduct additional Phase 3 clinical trials in order to gain approval, we will incur significant additional development costs and commercialization of these products would be prevented or delayed and our business would be adversely affected.

Our ongoing clinical trials may be subject to delays or setbacks for a variety of common and unpredictable reasons.

We may experience unforeseen delays or setbacks in our ongoing clinical trials, such as trial initiation timing, trial redesign or amendments, timing and availability of patient enrollment or successful trial completion. Such delays and setbacks are common and unpredictable in pharmaceutical drug development. Clinical trials can be delayed for a variety of reasons, including delays related to:

- regulatory objections to commencing a clinical trial, continuing a clinical trial that is underway, or proceeding to the next phase of investigation, including inability to reach agreement with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials or for other reasons such as safety concerns that might be identified through preclinical testing and animal studies or clinical trials, at any stage;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites (the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites);
- failure of CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- difficulty identifying and engaging qualified clinical investigators;
- obtaining IRB approval at each site;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as product candidates we seek to commercialize;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;

- inability to retain patients in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy, particularly for those patients receiving a placebo;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- adding new clinical trial sites;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- changes in applicable regulatory policies and regulations;
- insufficient data to support regulatory approval;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- manufacturing sufficient quantities of the product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including:

- failure by us, CROs or clinical investigators to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failed inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety or efficacy issues or any determination that a clinical trial presents unacceptable health risks;
- failure to demonstrate a benefit from using a drug; or
- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties, changes in governmental regulations or administrative actions, or other reasons.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If serious adverse events or other undesirable side effects are identified during the use of product candidates in investigator-sponsored trials, it may adversely affect our development of such product candidates.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of our product candidates are observed in investigator-sponsored trials, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidate at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our product candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect.

The regulatory approval processes of the FDA and similar foreign authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support a submission for regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and/or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, including KD025, tesevatinib and/or KD034, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may:

- approve any of our product candidates for fewer or more limited indications than we request;
- may not approve the price we intend to charge for our products;
- may grant approval contingent on the performance of costly post-marketing clinical trials; or
- may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we do not achieve our projected development goals in the timeframes we announce and expect, or we face significant competition from other biotechnology and pharmaceutical companies, the commercialization of our products may be delayed, our operating results may be lower that we expect, the credibility of our management may be adversely affected and, as a result, the value of our common stock may decline.

Even if we obtain regulatory approval for our product candidates, they may never be successfully launched or become profitable, in which case our business, prospects, operating results and financial condition may be materially harmed.

In order to successfully launch our product candidates and have them become profitable, we anticipate that we will have to dedicate substantial time and resources and hire additional personnel to expand and enhance our commercial infrastructure, which will at a minimum include the following:

- ensure the quality of the product candidate manufactured by our suppliers and by us;
- expand our sales and marketing force;
- expand and enhance programs and other procedures to educate physicians and drive physician adoption of our product candidates;
- create additional policies and procedures, and hire additional personnel to carry out those policies and procedures, to ensure customer satisfaction with our products;
- obtain reimbursement for hospitals and physicians; and/or
- expand and enhance our general and administrative operations to manage our anticipated growth in operations and to support public company activities.

Because of the numerous risks and uncertainties associated with launch and profitability of our product candidates, we are unable to predict the extent of any future losses, or when we will become profitable, if ever.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is obtained, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Undesirable or unexpected side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable or unexpected side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly; and/or
- our reputation may suffer.

In addition, a regulatory agency may:

- suspend or withdraw approvals of such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us, our collaborators or our potential future collaborators;
- require additional warnings on the label;
- require that we create a medication guide outlining the risks of such side effects for distribution to patients;
- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

- require us or our collaborators to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- impose restrictions on operations, including costly new manufacturing requirements; and/or
- seize or detain products or require a product recall.

Non-compliance may also result in potential whistleblower lawsuits and the potential for liability under the False Claims Act or other laws and regulations, as discussed above. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. In addition, data obtained from tests are susceptible to varying interpretations, and regulators may not interpret data as favorably as we do, which may delay, limit or prevent regulatory approval.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Further, at various points during the course of the preclinical and clinical trial process, companies must assess both the statistical and clinical significance of trial results. In this context, “statistical significance” refers to the likelihood that a result or relationship is caused by something other than random chance or error. Statistical significance is measured by a “p-value,” which indicates the probability value that the results observed in a study were due to chance alone. A p-value of < 0.05 is generally considered statistically significant, meaning that the probability of the results occurring by chance alone is less than five percent. The lower the p-value, the less likely that the results observed were random. “Clinical significance,” on the other hand, is a qualitative assessment of the results observed. Where we use the term “clinically significant,” we have not necessarily made a formal statistical assessment of the probability that the change in patient status was attributable to the study drug as opposed to chance alone, nor does such a statement necessarily mean that study endpoints have been met or the protocol has been completed. A clinically significant effect is one that is determined to have practical importance for patients and physicians, and includes benefits that are often defined by peer-reviewed literature as having a meaningful impact on a patient’s condition. An effect that is statistically significant may or may not also be clinically significant. When a study fails to result in statistical significance, the FDA may not consider such study to serve as substantial evidence of safety and effectiveness required for approval. Even if a study results in statistical significance, the FDA may also consider clinical significance in evaluating a marketing application. For example, the FDA typically requires more than one pivotal clinical study to support approval of a new drug. However, the FDA has indicated that approval may be based on a single study in limited situations in which a trial has demonstrated a clinically significant effect. In either case, the clinical or statistical significance of a particular study result in no way guarantees that FDA or other regulators will ultimately determine that the drug being investigated is safe and effective.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 1, Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in the FDA or other agencies' approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

We may not be successful in our efforts to use and expand our drug discovery platforms to build a pipeline of product candidates.

A key element of our strategy is to leverage our drug discovery platforms to identify and develop new product candidates for additional diseases with significant unmet medical needs. Although our research and development efforts to date have contributed to the development of product candidates directed at autoimmune and fibrotic diseases, oncology and genetic diseases, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect the price of our common stock.

Biologics carry particular risks and uncertainties, which could have a negative impact on future results of operations.

Through our drug discovery platform, we are currently engaged in the development of novel highly active bi-functional proteins for immunotherapy in various indications, including oncology. The successful development, testing, manufacturing and commercialization of biologics is a long, expensive and uncertain process. There are particular risks and uncertainties with biologics, including:

- There may be limited access to and supply of normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the European Union, could result in restricted access to, or transport or use of, such materials. If we lose access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, we may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures is required for human vaccine candidates and FDA approval is required for the release of each manufactured commercial lot.

- Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

- Biologics are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

- The use of biologically derived ingredients can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

Any of these events could result in substantial costs and result in a material adverse effect on our business and results of operations.

We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our products and product candidates.

The development and commercialization of new therapeutics is highly competitive. We face competition (from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide) with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete directly with companies that focus on NSCLC with brain metastases and/or leptomeningeal metastases, PKD, psoriasis, cGVHD and IPF, and companies dedicating their resources to novel forms of therapies for these indications. We also face competition from academic research institutions, governmental agencies and other various public and private research institutions. Many of these competitors are attempting to develop therapeutics for our target indications. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are products already approved for many of the diseases we are targeting. Many of these approved products are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates. Branded and generic therapies in our commercial operation, particularly RibaPak and Ribasphere, face significant direct competition from other generic high-dose ribavirin offerings, as well as competition from lower dose and lower cost generic versions of ribavirin. Additionally, the treatment of chronic HCV infection is rapidly changing as multiple new therapies have entered, such as Viekira Pak (AbbVie), Epclusa (Gilead Sciences, Inc.), Harvoni (Gilead Sciences, Inc.), Olysio (Janssen Pharmaceuticals, Inc.) and Zepatier (Merck & Co.), and will continue to enter the market that (either now or in the future) may not require the use of ribavirin as part of the treatment protocol. There are also a number of products in late stage clinical development to treat solid tumors, in viral and immunological disorders. Our competitors may develop products that are safer, more effective, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our product candidates for which we intend to seek approval may face competition sooner than anticipated, and for biologics there is additional uncertainty as the relevant law is relatively new and there is limited precedent.

Although we plan to pursue all available FDA exclusivities for our product candidates, we may face competition sooner than anticipated. Market and data exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, running from the time of NDA approval. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the five-year exclusivity period for a new chemical entity, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, the FDA may accept an ANDA or 505(b)(2) NDA for review after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example (for new indications, dosages, strengths or dosage forms of an existing drug). This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product.

Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

The PPACA, signed into law on March 23, 2010, includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological

product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product 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.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

None of our product candidates are approved for sale in any jurisdiction, including international markets, and we have limited experience in obtaining regulatory approval in international markets. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays.

In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. As described above, such effects include the risks that:

- any current or future product candidates we may seek to develop may not generate preclinical or clinical data that are deemed sufficient by regulators in a given jurisdiction;
- product candidates may not be approved for all indications requested, or any indications at all, in a given jurisdiction which could limit the uses of any future product candidates we may seek to develop and have an adverse effect on product sales and potential royalties; or
- such approval in a given jurisdiction may be subject to limitations on the indicated uses for which the product may be marketed or require costly post-marketing follow-up studies.

Foreign regulators may have requirements for marketing authorization holders or distributors to have a legal or physical presence in that country. Consideration of and compliance with these requirements may result in additional time and

expense before we can pursue or obtain marketing authorization in foreign jurisdictions. If we do receive approval in other countries, we may enter into sales and marketing arrangements with third parties for international sales of any approved products.

The environment in which our regulatory submissions may be reviewed changes over time, which may make it more difficult to obtain regulatory approval of any of our product candidates.

The environment in which our regulatory submissions are reviewed changes over time. Average review times at the FDA for NDAs and BLAs fluctuate, and we cannot predict the review time for any submission with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of Risk Evaluation and Mitigation Strategies that may, for instance, restrict distribution of drug or biologic products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from preclinical studies and clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

In addition, data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of our product candidates. Changes in FDA personnel responsible for review of our submissions could also impact the manner in which our data are viewed. Further, regulatory attitudes toward the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information (including on other products), policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

We may seek breakthrough therapy designation by the FDA for any of our product candidates but there is no assurance that we will request or receive such designation, and, in any event, even if we do receive such designation, it may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates without the breakthrough therapy designation and, in any event, does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track, Accelerated Approval and/or Priority Review designation of some of our product candidates. There is no assurance that the FDA will grant such designations and, even if it does grant any such designation for one of our product candidates, that designation may not ultimately lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.

We may seek Fast Track, Accelerated Approval and/or Priority Review designation and review for our product candidates. We have not, at this point, had any specific discussions with the FDA about the potential for any of our product candidates to take advantage of these potential pathways. The FDA has broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for such a designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development

program. In addition, any such designation does not have any impact on the likelihood that a product candidate will ultimately be granted marketing approval in the United States.

We plan to seek orphan product designation for certain of our product candidates for certain indications, and we may be unable to obtain orphan product designation, and even if we do, we may be unable to maintain the benefits associated with orphan product designation, including the potential for marketing exclusivity. Moreover, if our competitors are able to obtain orphan product designation and the associated exclusivity for their products that are competitors with our product candidates, the applicable regulatory authority may be prohibited from approving our products for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as having a prevalence of 200,000 affected individuals in the United States or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In the European Union, EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Moreover, even if we obtain orphan designation, we may not be the first to obtain marketing approval of our product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation for our product candidates, we may never receive such designations.

Independent clinical investigators or CROs that we engage may not devote sufficient time or attention to conducting our clinical trials or may not be able to repeat their past success.

We expect to continue to depend on independent clinical investigators and may depend on CROs to conduct some of our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs, if any, will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA requires that we comply with standards, commonly referred to as cGCP for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of

clinical investigators or CROs to meet their obligations to us or comply with cGCP procedures could adversely affect the clinical development of our product candidates and harm our business.

We may not be able to attract collaborators or external funding for the development and commercialization of our product candidates.

Our product development programs and potential commercialization of our product candidates will require substantial additional capital to fund expenses. As part of our ongoing strategy, we may seek additional collaborative arrangements with pharmaceutical and biotechnology companies or other third parties or external funding for certain of our development programs and/or seek to expand existing collaborations to cover additional commercialization and/or development activities. We have a number of research programs and early-stage clinical development programs. At any time, we may determine that in order to continue development of a product candidate or program or successfully commercialize a drug we need to identify a collaborator or amend or expand an existing collaboration. Potentially, and depending on the circumstances, we may desire that a collaborator either agree to fund portions of a drug development program led by us, or agree to provide all the funding and directly lead the development and commercialization of a program. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing collaboration agreements from entering into agreements on certain terms with other potential collaborators. No assurance can be given that any efforts we make to seek additional collaborative arrangements will be successfully completed on acceptable terms, a timely basis or at all.

If we are unable to negotiate favorable collaborations, we may have to curtail the development of a particular product candidate, reduce or delay its development program and its potential commercialization, reduce the scope of our sales or marketing activities, and/or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

Risks Related to Our Marketed Products and Product Candidates

Our current and, in part, our future revenue depends on our ribavirin marketed product portfolio and near-term line extensions.

Our current and, in part, our future revenue depends upon continued sales of our ribavirin portfolio of products, which has represented a substantial portion of our total revenues to date. Additionally, we distribute tetrabenazine for chorea, an involuntary movement disorder associated with Huntington’s disease. We also distribute valganciclovir for the treatment of CMV retinitis, a viral inflammation of the retina of the eye, in patients with AIDS and for the prevention of CMV disease, a common viral infection complicating solid organ transplants, in kidney, heart and kidney-pancreas transplant patients, Abacavir tablets, USP, a medicine that is used in combination with other antiretroviral agents for the treatment of HIV-1 infection; Entecavir, a medicine that is used for the treatment of chronic HBV infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease; Lamivudine tablets, a nucleoside analogue medicine used in combination with other antiretroviral agents for the treatment of HIV-1 infection; Lamivudine tablets (HBV), a medicine that is used for the treatment of chronic HBV infection associated with evidence of hepatitis B viral replication and active liver inflammation; and Lamivudine and Zidovudine tablets, USP, a combination of two nucleoside analogue medicines, used in combination with other antiretrovirals for the treatment of HIV-1 infection. Although we have acquired the rights to co-promote tetrabenazine, valganciclovir, Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine, our revenue will likely be dependent on sales from our ribavirin product portfolio for the next few years. Our competitors have developed and introduced and are continuing to develop and introduce additional products for chronic HCV infection that may, or may not, require the use of ribavirin in combination, or may require lower doses or shorter durations of treatment with ribavirin. Accordingly, we expect sales from our ribavirin product portfolio to continue to decrease over the next few years. Such decrease will have a negative impact on our sales and profits.

Any issues relating to any of these products, such as safety or efficacy issues, reimbursement and coverage issues, marketing or promotional issues, the introduction or greater acceptance of competing products, including generics, or adverse regulatory or legislative developments may reduce our revenues and adversely affect our results.

If we fail to maintain our competitive position with RibaPak and Ribasphere versus generics or other high-dose ribavirin product offerings, our business and market position will suffer, and our competitive position may be significantly impacted by the availability of new innovator treatments for chronic HCV infection.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, such as pharmaceutical

companies, generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for drug product candidates and other resources than us.

In particular, RibaPak and Ribasphere face significant direct competition from other generic high-dose ribavirin offerings, as well as competition from lower dose and lower cost generic versions of ribavirin. Additionally, the treatment of chronic HCV infection is rapidly changing as multiple new therapies have entered, such as Viekira Pak (AbbVie), Harvoni (Gilead Sciences, Inc.), Olysio (Janssen Pharmaceuticals, Inc.) and Zepatier (Merck & Co.), and will continue to enter the market that (either now or in the future) may not require the use of ribavirin as part of the treatment protocol. Multiple ribavirin free treatment regimens, including novel direct acting antivirals, have entered the market and become the new standard of care. As a result, we expect sales of our ribavirin portfolio of products to continue to decline in 2017 and beyond.

With scrutiny on drug costs, payors may look for ways to reduce their overall cost of treatment by switching from RibaPak and other generic high-dose formulations of ribavirin to a lower dose and lower cost generic version of ribavirin. If healthcare providers receive pressure from patients, or they are encouraged by insurers, to prescribe less expensive generics, or insurers impose additional formulary controls or restrictions on coverage of RibaPak and Ribasphere, our business would be significantly harmed. Additionally, we cannot assure you that other companies will not develop new products that may require a lower dose, shorter duration or complete removal of ribavirin from the treatment combination.

If RibaPak and Ribasphere are unable to be used successfully in combination with new therapies or if new therapies in development are able to achieve sufficiently high sustained virologic cure rates without ribavirin, we may be unable to compete effectively and our business would be materially and adversely affected. Additionally, generic manufacturers of ribavirin and direct high-dose ribavirin competitors may try to compete with RibaPak and Ribasphere by reducing their prices or adopting other competitive marketing and promotional tactics that could harm our business.

We cannot be certain how profitable, if at all, the commercialization of our marketed products will be.

To become and remain profitable, we must compete effectively against other therapies with our ribavirin portfolio of products, tetrabenazine, valganciclovir, Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine or any of our product candidates for which we obtain marketing approvals, as well as developing and eventually commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials for our product candidates and obtaining regulatory approval for these line extensions and product candidates, in addition to the manufacturing, marketing and selling of those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from our commercialized products will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for our products;
- the effectiveness of our collaborators' efforts in marketing and selling our products;
- our ability to successfully manufacture, or have manufactured, commercial quantities of our products at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient organization and, to the extent we seek to do so, to collaborate successfully with additional third parties;
- our ability to expand and maintain intellectual property protection for our products successfully;
- the efficacy and safety of our products; and/or
- our ability to comply with regulatory requirements, which are subject to change.

Because of the numerous risks and uncertainties associated with our commercialization efforts, we may not be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. A failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our inability to accurately estimate demand for our products, the uptake of new products or the timing of fluctuations in the inventories maintained by customers makes it difficult for us to accurately forecast sales and may cause our financial results to fluctuate.

We are unable to accurately estimate demand for our products, including uptake from new products, as demand is dependent on a number of factors. We sell products primarily to wholesalers and specialty pharmacies. These customers maintain and control their own inventory levels by making estimates to determine end user demand. Our customers may not be effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by our customers can cause our operating results to fluctuate unexpectedly. Adverse changes in economic conditions or other factors may cause our customers to reduce their inventories of our products, which would reduce their orders from us, even if end user demand has not changed. If our inventory exceeds demand from our customers and exceeds its shelf life, we will be required to destroy unsold inventory and write off its value. As our inventory and distribution channels fluctuate from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

In addition, the non-retail sector in the United States, which includes government institutions, including state drug assistance programs, correctional facilities and large health maintenance organizations, may be inconsistent in terms of buying patterns and may cause quarter over quarter fluctuations that do not necessarily mirror patient demand. Federal and state budget pressure may cause purchasing patterns to not reflect patient demand.

If we discover safety issues with any of our products or if we fail to comply with continuing U.S. and applicable foreign regulations, commercialization efforts for the product could be negatively affected, the approved product could be subject to withdrawal of approval or sales could be suspended, and our business could be materially harmed.

Our products are subject to continuing regulatory oversight, including the review of additional safety information. Drugs are more widely used by patients once approval has been obtained and therefore side effects and other problems may be observed after approval that were not seen or anticipated, or were not as prevalent or severe, during pre-approval clinical trials or nonclinical studies. The subsequent discovery of previously unknown problems with a product, or public speculation about adverse safety events, could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific products, product recalls and seizures, injunctions, consent decrees or other operating restrictions and/or criminal prosecutions. In addition, the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale.

If physicians, nurses, pharmacists, patients, the medical community and/or third-party payors do not accept our drugs or product candidates, we may be unable to generate significant revenue in future periods.

Our drugs may not gain or maintain market acceptance among physicians, nurses, pharmacists, patients, the medical community and/or third-party payors. Effectively marketing our products and any of our product candidates, if approved, requires substantial efforts and resources, both prior to launch and after approval; and marketing efforts are subject to numerous regulatory restrictions as well as fraud and abuse laws. The demand for our drugs and degree of market acceptance of our product candidates will depend on a number of factors including:

- limitations or warnings contained in the approved labeling for any of our drugs or product candidates;
- changes in the standard of care for the targeted indications for any of our drugs or product candidates;
- lower demonstrated efficacy, safety and/or tolerability compared to other drugs;
- prevalence and severity of adverse side-effects;
- lack of cost-effectiveness;
- limited or lack of reimbursement and coverage from government authorities, managed care plans and other third-party payors;
- a decision to wait for the approval of other therapies in development that have significant perceived advantages over our drug;

- the clinical indications for which the product is approved;
- adverse publicity about any of our drugs or product candidates or favorable publicity about competitive products;
- the timing or market introduction of any approved products as well as competitive products;
- the extent to which our drugs and product candidates are approved for inclusion on formularies of hospitals and manages care organizations;
- whether our drugs and product candidates are designated under physician treatment guidelines as first-line therapies or as a second- or third-line therapies for particular diseases;
- convenience and ease of administration;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- other potential advantages of alternative treatment methods;
- ineffective sales, marketing and/or distribution support; and/or
- potential product liability claims.

If any of our drugs or product candidates fails to maintain or achieve, as applicable, market acceptance, we will not be able to generate significant revenue in future periods.

Failure to comply with FDA promotional rules may subject us to withdrawal, and correction, of related product promotion, seizure of product and other administrative or enforcement actions as well as the potential for ancillary liability under the False Claims Act (False Claims Act) and/or product liability litigation.

The FDA regulates the promotion of our products, which may only be promoted within their approved indication for use. Promotional materials and activity must be presented with fair balance of the risks and benefits of any product in a manner which is not otherwise inaccurate or misleading. The FDCA and the FDA's implementing regulations require that manufacturers label, advertise and promote their products with appropriate safety warnings and adequate directions for their FDA-approved use. However, the FDA does not have the legal authority to regulate the practice of medicine. Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market RibaPak and Ribasphere in a combination treatment with peginterferon alfa-2a for the treatment of adults with chronic HCV infection who have compensated liver disease and have not been previously treated with interferon alpha. We currently co-promote Qsymia, which should be used together with a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes or high cholesterol. We also distribute tetrabenazine tablets, which are indicated for the treatment of chorea and valganciclovir tablets, which are indicated for the treatment of CMV retinitis in patients with AIDS and for the prevention of CMV disease in kidney, heart and kidney-pancreas transplant patients.

Due to the evolving chronic HCV infection treatment landscape, the indication for RibaPak and Ribasphere is inconsistent with the current standard of care. This increases the risk of potential off-label promotional activity, which could result in increased regulatory scrutiny. If the FDA determines that our promotional materials, training or other activities constitute off-label promotion, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed.

Although recent decisions of the United States Supreme Court, the U.S. Court of Appeals for the Second Circuit and the U.S. District Court for the Southern District of New York have clarified that the United States may not, consistent with the First Amendment, restrict or punish a pharmaceutical manufacturer's truthful and non-misleading speech promoting the lawful use of an approved drug, there are still significant risks in this area. It is unclear how these court decisions will impact the FDA's enforcement practices, and there is likely to be substantial disagreement and difference of opinion regarding whether any particular statement is truthful and not misleading.

In the past we have been subject to enforcement action relating to allegations of improper promotion of our products. In March 2011, Kadmon Pharmaceuticals received a warning letter from the FDA's Division of Drug Marketing, Advertising, and Communications (now known as the Office of Prescription Drug Promotion (OPDP)) alleging false or misleading promotional materials for Infergen, a product we then marketed, due to omission of important risk information, broadening of the approved indication, omission of material statements relating to the approved indication, overstatements of efficacy, and unsubstantiated promotional claims. The promotional piece that gave rise to the warning letter was circulated prior to the date on which we acquired the product at issue, through our acquisition of Three Rivers Pharmaceuticals, LLC in 2010, and the matter was closed out with the FDA in August 2011. We subsequently divested the product at issue in 2013.

Subsequently, in November 2013, we received a warning letter from OPDP regarding a January 2013 RibaPak Intro Letter for RibaPak sent by Kadmon Pharmaceuticals to a select group of healthcare providers. In its warning letter, OPDP stated that Kadmon Pharmaceuticals' letter omitted important risk information for Ribasphere RibaPak, suggested that the drug is useful in a broader range of patients or conditions than has been substantiated, omitted material facts, made unsubstantiated efficacy claims and failed to provide adequate directions for use in violation of the FDCA.

In response to the 2013 warning letter, we immediately ceased the dissemination of all marketing and promotional materials at issue, and commenced discussions with OPDP. A corrective letter was disseminated and on April 21, 2014, OPDP informed us that the matter was closed. We cannot guarantee that the FDA will not raise issues in the future regarding our promotional materials or promotional practices, and if so, we could be subject to additional enforcement action.

If we cannot successfully manage the promotion of our currently marketed products, and product candidates, if approved, we could become subject to significant liability which would materially adversely affect our business and financial condition. It is also possible that other federal, state or foreign enforcement authorities, or private parties, might take action if they believe that an alleged improper promotion led to inappropriate use of one of our products and/or the submission and payment of claims for an off-label use, which could result in significant fines or penalties under other statutory provisions, such as the False Claims Act and similar laws. Even if it is later determined that we were not in violation of these laws, we may face negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. In addition, there are a number of specific FDA requirements related to drug labeling and advertising, and failure to adhere to these requirements could result in our products being deemed "misbranded."

The manufacture of pharmaceutical products is a highly exacting and complex process, and if our suppliers encounter problems manufacturing our products, our business could suffer.

The manufacture of pharmaceutical products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Risks Related to Government and Regulatory Agencies

If we engage in research or commercial activities involving any of our products or pipeline assets in a manner that violates federal or state healthcare laws, including fraud and abuse laws, false claims laws, disclosure laws, government price reporting and healthcare information privacy and security laws or other similar laws, we may be subject to corporate or individual civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our business operations and activities are subject to extensive federal, state and local fraud and abuse and other healthcare laws and regulations, such as the False Claims Act and the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act (FCPA), federal Civil Monetary Penalty statute, the PPACA program integrity requirements, and patient privacy laws and regulation. These laws and regulations constrain, among other things, the business or financial arrangements and relationships through which we may research and develop any product candidate, as well as market, sell and distribute any approved products. The laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, either the referral of an individual, or the ordering, purchasing, furnishing, or recommending of, or arranging for, any good, facility, item or service that is reimbursable, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other hand, and therefore constrains our sales and marketing practices and our various service arrangements with physicians, including physicians who make clinical decisions to use our products. Due to the breadth of, and the narrowness of the statutory exceptions and safe harbors available under, the federal Anti-Kickback Statute, it is possible that some of our business activities, including our patient assistance programs and our relationship with physicians, hospitals, specialty pharmacies, group purchasing organizations and distributors could be subject to challenge under the federal Anti-Kickback Statute. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases.

- The False Claims Act and Civil Monetary Penalty statute prohibit any person from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making, or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as "off-label" uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated "best price" information to the Medicaid Drug Rebate Program.

- HIPAA and its implementing regulations, which created federal criminal laws that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- HIPAA, as amended by HITECH, and their respective implementing regulations, imposes requirements, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the

creation, use, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization.

- The federal Physician Payments Sunshine Act enacted under the PPACA and its implementing regulations requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), nurse practitioners and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. We were required to begin collecting information regarding such payments starting August 1, 2013 with our first report due March 31, 2014. Manufacturers are required to submit reports to the government by the 90th day of each calendar year. The PPACA also requires the CMS to forward data submitted by manufacturers to Congress and State Attorneys General on a regular basis. We have dedicated significant resources to enhance our systems and processes in order to comply with these regulations. Failure to comply with the reporting requirements would result in significant civil monetary penalties as well as reputational harm, and could draw scrutiny to financial relationships with physicians, which as a general matter could increase anti-kickback statute and False Claims Act enforcement risks.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner, and potentially limit our ability to offer certain marketplace discounts.

- State law equivalents of each of the above federal laws, such as anti-kickback, false claims which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances and often are not preempted by HIPAA, many of which differ from each other in significant ways, with differing effects, complicating compliance efforts.

In addition, any sales of our products or product candidates, if approved, commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We have entered into consulting agreements, scientific advisory board, and other financial arrangements with physicians, including some who prescribe our products and may prescribe our product candidates, if approved. Compensation for some of these arrangements includes the provision of stock options. While these arrangements were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these arrangements as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support to our customers and patients. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action against by government authorities.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. The sales and marketing practices of our industry are the subject of immense scrutiny from federal and state government agencies. Despite sequestration measures, governmental enforcement funding continues at

robust levels and enforcement officials are interpreting fraud and abuse laws broadly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources, divert our management's attention from the operation of the business, and generate negative publicity, which could harm our business. If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations. If we were to be excluded from federal healthcare programs, it would mean that no federal healthcare program payment could be made for any of our products.

We are planning to pursue the FDA 505(b)(2) pathway for one of our product candidates (KD034), and if we are not able to successfully do so, seeking approval of this product candidate through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness. Even if we are able to pursue the 505(b)(2) pathway, we could be subject to legal challenges and regulatory changes which might result in extensive delays or result in our 505(b)(2) application being unsuccessful.

Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We plan to pursue this pathway for one of our product candidates: KD034.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we would need to reconsider our plans for this product and might not be able to commercialize it in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, would be subject to the full requirements and risks described for our other product candidates.

In some instances over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) and legally challenged decisions by the agency. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for KD034.

The pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. A claim by the applicant that a patent is invalid or will not be infringed is subject to challenge by the patent holder, requirements may give rise to patent litigation and mandatory delays in approval (i.e., a 30-month stay) of a 505(b)(2) application. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

In the Federal Register of February 6, 2015, the FDA published a proposed rule to implement statutes that govern the approval of 505(b)(2) applications and ANDAs. The FDA also requested comment on its proposal to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act. Comments on the proposed rule will inform the FDA's rulemaking on ANDAs and 505(b)(2) applications, and at this time the implications of these potential regulatory changes is uncertain.

Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Even if approved pursuant to the Section 505(b)(2) regulatory pathway, a drug may be subject to the same post-approval limitations, conditions and requirements as any other drug.

Our commercial success depends on adequate reimbursement and coverage from third-party commercial and government payors for our products, and changes to coverage or reimbursement policies, as well as healthcare reform measures, may materially harm our sales and potential revenue.

Our current sales in the United States of Ribasphere tablets and capsules and RibaPak are dependent on the formulary approval and the extent of reimbursement from third-party payors, including government programs (such as Medicare and Medicaid) and private payor healthcare and insurance programs. Coverage and reimbursement for our products can differ significantly from payor to payor. Even when we obtain coverage and reimbursement for our products, we may not be able to maintain adequate coverage and reimbursement in the future.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved products. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and commercial success of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Additionally, coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Assuming that coverage is obtained for a given product, the resulting reimbursement rates might not be adequate or may require co-payments that patients find unacceptably high. Patients, physicians, and other healthcare providers may be less likely to prescribe, dispense or use, as applicable, our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Government payors and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug or biologic products when more established or lower-cost therapeutic alternatives are already available or subsequently become available. Based upon a number of factors, including clinical and economic standards, our products may not qualify for coverage and reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective;
- neither experimental nor investigational;
- prescribed by a practitioner acting within the scope of license and health plan participation agreements;
- documented adequately in the patient's medical record;
- dispensed by a participating pharmacy; and/or
- logged and documented appropriately by the dispensing pharmacy.

The market for our products will depend significantly on access to third-party payors' drug formularies for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. If coverage and reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In the United States, our products may be subject to discounts from list price and rebate obligations, and we have experienced increased pricing pressure and restrictions on patient access, such as prior authorizations, due to new and expensive therapies that have entered the hepatitis C market. Third-party payors have from time to time refused to include our

products in their formularies, limit the type of patients for whom coverage will be provided, or restrict patient access to our products through formulary control or otherwise, in favor of less-costly generic versions of ribavirin or other treatment alternatives. Any change in formulary coverage, treatment paradigm, reimbursement levels, discounts or rebates offered on our products may impact our anticipated revenues.

In the United States, governmental and commercial third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. We believe that pricing pressure for our products will continue, and future coverage and reimbursement will likely be subject to increased restrictions. For example, the PPACA, which has already imposed significant healthcare cost containment measures, also encourages the development of comparative effectiveness research and any adverse findings for our products from such research may reduce the extent of coverage and reimbursement for our products. The PPACA created the Patient-Centered Outcomes Research Institute to review the effectiveness of treatments and medications in federally-funded healthcare programs. The PCORI publishes the results of its studies. An adverse finding result may result in a treatment or product being removed from Medicare or Medicare coverage.

Managed care organizations continue to seek price discounts and in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs, which may result in managed care organizations influencing prescription decisions for a larger segment of the population, which could constrain pricing, formulary position or reimbursement for our products. Economic pressure on state budgets may also have a similar impact on Medicaid coverage and reimbursement. A reduction in the availability or extent of reimbursement or removal from and restrictions in use on formularies from U.S. government programs and other third-party payors could have a material adverse effect on the sales of RibaPak.

If adequate coverage and reimbursement by third-party payors, including Medicare and Medicaid in the United States, is not available, our ability to continue to successfully market the RibaPak and Ribasphere line of ribavirin products will be materially adversely impacted and it would cause irreversible damage to our financial position, unless we are successful in developing or acquiring rights to promote another product. We can make no assurances that we can do so on a timely basis or on favorable terms, if at all. In certain countries in the European Union and some other international markets, governments provide healthcare at low-cost to consumers and regulate pharmaceutical pricing, patient eligibility or reimbursement levels to control costs for the government-sponsored healthcare system. We expect to see strong efforts to reduce healthcare costs in our international markets, including: patient access restrictions; suspensions on price increases; prospective and possibly retroactive price reductions, mandatory discounts and rebates, and other recoupments; recoveries of past price increases; and greater importation of drugs from lower-cost countries to higher-cost countries. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets.

Healthcare reform measures could hinder or prevent our product candidates' commercial success and could increase our costs.

In both the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is a significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding individual access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in 2010, the PPACA was enacted, which was intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, strengthening of program integrity measures and enforcement authority, and expansion of the Medicaid program. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. In this regard, the PPACA includes the following provisions:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs that began in 2011;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- an extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;

- changes to the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other healthcare entities;

- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- creation of the Independent Payment Advisory Board which has the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the CMS and other federal and state agencies issue and finalize all applicable regulations or guidance. We will continue to evaluate the PPACA, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially have an impact on our business over time. The cost of implementing more detailed record keeping systems and otherwise complying with these regulations could substantially increase our costs. The changes to the way our products are reimbursed by the CMS could reduce our revenues. Both of these situations could adversely affect our results of operations. There have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. Significant uncertainty exists regarding the effect of the PPACA, particularly in light of the recent election and campaign pledges to repeal or reform the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and suppliers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws and future healthcare reform laws may result in additional reductions in Medicare and other healthcare funding.

There also have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels and elsewhere directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. In addition, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;

- our ability to set a price that we believe is fair for our products;

- our ability to generate revenues and achieve or maintain profitability;

- the level of taxes that we are required to pay; and/or

- the availability of capital.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products.

International operations are also generally subject to extensive price and market regulations and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property portfolio or may make it economically unsound to launch our products in certain countries. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. Future price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

Additionally, in some countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various European Union member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

Guidelines and recommendations published by government agencies, professional societies, and private foundations and organizations can reduce the use of our products and product candidates, if approved.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. In addition, from time to time, professional societies, practice management groups, private health/science foundations and organizations publish guidelines or recommendations directed to certain healthcare and patient communities. These recommendations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws.

We are subject to the FCPA, which generally prohibits companies and their intermediaries from making payments to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to anti-bribery laws in the jurisdictions in which we operate. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the FCPA and other anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under the FCPA or other laws for actions taken by our agents, employees and intermediaries with respect to our business or any businesses that we acquire. We do business in a number of countries in which FCPA violations have recently been enforced. Failure to comply with the FCPA, other anti-bribery laws or other laws governing the conduct of business with foreign government entities, including local laws, could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

If our processes and systems are not compliant with regulatory requirements, we could be subject to restrictions on marketing our products or could be delayed in submitting regulatory filings seeking approvals for our product candidates.

We have a number of regulated processes and systems that are required to obtain and maintain regulatory approval for our drugs and product candidates. These processes and systems are subject to continual review and periodic inspection by the FDA and other regulatory bodies. 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 product candidates, or delays in obtaining regulatory approval after filing. 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. Given the number of high profile adverse safety

events with certain drug products, regulatory authorities may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more intended indications. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us or our collaborators to conduct costly studies.

In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. Approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers, which we are responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to our product candidates and commercial products. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs we market or for which we or they obtain approval may be deemed adulterated, which carries significant legal implications, and may be subject to later restrictions on manufacturing or sale, which could have a material adverse effect on our business.

Risks Related to Our Intellectual Property Rights

If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution 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. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, collaboration partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We may license patent rights that are valuable to our business from third parties, in which event we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties also apply to patent rights we own.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner. Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use or sale of our proprietary medicines and technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, prior to March 2013, in the United States, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. Beginning in March 2013, the United States transitioned to a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first-inventor-to-file a patent application will be entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (U.S. PTO) or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. Participation in these proceedings can be very complex, expensive and may divert our management's attention from our core business. Furthermore, an adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize medicines without infringing third-party patent rights.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Patent protection may not be available for some of our products or the processes under which they are used or manufactured. Our Ribasphere (ribavirin) tablets, capsules and the RibaPak products were approved under an ANDA in the United States. Although we hold patents for the RibaPak product, other generic manufacturers may file ANDAs in the United States seeking FDA authorization to manufacture and market additional generic versions of RibaPak, together with Paragraph IV certifications that challenge the scope, validity or enforceability of the RibaPak patents. If we must spend significant time and money protecting or enforcing our intellectual property rights, potentially at great expense, our business and financial condition may be harmed.

Issued patents covering one or more of our products could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Although we have conducted due diligence on patents we have exclusively in-licensed, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products and product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and

foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we or our future strategic collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Most of our competitors are larger than we are and have substantially greater resources and may be able to sustain the costs of complex patent litigation longer than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or enter into strategic collaborations that would help us bring our product candidates to market.

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

Competitors may infringe our patents or the patents of our licensors. 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 or our licensors is not valid, is unenforceable and/or is not infringed, 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. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy in order to protect our competitive position in medical research and development. Trade secrets are difficult to

protect, and it is possible that our trade secrets and know-how will over time be disseminated within the industry through independent development and intentional or inadvertent disclosures.

We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaboration partners, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Our agreements with research and development collaboration partners contain contractual limitations regarding the publication and public disclosure of data and other information generated during the course of research. Despite these efforts, any of these parties may breach the agreements and intentionally or inadvertently disclose or use our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets or the equivalent knowledge, methods and know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business, or permit us to maintain our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or collaboration partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and/or
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors 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 any of our employee's 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, which could adversely impact our business. 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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may also have, in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Risks Related to Our Dependence on Third Parties

We expect to continue to contract with third-party suppliers for the production of our commercial product portfolio as well as our developmental product candidates for clinical trial use and, if approved, for commercialization.

We currently employ third parties for the manufacturing of our commercial products and product candidates. This increases the risk that we will not have sufficient quantities of our products or product candidates within the timeframe and at an acceptable cost which could delay, prevent or impair our development or commercialization efforts. Additionally, we may not be able to quickly respond to changes in customer demand which could harm our business as a result of the inability to supply the market or an excess of inventory that we are unable to sell.

The facilities used by our contract manufacturers to manufacture our product candidates must adhere to FDA requirements, and are subject to inspections that may be conducted after we submit our marketing applications to the FDA in connection with review of our application, and on an ongoing basis relevant to postmarketing compliance. Although we are subject to regulatory responsibility for the quality of products manufactured by our contract manufacturers and oversight of their activities, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will be subject to enforcement action, and if substantial noncompliance is identified and not corrected, they may be precluded from manufacturing product for the United States or other markets. In addition, although the FDA will hold us responsible for due diligence in the selection of, and oversight in the operations of, our contract manufacturers, we do not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority identified significant compliance concerns with our contract manufacturers, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates, if approved.

We have agreements with third-party manufacturers for the provision of API, drug product manufacturing and packaging of our commercial products. Reliance on third-party manufacturers carries additional risks, such as not being able to comply with cGMP or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

We still currently rely on one third-party supplier for the ribavirin API. Additionally, tetrabenazine, valganciclovir, Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine are sourced by Camber through a single supplier. In the event that any of these third-party manufacturers fail regulatory compliance, fail to meet quality assurance specifications or experience an unavoidable extraordinary event, our business would be materially adversely affected.

Any products that we may develop may compete with other product candidates and commercialized products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure or refusal to supply on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers cannot perform as agreed, we may be required to replace one or more of these suppliers. Although we believe that there are a

number of potential long-term replacements to each supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

We rely on third parties to store and distribute supplies for our clinical trials and for the manufacture of our product candidates. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval or our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We have acquired or in-licensed many of our products from external sources and may owe milestones or royalties based on the achievement of future successes or penalties if certain diligence requirements are not met.

In certain cases, our license or acquisition agreements require us to conduct research or clinical trials within a specified time frame, or we may owe a penalty or lose the right to the product for development. If we do not conduct the necessary research or clinical trials within the specified time frame, we may be required to pay cash penalties to extend the time frame during which studies may be conducted or our collaborators may exercise a right to have the product returned.

On some of the products we have licensed, we may be obligated in future periods to make significant development and commercial milestone payments as well as royalties. As a result, we may have to raise additional capital (which would likely cause our equity holders to experience dilution) to cover the required milestone payments. The milestone payments and royalties we may owe on the sale of our products may reduce the overall profitability of our operations and if we are unable to sell sufficient product to cover the costs of these milestone payments, our operating profitability, business and value of our equity securities may be adversely impacted.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and/or
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our collaboration partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend and enforce patents and patent applications that are material to our business.

Patents relating to our product candidates are controlled by certain of our licensors. Each of our licensors generally has rights to file, prosecute, maintain and defend the patents we have licensed from such licensor. We generally have the first right to enforce our patent rights, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain or defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to

the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

We rely in part on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as medical institutions and clinical investigators, and may in the future rely on other third parties, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, we, along with medical institutions and clinical investigators, are required to comply with "good clinical practices" or "GCP," which is an international ethical and scientific quality standard for designating, recording and reporting trials that involve the participation of human subjects, and which is implemented via regulations and guidelines enforced by, among others, the FDA, the EMA, the Competent Authorities of the Member States of the European Economic Area (EEA), and comparable foreign regulatory authorities for all of our products in clinical development. GCP is designed to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, study sites, or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials and create other regulatory and litigation exposure, which would among other things delay the regulatory approval process.

We face risks in connection with existing and future collaborations with respect to the development, manufacture and commercialization of our products and product candidates.

The risks that we face in connection with our current and any future collaborations include the following:

- Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively develop our product candidates. The ability of some of our products and product candidates to reach their potential could be limited if collaborators decrease or fail to increase development or commercialization efforts related to those products or product candidates.

- Any future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties.

- Collaborators may develop and commercialize, either alone or with others, drugs that are similar to or competitive with the drugs or product candidates that are the subject of their collaborations with us.

Our collaboration agreements are subject to termination under various circumstances.

Risks Related to Our Operations

Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

The biopharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the

hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities. This may limit their availability to us.

In order to induce valuable employees to continue their employment with us, we have provided equity incentives that vest over time. The value to employees of equity incentives that vest over time is significantly affected by the success of our operations and clinical trials for our new product candidates, much of which is beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements generally provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses and institutions. Many of the other companies and institutions that we compete with for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

Our employees, independent contractors, principal investigators, agents, consultants, commercial partners and vendors 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 that our employees, independent contractors, principal investigators, agents, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent failures to:

- comply with regulations by the FDA and other similar foreign regulatory bodies;
- provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies;
- comply with manufacturing standards;
- comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and similar foreign laws;
- report financial information or data accurately; and/or
- disclose unauthorized activities to us.

In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including off-label uses of our products, structuring and commission(s), certain customer incentive programs, patient assistance programs, and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics. However, it is not always possible to identify and deter misconduct by employees and other third-parties, and 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, possible exclusion from participation in Medicare, Medicaid and

other federal healthcare programs or other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates and marketed products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, whether by us, on our behalf or by unaffiliated third parties or investigators, and will face an even greater risk for any products that we commercialize. For example, we may be sued if any product we develop or sell allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved, or our other marketed products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop or sell;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and/or
- the inability to commercialize our product candidates or our marketed products.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry an aggregate of $20.0 million of product liability insurance, which we believe is adequate for our commercial products and our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our operating results are subject to significant fluctuations.

Our quarterly revenues, expenses and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the timing of charges and expenses that we may encounter. In recent periods, for instance, we have recorded charges that include:

- impairments that we are required to take with respect to investments;
- financing related costs and expenses;
- milestone payments under license and collaboration agreements; and
- payments in connection with acquisitions and other business development activity.

Our quarterly revenues, expenses and net income (loss) may fluctuate significantly from quarter to quarter and year to year, such that a period to period comparison of our results of operations may not be a good indication of our future performance.

If we are unable to successfully implement our strategic plan, our business may be materially harmed.

We plan to continue to develop and commercialize novel drugs that will have a significant clinical impact on important unmet medical needs while we continue to market our commercial products to eligible patients to generate revenue. Absent a successful launch of one or more of our product candidates, we expect our total revenue to decline significantly as the HCV treatment landscape continues to evolve. Furthermore, our patent protection for our RibaPak product expires in 2028. In order to maintain a strong financial position, we are focusing our investment on development programs for our most advanced product candidates. In an effort to mitigate our drug development risk and improve our chance of ultimate commercial success, we are developing multiple product candidates in a wide variety of disease indications. There can be no assurance that our development programs will be successful or that our research programs will result in drugs that we can successfully develop and commercialize.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and/or
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our equity holders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and/or
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we acquire or license technologies, products or product candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we might license or acquire technologies, resources, drugs or product candidates. We might never realize the anticipated benefits of such a transaction, and we may later incur impairment charges related to assets acquired in any such transaction. For example, due to a decline in demand for Ribasphere, we incurred an intangible asset impairment charge of $31.3 million during the year ended December 31, 2015 related to Ribasphere product rights, which were acquired in conjunction with the 2010 acquisition of Three Rivers Pharmaceuticals, LLC. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the product candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

At December 31, 2016, we had 118 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

We depend on information technology and a failure of those systems could adversely affect our business.

We rely on sophisticated information technology systems to operate our business. These systems are potentially vulnerable to malicious intrusion, random attack, loss of data privacy, or breakdown. Although we have invested in the protection of our data and information technology and also monitor our systems on an ongoing basis, there can be no assurance that these efforts will prevent breakdowns or breaches in our information technology systems that could adversely affect our business.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly.

The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. The trading price of our common stock also may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- adverse results or delays in the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products and product candidates, including clinical trial requirements for approvals;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- failure to commercialize our product candidates or if the size and growth of the markets we intend to target fail to meet expectations;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introductions or announcements of new products offered by us or significant acquisitions, strategic collaborations, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;
- our ability or inability to effectively manage our growth;
- changes in the structure of healthcare payment systems;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and/or
- significant lawsuits, including patent or stockholder litigation.

The stock market in general, and market prices for the securities of pharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain research coverage by securities and industry analysts. If no or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or securities convertible into our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

At December 31, 2016, we had 45,078,666 shares of our common stock outstanding. All shares of common stock sold in our IPO and pursuant to the Selling Stockholder Resale Prospectus are freely tradable without restriction or further registration under the Securities Act unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining 36,745,330 shares, or approximately 81% of our shares currently outstanding, are either freely tradable subject to applicable securities law restrictions unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, or the holders of such shares have rights requiring us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, subject to certain conditions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market stand-off and lock-up agreements, Rule 144 and Rule 701 under the Securities Act, as well as, to the extent applicable, under the registration statement on Form S-8 that we have filed.

Once we register the offer and sale of shares for the holders of registration rights and shares to be issued under our equity incentive plans, they can be freely sold in the public market upon issuance or resale (as applicable).

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as early as our annual report on Form 10-K for the fiscal year ending December 31, 2017. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years following the date of our IPO. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

The holders of the convertible preferred stock will be entitled to be paid a liquidation preference, which under some circumstances will include a substantial premium.

In the event of a liquidation (as defined in the certificate of designations governing our convertible preferred stock), certain bankruptcy events, a material breach by us of the exchange agreement or a failure to make any payment due on our or our subsidiaries' indebtedness after giving effect to any applicable cure period, the holders of the convertible preferred stock will be entitled to payment of a liquidation preference. The liquidation preference for each share of convertible preferred stock will equal the greater of (i) (A) (I) the original purchase price per share of convertible preferred stock plus dividend arrearages thereon in cash *plus* (II) any dividends accrued and unpaid thereon from the last dividend payment date to the date of the final distribution to such holder *plus* (B) in the majority of the events identified in the previous sentence, a premium equal to 20.2% of the amount described in clause (i)(A) of this sentence at such time or (ii) an amount per share of convertible preferred stock equal to the amount which would have been payable or distributable if each share of convertible preferred stock been converted into shares of our common stock immediately before the liquidation event.

Until the holders of the convertible preferred stock have been paid their liquidation preference in full, no payment will be made to any holder of common stock. If our assets, or the proceeds from their sale, distributable among the holders of the convertible preferred stock are not sufficient to pay the liquidation preference in full and the liquidating payments on any parity securities, then those assets or proceeds will be distributed among the holders of the convertible preferred stock and those parity securities on a pro rata basis. In that case, there would be no assets or proceeds remaining to be distributed to holders of our common stock, which would have a material adverse effect on the trading price of our common stock.

The holders of the convertible preferred stock are entitled to have their shares of convertible preferred stock redeemed at a substantial premium in certain events

Our convertible preferred stock is redeemable if we or our significant subsidiaries are the subject of certain bankruptcy events, upon the occurrence of a material breach by us of the exchange agreement and upon the failure to make payments of amounts due on our or any of our subsidiaries' indebtedness after giving effect to any applicable cure period. Upon the occurrence of any of these events, the holders of our convertible preferred stock shall, in their sole discretion, be entitled to receive an amount equal to the original purchase price per share of convertible preferred stock plus dividend arrearages thereon *plus* any dividends accrued and unpaid thereon from the last dividend payment date to, but excluding, the date of such redemption *plus* the premium described under "The holders of the convertible preferred stock will be entitled to be paid a liquidation preference, which under some circumstances will include a substantial premium." If we were to become obligated to redeem all or a substantial portion of the outstanding convertible preferred stock, that could have a material adverse effect on the trading price of our common stock.

Shares of our convertible preferred stock are convertible into shares of our common stock and, upon conversion, will dilute your percentage of ownership.

Concurrently with the closing of our IPO, we issued 30,000 shares of our convertible preferred stock pursuant to an exchange agreement with holders of our Senior Convertible Term Loan. Holders of the convertible preferred stock shall be entitled to receive a cumulative dividend at an annual rate of 5% of the sum of the original purchase price per share of convertible preferred stock plus any dividend arrearages. In addition, holders of the convertible preferred stock shall be entitled to receive dividends paid or payable on our common stock with respect to the number of shares of our common stock into which each share of convertible preferred stock is then convertible at the then applicable conversion price. Shares of our convertible preferred stock are convertible at any time at the option of the holder into shares of our common stock at a conversion price equal to their original purchase price plus any accrued but unpaid dividends. At December 31, 2016, 3,191,843 shares of our common stock are issuable upon conversion of our convertible preferred stock. This issuance of common stock upon the conversion will dilute the percentage ownership of holders of our common stock by approximately 7.1% as of December 31, 2016. The dilutive effect of the conversion of these securities may adversely affect our ability to obtain additional equity financing.

Holders of the convertible preferred stock may exert substantial influence over us and may exercise their control in a manner adverse to your interests.

So long as shares of our convertible preferred stock remain outstanding, without the consent of at least a majority of the then outstanding shares of the convertible preferred stock, we may not (i) authorize or approve the issuance of any convertible preferred stock, senior securities or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto) or authorize or create or increase the authorized amount of any convertible preferred stock, senior securities or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto); (ii) authorize or approve the purchase or redemption of any parity securities or junior securities; (iii) amend, alter or repeal any of the provisions of the certificate of designations, our certificate of incorporation or our by-laws in a manner that would adversely affect the powers, designations, preferences and rights of the convertible preferred stock;

(iv) contract, create, incur, assume or suffer to exist any indebtedness or guarantee any such indebtedness with an aggregate value of more than $5,000,000 (subject to certain exceptions); or (v) agree to take any of the above actions. The holders of convertible preferred stock will have one vote for each share of common stock into which such holders' shares could then be converted at the time, and with respect to such vote, will have voting rights and powers equal to the voting rights and powers of the holders of our common stock.

The certificate of designations governing the convertible preferred stock also provides that no amendment or waiver of any provision of the certificate of designations or our charter or bylaws shall, without the prior written consent of all holders of the convertible preferred stock who are known to us to hold, together with their affiliates, more than 5% of the convertible preferred stock then outstanding (i) reduce any amounts payable or that may become payable to holders of the convertible preferred stock; (ii) postpone the payment date of any amount payable to holders of the convertible preferred stock or waive or excuse any payment; (iii) modify or waive the conversion rights of the convertible preferred stock in a manner that would adversely affect any holder of the convertible preferred stock; or (iv) change any of the voting-related provisions or any other provision of the certificate of designations specifying the number or percentage of holders of the convertible preferred stock which are required to waive, amend or modify any rights under the certificate of designations or make any determination or grant any consent under that document.

In addition, for so long as affiliates of GoldenTree Asset Management LP collectively own at least 7.5% of our common stock (calculated on an "as if" converted basis and taking into account the exercise of all other options, warrants and other equity-linked securities held by such GoldenTree affiliated entities), GoldenTree Asset Management LP will have the right, at its option, to designate (i) one director to our board of directors and, upon such designation, the board of directors shall recommend to the stockholders to vote for the election of GoldenTree Asset Management LP's designee at any meeting of stockholders convened to elect our directors and use commercially reasonable efforts to cause that designee to be elected at that meeting or (ii) one observer to our board of directors. As a result of these contractual rights, holders of our convertible preferred stock may exert substantial influence over our company and may exercise their control in a manner that is adverse to the interests of other holders of our common stock. As of the date of this Annual Report, GoldenTree has not designated a director or observer to our board of directors.

We will require additional capital in the future, which may not be available to us. Issuances of our equity securities to provide this capital may dilute your ownership in us.

We will need to raise additional funds through public or private debt or equity financings in order to:

- take advantage of expansion opportunities;
- acquire complementary products, product candidates or technologies;
- develop new products or technologies; and/or
- respond to competitive pressures.

Pursuant to the second amendment to the 2015 Credit Agreement we entered into in November 2016, we are under a contractual obligation to raise $40.0 million of additional equity capital by the end of the second quarter of 2017, and a failure to comply with this covenant is an event of default under our 2015 Credit Agreement. Any additional capital raised through the issuance of our equity securities may dilute your percentage ownership interest in us. Furthermore, any additional financing we may need may not be available on terms favorable to us or at all. The unavailability of needed financing could adversely affect our ability to execute our business strategy. See "—Risks Related to Our Financial Position—Our 2015 Credit Agreement matures on June 17, 2018. We may not be able to comply with the covenants under the 2015 Credit Agreement or refinance our debt under this facility before the maturity date, in which event our ability to continue our operations would be materially and adversely impacted" for more information.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and holders of 5% or more of our capital stock, together with their respective affiliates, beneficially owned 54.8% of our common stock as of March 8, 2017, of which 4.4% is beneficially owned by our executive officers. Accordingly, our executive officers, directors and principal stockholders are able to determine the composition of the board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn

could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, our certificate of incorporation and bylaws:

- permit the board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; and
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15.0% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15.0% equity interest in us.

We will continue to incur significant costs by being a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with corporate governance requirements, including requirements of the SEC and the New York Stock Exchange (NYSE). We expect these rules and regulations to continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may continue to make it more difficult and expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

When we cease to be an “emerging growth company” and when our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

We are an “emerging growth company,” as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO, (iii) the date on which we have issued

more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Our management has broad discretion in using the net proceeds from our IPO and our other capital resources.

We expect to continue to use the net proceeds from our IPO, March 2017 private placement and our other capital resources to fund the clinical development of our pipeline and for general corporate purposes. Our management has broad discretion in the application of the balance of the net proceeds of our IPO, March 2017 private placement and our other capital resources and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish available cash flows available to service our debt, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from our IPO, March 2017 private placement and our other capital resources in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

Future sales and issuances of equity securities, convertible securities or other securities could result in additional dilution of the percentage ownership of holders of our common stock.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell equity securities, convertible securities or other securities in one or more transactions at prices and in a manner we determine from time to time. If we sell equity securities, convertible securities or other securities in more than one transaction, investors in such future offerings may be materially diluted by subsequent sales. Such sales would also likely result in material dilution to our existing equity holders, and new investors could gain rights, preferences and privileges senior to those of holders of our existing equity securities.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We have three primary operating locations which are occupied under long-term leasing arrangements. In October 2010, Kadmon Corporation, LLC entered into a corporate headquarters and laboratory lease in New York, New York, expiring in February 2021 and opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $2.0 million. Since inception, there have been four amendments to this lease agreement, which have altered office and laboratory capacity and extended the lease term through October 2024. We have the ability to extend portions of the lease on the same terms and conditions as the current lease, except that the base rent will be adjusted to the fair market rental rate for the building based on the rental rate for comparable space in the building at the time of extension.

We are party to an operating lease in Warrendale, Pennsylvania (our specialty-focused commercial operation), which expires on September 30, 2019, with a five-year renewal option. Rental payments under the renewal period will be at market rates determined from the average rentals of similar tenants in the same industrial park.

In August 2015, we entered into an office lease agreement in Cambridge, Massachusetts (our clinical office) effective January 2016 and expiring in April 2023. We opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $91,000.

For additional information, see Contractual Obligations and Commitments in Part II, Item 7 of this Annual Report on Form 10-K.

Item 3. Legal Proceedings

Please refer to Note 17, “Contingencies,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a discussion related to our 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.

Market Information

Our common stock has been listed on the NYSE under the symbol "KDMN" since our initial public offering, or IPO, of our common stock on July 27, 2016. Prior to that time, there was no public market for our common stock. The following table sets forth for the indicated periods the high and low intra-day sales prices per share for our common stock on the NYSE:

	2016	
	High	Low
Third quarter (Beginning July 27, 2016)	$ 11.73	$ 7.01
Fourth quarter	7.82	4.13

Holders of Record

On March 8, 2017, there were approximately 2,850 stockholders of record of our common stock and the closing price of our common stock was $3.42 per share as reported by the NYSE. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business and repayment of debt. We have never declared nor paid any dividends on our common stock and do not anticipate paying cash dividends to holders of our common stock in the foreseeable future. In addition, the 2015 Credit Agreement, as well as any future borrowings, will restrict our ability to pay dividends. See "Risk Factors—Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain." Any determination to pay dividends on our common stock in the future will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and covenants in our existing financing arrangements and any future financing arrangements. Holders of the convertible preferred stock are entitled to receive a cumulative dividend at an annual rate of 5% of the original purchase price per share of convertible preferred stock, when and as declared by our board of directors and to the extent of funds legally available for the payment of dividends. Holders of the convertible preferred stock are also entitled to participate in all dividends declared and paid to holders of our common stock on an "as if" converted basis.

Purchases of Equity Securities by the Issuer of Affiliated Purchasers

None.

Sales of Unregistered Securities

Recent Sales of Unregistered Equity Securities

In March 2017, we raised approximately $22.7 million in gross proceeds from the issuance of 6,767,855 shares of our common stock, at a price of $3.36 per share, and warrants to purchase 2,707,138 million shares of our common stock at an initial exercise price of $4.50 per share and a term of 13 months from the date of issuance. In connection with the offering, we have agreed to file a registration statement to register the shares of common stock underlying the common stock and warrants for resale. Under the agreement, the registration statement must be filed within 30 days of the closing of the financing and declared effective within the timeline provided in the agreement. If the applicable deadlines are not met, monthly liquidated damages of 2.0% of the subscription amount (with an 8.0% cap) will be due to the purchaser.

In August 2016, we issued 208,334 shares of our common stock to settle an aggregate liability of $2.5 million with two former employees. The sales of these securities were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act.

In June 2016, we raised $5.5 million in gross proceeds, with no transaction costs, through the issuance of 478,266 Class E redeemable convertible units. Dr. Harlan W. Waksal, our President and Chief Executive Officer, certain entities affiliated with GoldenTree Asset Management LP, Bart M. Schwartz, Esq., the Chairman of our Board of Directors, and D. Dixon Boardman, a member of our Board of Directors subscribed for 86,957, 43,479, 21,740 and 21,740 Class E redeemable

convertible units, respectively. See Note 4, “Stockholders’ Deficit - Class E Redeemable Convertible Units” of the notes to our audited consolidated financial statements for more information about the Class E redeemable convertible units.

Use of Proceeds from IPO of Common Stock

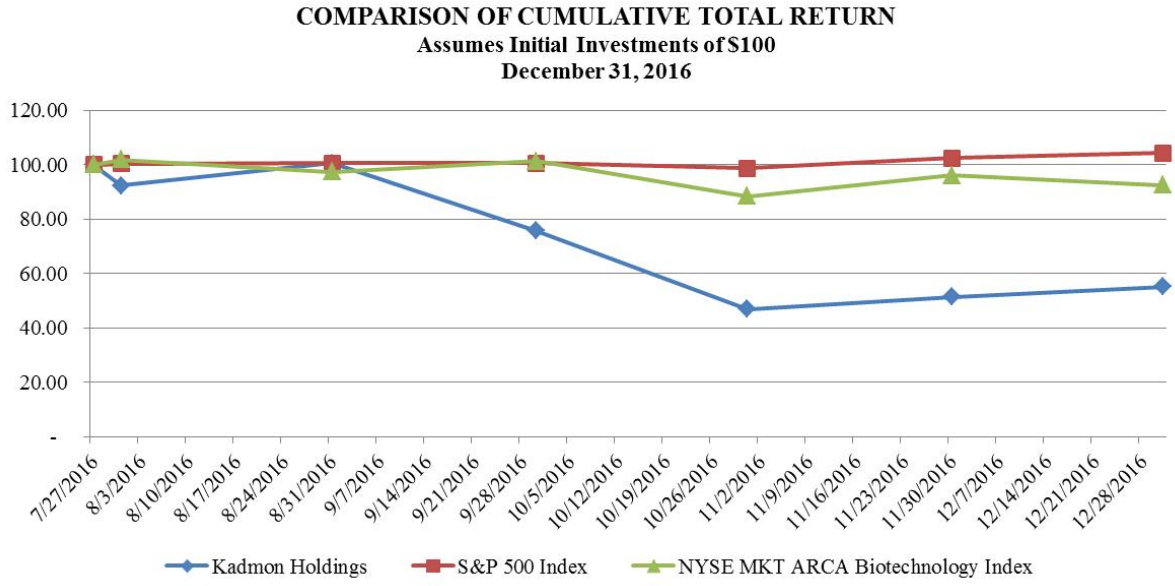
On August 1, 2016, we consummated our IPO, in which we sold 6,250,000 shares of common stock at a price of $12.00 per share. We received net proceeds from the IPO of approximately $66.0 million, after deducting underwriting discounts, commissions and offering expenses. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates.

The offer and sale of the shares in our IPO were registered pursuant to our Registration Statement on Form S-1 (File No. 333-211949), which was declared effective by the SEC on July 26, 2016. Citigroup and Jefferies acted as joint book-running managers; JMP Securities acted as lead manager; and H.C. Wainwright & Co., acted as manager for the offering. The offering commenced on July 26, 2016 and did not terminate until the sale of all the shares offered.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on July 27, 2016, pursuant to Rule 424. We invested the funds received in cash and cash equivalents in accordance with our investment policy.

Stock Performance Graph

The following graph illustrates a comparison from July 27, 2016, which is the date our common stock first began trading on the NYSE, through December 31, 2016, of the total cumulative stockholder return on our common stock, the Standard & Poor's 500 Stock Index (S&P 500 Index) and the NYSE MKT ARCA Biotechnology Index. The graph assumes that $100 was invested at the market close on July 27, 2016 in the common stock of Kadmon Holdings, Inc., the S&P 500 Index and the NYSE MKT ARCA Biotechnology Index and data for the S&P 500 Index and the NYSE MKT ARCA Biotechnology Index assumes reinvestments of dividends. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Item 6. Selected Financial Data.

The following selected financial data are derived from the consolidated financial statements. The data presented below should be read in conjunction with our consolidated financial statements, the notes to the consolidated financial statements, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The consolidated statement of operations data for the years ended December 31, 2016, 2015 and 2014, and the consolidated balance sheet data at December 31, 2016 and 2015, are derived from, and qualified by reference to, our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands, except per share data)		
Statement of Operations Data:			
Total revenue	$ 26,055	$ 35,719	$ 95,018
Cost of sales	3,485	3,731	6,123
Write-down of inventory	385	2,274	4,916
Gross profit	22,185	29,714	83,979
Research and development	35,840	33,558	32,947
Selling, general and administrative	105,880	104,740	89,321
Impairment of intangible asset	—	31,269	—
Gain on settlement of payable	(4,131)	—	—
Total operating expenses	137,589	169,567	122,268
Loss from operations	(115,404)	(139,853)	(38,289)
Total other expense	93,009	7,232	26,096
Net loss	(208,755)	(147,082)	(64,356)
Deemed dividend on convertible preferred stock	21,733	—	—
Net loss attributable to common stockholders	(230,488)	(147,082)	(64,356)
Basic and diluted net loss per share of common stock	$ (9.74)	$ (18.10)	$ (8.27)
Weighted average basic and diluted shares of common stock outstanding	23,674,512	8,127,781	7,785,637

	December 31,	
	2016	2015
Balance Sheet Data:		
Cash and cash equivalents	$ 36,093	$ 21,498
Other current assets	4,194	11,243
Other noncurrent assets	22,269	51,396
Total assets	62,556	84,137
Current liabilities	24,746	49,686
Other long term liabilities	34,325	36,783
Secured term debt – net of current portion and discount	28,677	26,264
Convertible debt, net of discount	—	183,457
Total liabilities	87,748	296,190
Series E redeemable convertible units	—	58,856
Total stockholders' deficit	(25,192)	(270,909)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a fully integrated biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address disease areas of significant unmet medical need. We are developing product candidates within autoimmune and fibrotic diseases, oncology and genetic diseases. We leverage our multi-disciplinary research and clinical development team members, who prior to joining Kadmon had brought more than 15 drugs to market, to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing our small molecule and biologics platforms. By retaining global commercial rights to our lead product candidates, we believe that we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. We expect to continue to progress our clinical candidates and have clinical trial data to report throughout 2017.

Our operations to date have been focused on developing first-in-class innovative therapies for indications with significant unmet medical needs while leveraging our commercial infrastructure. We have never been profitable and had an accumulated deficit of $155.7 million at December 31, 2016. Our net losses were $208.8 million, $147.1 million and $64.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. Although our commercial business generates revenue, we expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our additional product candidates, hire additional personnel and initiate commercialization of any products that receive regulatory approval. We anticipate that our expenses will increase substantially if, or as, we:

- invest significantly to further develop our most advanced product candidates, including KD025, tesevatinib and KD034;
- initiate additional clinical trials and preclinical studies for our other product candidates;
- seek regulatory approval for our product candidates that successfully complete clinical trials;
- continue to invest in our ROCK2 inhibitor and other research platforms;
- seek to identify additional product candidates;
- scale up our sales, marketing and distribution infrastructure and product sourcing capabilities;
- acquire or in-license other product candidates and technologies;
- scale up our operational, financial and management information systems and personnel, including personnel to support our product development;
- make milestone or other payments under any in-license agreements;
- maintain, expand and protect our intellectual property portfolio; or
- operate as a public company.

On July 26, 2016, prior to the closing of our IPO we completed a corporate conversion transaction whereby we converted from a Delaware limited liability company into a Delaware corporation and changed our name to Kadmon Holdings, Inc., which we refer to herein as the "Corporate Conversion." As required by the Second Amended and Restated Limited Liability Company Agreement of Kadmon Holdings, LLC, the Corporate Conversion was approved by our board of directors. In connection with the Corporate Conversion, holders of our outstanding units received one share of common stock for every 6.5 membership units held immediately prior to the Corporate Conversion, and options and warrants to purchase units became options and warrants to purchase one share of common stock for each unit underlying such options or warrants immediately prior to the Corporate Conversion, at the same aggregate exercise price in effect prior to the Corporate Conversion.

Components of Statement of Operations

Revenue

Our revenue is substantially derived from sales of our portfolio of products, including our ribavirin portfolio of products and to a lesser extent sales of tetrabenazine and valganciclovir. No meaningful revenue has been generated from sales of Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine. Revenue also includes the recognition of upfront licensing fees and milestone payments received primarily under our license agreement with AbbVie.

Cost of Sales

Cost of sales consists of product costs, including ingredient costs and costs of contract manufacturers for production, and shipping and handling of the products. Also included are costs related to quality release testing and stability testing of the products. Other costs included in cost of sales are packaging costs, warehousing costs and certain allocated costs related to management, facilities and other expenses associated with supply chain logistics.

Research and development expenses

Research and development expenses and selling, general and administrative expenses have been revised to conform to the current presentation with regard to our method of allocating a portion of facility-related expenses to research and development expenses. Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- license fees related to our license and collaboration agreements;
- research and development-based employee-related expenses, including salaries, benefits, travel and other compensation expenses;
- expenses incurred under our agreements with contract research organizations that conduct nonclinical and preclinical studies, and clinical sites and consultants that conduct our clinical trials;
- costs associated with regulatory filings;
- costs of laboratory supplies and the acquisition, development and manufacture of preclinical and clinical study materials and study drugs; and/or
- allocated facility-related expenses.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials. We do not allocate personnel-related costs, including stock-based compensation, costs associated with broad technology platform improvements and other indirect costs to specific product candidates. We do not allocate these costs to specific product candidates because they are deployed across multiple overlapping projects under development, making it difficult to specifically and accurately allocate such costs to a particular product candidate.

The successful development of our product candidates is highly uncertain and subject to numerous risks including, but not limited to:

- the scope, rate of progress and expense of our research and development activities;
- clinical trial results;
- the scope, terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost, timing and our ability to acquire sufficient clinical and commercial supplies for any product candidates and products that we may develop; and/or
- the risks disclosed in the section entitled “Risk Factors” in this Annual Report on Form 10-K.

A change in the outcome of any of these variables could mean a significant change in the expenses and timing associated with the development of any product candidate.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for non-research personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, commercial, regulatory, pharmacovigilance and human resource functions. Other selling, general and administrative expenses include facility-related costs, commercial royalty expense and director compensation, accounting and legal services, consulting costs and programs and marketing costs to support the commercial business.

Other income (expense)

Other income (expense) is comprised of interest income earned on cash and cash equivalents and restricted cash and interest expense on our outstanding indebtedness, including paid-in-kind interest on our convertible debt and non-cash interest related to the write-off and amortization of debt discount and deferred financing costs associated with our indebtedness. Our loss on equity method investment in MeiraGTx, as well as, gains and losses arising from changes in fair value of our financial instruments are recognized in other income (expense) in the consolidated statements of operations. Such financial instruments include a success fee and warrant liabilities for which the exercise price was contingent on our per share price in a qualified public offering. The change in fair value is based upon the fair value of the underlying security at the end of each reporting period, as calculated using the Black-Scholes option pricing model, in the case of certain warrant liabilities and the success fee, and a binomial model, in the case of certain warrant liabilities.

In addition, we operate in currencies other than the U.S. dollar to fund research and development and commercial activities performed by various third-party vendors. The translation of these currencies into U.S. dollars results in foreign currency gains or losses, depending on the change in value of these currencies against the U.S. dollar. These gains and losses are included in other income (expense).

Income taxes

Prior to the Corporate Conversion, we were a limited liability company but taxed as a C corporation for federal and state tax purposes. On July 26, 2016, we converted from a limited liability company to a Delaware corporation pursuant to a statutory conversion. At December 31, 2016 and 2015, we had a deferred tax liability of $1.3 million and a full valuation allowance for our deferred tax assets. We experienced ownership changes under Internal Revenue Code Section 382 in 2010, 2011 and 2016, which limits our ability to utilize net operating loss carry-forwards. We did not reduce the gross deferred tax assets related to the net operating loss carry-forwards, however, because the limitations do not hinder our ability to potentially utilize all of the net operating loss carry-forwards

As of December 31, 2016, we have unused federal and state net operating loss carry-forwards of $432.8 million and $362.9 million, respectively, that may be applied against future taxable income. These carry-forwards expire at various dates through December 31, 2036. We recorded a valuation allowance to fully offset the gross deferred tax asset, because it is more likely than not that we will not realize future benefits associated with these deferred tax assets at December 31, 2016 and December 31, 2015.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reporting amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to intangible assets and goodwill, derivative liabilities, unit-based compensation and accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our significant accounting policies are more fully described in Note 3, "Summary of Significant Accounting Policies" of the notes to our audited consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K.

Share-based compensation expense

Prior to our IPO, we were a privately held company with no active public market for our Class A units. Therefore, our management had estimated the fair value of our Class A units at various dates considering our most recently available third-party valuations of Class A units and management's assessment of additional objective and highly subjective factors that it believed were relevant. The consummation of our IPO on August 1, 2016 established a public trading market for shares of our common stock; therefore it is no longer necessary for management to estimate the fair value of our equity in connection with our accounting for granted stock options. In the absence of a public trading market for shares of our common stock, we applied the fair value recognition provisions of FASB ASC Topic 718, "Compensation—Stock Compensation." ASC 718 requires all unit-based payments to employees and directors, including unit option grants and modifications to existing unit options, to be recognized in the statements of operations based on their fair values. We recognize compensation expense over the period during which the recipient renders the required services using the straight-line, single option method.

In the fourth quarter of 2016, we adopted ASU 2016-09, "*Compensation—Stock Compensation.*" ASU 2016-09 requires that certain amendments relevant to us be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to accumulated deficit as of the beginning of the period in which the guidance is adopted. As a result of adopting ASU 2016-09 during the three months ended December 31, 2016, we adjusted accumulated deficit for amendments related to an entity-wide accounting policy election to recognize share-based award forfeitures only as they occur rather than estimate a forfeiture rate. We recorded a $2.0 million charge to accumulated deficit as of January 1, 2016 and an associated credit to additional paid-in capital for previously unrecognized stock compensation expense as a result of applying this policy election. Upon the election, we also recorded $0.8 million in additional share-based compensation expense related to the nine months ended September 30, 2016 in the quarter ended December 31, 2016. When the consolidated statement of operations for the three months ended March 31, June 30 and September 30, 2016 is presented in future periods, it will include $0.3 million, $0.3 million and $0.2 million of additional share-based compensation expense.

ASU 2016-09 also requires the recognition of the income tax effects of awards in the consolidated statement of operations when the awards vest or are settled, thus eliminating addition paid-in capital pools. We elected to adopt the amendments related to the presentation of excess tax benefits on the condensed consolidated statement of cash flows using a prospective transition method.

As there had been no public market for our Class A units prior to our IPO, the estimated fair value of our Class A units had been determined contemporaneously by our board of directors utilizing independent third-party valuations prepared in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, also known as the Practice Aid for financial reporting purposes. We performed contemporaneous valuations of our Class A units concurrently with the achievement of significant milestones or with major financing events as of October 31, 2014 ($39.00) and September 30, 2015 ($32.50). In conducting these valuation analyses, we considered all objective and subjective factors that we believed to be relevant for each valuation conducted, including:

- recent equity financings and the related valuations;
- industry information such as market size and growth;
- market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and/or
- macroeconomic conditions.

On July 13, 2016, the compensation committee of our board of directors approved an option award for Dr. Harlan W. Waksal, increasing the number of options (giving effect to the Corporate Conversion) subject to his original option grant. The number of shares subject to this option award was equal to the difference between the 769,231 options originally granted to Dr. Harlan W. Waksal and 5% of our outstanding common equity determined on a fully diluted basis on the IPO date, which amounted to 1,630,536 options. The effective date of the new option award was the IPO date of July 26, 2016. The exercise price per share of common stock subject to the new incremental options awarded was equal to the price per share of common stock at the IPO date of $12.00. The option award is subject to the same vesting schedule applicable to the original option grant such that all options awarded will vest on August 4, 2017. In consideration for the new option award, Dr. Harlan W. Waksal has committed to perform an additional year of service through August 4, 2018 in connection with receipt of the additional option shares. In the event Dr. Harlan W. Waksal voluntarily terminates his employment prior to completion of this additional year of service, Dr. Harlan W. Waksal shall forfeit 25% of the additional options, or 25% of the aggregate additional option gain associated with the additional option shares in the event the options are exercised, as applicable. This modification resulted in a $12.4 million charge, of which the incremental value of the previously vested portion of the awards totaling $8.3 million was expensed during the third quarter of 2016 and the remaining amount of the unvested portion totaling $4.1 million will be recognized over the remaining service period through August 4, 2018.

The assumptions relating to the valuation of our options granted for the years ended December 31, 2016, 2015 and 2014 are shown below.

	Year Ended		
	December 31, 2016	December 31, 2015	December 31, 2014
Weighted average fair value of grants	$7.12	$20.67	$28.15
Expected volatility	74.98% - 79.35%	77.23% - 93.85%	58.70% - 93.94%
Risk-free interest rate	1.15% - 2.20%	1.54% - 1.93%	1.73% - 1.81%
Expected life	5.0 - 6.0 years	5.2 - 6.0 years	5.5 - 6.0 years
Expected dividend yield	0%	0%	0%

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2014, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options	Fair Value of Common Stock per Share on Date of Option Grant	Per Share Estimated Fair Value of Options
October 10, 2014	74,462	$ 39.00 (1)	$ 45.50	$ 25.22
December 31, 2014	160,769	$ 39.00	$ 39.00	$ 29.51
January 5, 2015	8,693	$ 39.00	$ 39.00	$ 28.99
January 12, 2015	193	$ 39.00	$ 39.00	$ 29.64
August 1, 2015	17,437	$ 39.00	$ 39.00	$ 28.08
December 31, 2015	769,231	$ 39.00 (2)	$ 39.00	$ 19.83
December 31, 2015	359,379	$ 32.50 (3)	$ 32.50	$ 21.91
July 26, 2016	1,630,536	$ 12.00	$ 12.00	$ 7.60
December 15, 2016	3,227,924	$ 4.66	$ 4.66	$ 3.06

(1) At the time of the option grants on October 10, 2014, management determined that the fair value of our Class A membership units of $45.50 per unit calculated in the valuation as of May 31, 2014 reasonably reflected the per unit fair value of Class A membership units as of the grant date. However, as described below, the exercise price of these grants was adjusted to $39.00 per unit.

(2) In December 2014, our board of directors approved an option grant to the Chief Executive Officer when the fair value of our Class A membership units was $39.00 per unit calculated in the valuation as of October 31, 2014. The option grant was not issued until December 31, 2015, however, management determined that the exercise price should be the fair value of our Class A membership units when the grant was approved by our board of directors in December 2014 of $39.00 per unit.

(3) At the time of the option grants on December 31, 2015, management determined that the fair value of our Class A membership units of $32.50 per unit calculated in the valuation as of September 30, 2015 reasonably reflected the per unit fair value of Class A membership units as of the grant date.

In January 2015, the compensation committee of our board of directors approved the amendments of all outstanding option awards under the 2011 Equity Incentive Plan with an exercise price above $39.00 per unit to reduce the exercise price of such options to $39.00 per unit, the estimated fair value of our Class A membership units as of October 31, 2014. The vesting schedule of such awards was not amended. The amendment to the option awards resulted in a modification charge of $1.1 million, of which $668,000 was expensed immediately during the first quarter of 2015 and the remaining amount is being recognized over the vesting periods of each award, which range from one to two years.

On July 13, 2016, the compensation committee of our board of directors approved the amendment of all outstanding option awards issued under our 2011 Equity Incentive Plan whereby, effective upon pricing of our IPO, the exercise price (on a post-Corporate Conversion, post-split basis) was adjusted to equal the price per share of our common stock in the IPO. Options to purchase an aggregate of approximately 1.6 million shares of our Class A units were modified. The vesting schedule of such awards was not modified. The modification resulted in a $4.0 million charge, of which the incremental value of the previously vested portion of the awards totaling $1.8 million was expensed immediately during the third quarter of 2016 and the remaining $2.2 million will be recognized over the remaining vesting periods of each award. These vesting periods range from one to three years.

A total of 9,750 units were granted under the LTIP at December 31, 2016 and 2015. The liability and associated compensation expense for these awards was recognized upon consummation of our IPO on August 1, 2016. No compensation expense had been recorded prior to this date. We utilized a Monte-Carlo simulation to determine the fair value of the awards granted under the LTIP of $22.6 million, which was recorded during the third quarter of 2016 as these awards are not forfeitable. The LTIP is payable upon the fair market value of our common stock exceeding 333% of the $6.00 grant price ($20.00) per share prior to December 7, 2024. The holders of the LTIP have no right to demand a particular form of payment, and we reserve the right to make payment in the form of cash or common stock.

Recent Accounting Pronouncements

See Note 3 “Summary of Significant Accounting Policies,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a summary of recently issued and adopted accounting pronouncements.

Results of Operations

	Years Ended December 31,		
	2016	2015	2014
	(in thousands)		
Revenues			
Net sales	$ 18,514	$ 29,299	$ 63,530
License and other revenue	7,541	6,420	31,488
Total revenue	26,055	35,719	95,018
Cost of sales	3,485	3,731	6,123
Write-down of inventory	385	2,274	4,916
Gross profit	22,185	29,714	83,979
Operating expenses:			
Research and development	35,840	33,558	32,947
Selling, general and administrative	105,880	104,740	89,321
Impairment of intangible asset	—	31,269	—
Gain on settlement of payable	(4,131)	—	—
Total operating expenses	137,589	169,567	122,268
Loss from operations	(115,404)	(139,853)	(38,289)
Other expense	93,009	7,232	26,096
Income tax expense (benefit)	342	(3)	(29)
Net loss	$ (208,755)	$ (147,082)	$ (64,356)
Deemed dividend on convertible preferred stock and Class E redeemable convertible units	21,733	—	—
Net loss attributable to common stockholders	$ (230,488)	$ (147,082)	$ (64,356)

Comparison of the years ended December 31, 2016 and 2015

Revenues

Total revenue decreased by 26.9%, or approximately $9.6 million, from $35.7 million in the year ended December 31, 2015 to $26.1 million for the year ended December 31, 2016. The decrease in total revenue was primarily attributable to the decline in sales of our ribavirin portfolio products. The decrease in total revenue for the year ended December 31, 2016 was partially offset by a $2.0 million milestone payment earned pursuant to a license agreement entered into with Jinghua to develop products using human monoclonal antibodies. We recognized previously deferred revenue from our license and collaboration agreements amounting to $4.4 million for each of the years ended December 31, 2016 and 2015, respectively. Service revenue from our affiliate MeiraGTx Limited (MeiraGTx) was $1.0 million for each of the years ended December 31, 2016 and 2015.

International product sales represented approximately 21.0% and 10.0% of total product sales for the years ended December 31, 2016 and 2015, respectively, the majority of which were sales in Germany and Ireland.

Sales from our ribavirin portfolio continued to decline in 2016, from $29.3 million for the year ended December 31, 2015 to $17.0 million for the year ended December 31, 2016 as the treatment landscape for chronic HCV infection has rapidly evolved, with multiple ribavirin-free treatment regimens, including novel direct-acting antivirals, having entered the market and becoming the new standard of care. As a result, we expect sales of our ribavirin portfolio of products to contribute insignificantly to revenue in 2017 and beyond.

We recognized revenue of $0.6 million from sales of tetrabenazine during the year ended December 31, 2016. No revenue was generated from sales of tetrabenazine in 2015. We recognized revenue of $0.9 million from sales of valganciclovir during the year ended December 31, 2016. No revenue was generated from sales of valganciclovir in 2015. No meaningful revenue was generated from sales of Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine for the years ended December 31, 2016 and 2015.

On November 4, 2016, we notified Vivus that we will not renew our agreement for the co-promotion of Qsymia®, and therefore the agreement terminated on December 31, 2016. No meaningful revenue was generated under this agreement for each of the years ended December 31, 2016 and 2015, and as a consequence of the termination of the agreement we will not generate any revenue from the co-promotion of Qsymia® after December 31, 2016.

Cost of sales

Cost of sales was $3.5 million and $3.7 million for the years ended December 31, 2016 and 2015, respectively, which relates primarily to the sales volume of our ribavirin portfolio of products.

Write-down of inventory

We recognized $0.4 million and $2.3 million of inventory write-downs during the years ended December 31, 2016 and 2015, respectively, of our Ribasphere inventory based on our expectation that such inventory will not be sold prior to reaching its product expiration date.

Research and development expenses

Research and development expenses increased by 6.6%, or approximately 2.2 million, to $35.8 million, including $3.0 million of non-cash items, for the year ended December 31, 2016 from $33.6 million, including $2.2 million of non-cash items, for the year ended December 31, 2015. The increase in research and development expense was primarily related to unallocated internal and external costs of developing our product candidates across multiple projects. For the years ended December 31, 2016 and 2015, we recognized $4.8 million and $4.6 million, respectively, in development expenses for tesevatinib; $2.2 million and $3.0 million, respectively, for KD025; $1.6 million and $1.0 million, respectively, for KD034; $1.4 million and $2.5 million, respectively, for other product candidates; and $25.8 million and $22.5 million, respectively, was related to unallocated internal and external costs of developing our product candidates across multiple projects.

In June 2016, research and development expenses, and selling, general and administrative expenses were revised to conform to the current presentation with regard to our method of allocating a portion of facility-related expenses to research and development expenses to more accurately reflect the effort spent on research and development. We reclassified $2.2 million and $3.9 million from selling, general and administrative expense to research and development expense for the years ended December 31, 2016 and 2015, respectively.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by 1.1%, or approximately $1.2 million, to $105.9 million, including $69.1 million of non-cash items, for the year ended December 31, 2016 from $104.7 million, including $61.8 million of non-cash items, for the year ended December 31, 2015. The increases in selling, general and administrative expenses is primarily related to an increase in share-based compensation of $36.9, of which $22.0 million is related to the LTIP, $3.6 million is related to the repricing of employee options, $9.3 million is related to an option grant to our Chief Executive Officer, and $3.0 million is related to an increase in severance expense primarily related to the separation agreement with Dr. Samuel D. Waksal. These increases were partially offset by a decrease in salary and salary-related expenses of $3.7 million related to a reduction in headcount, legal expense of $17.6 million related to legal settlements entered into during 2015, amortization of intangible assets of $12.2 million due to a change to proportional performance method of amortization starting October 1, 2015, royalty expense of $1.5 million and consulting fees of $3.0 million resulting from the expiration of an advisory agreement entered into in April 2015.

Impairment loss on intangible asset

In September 2015, we reviewed the estimated useful life of the Ribasphere product rights and determined that the actual life of the Ribasphere product rights intangible asset was shorter than the estimated useful life used for amortization purposes in our financial statements due to changes in HCV market conditions. As a result, effective September 30, 2015, we changed the estimate of the useful life of our Ribasphere product rights intangible asset to 1.25 years to better reflect the estimated period during which the asset will generate cash flows. We also determined that the estimated fair value of the Ribasphere product rights was impaired and recorded an impairment loss of $31.3 million in September 2015.

Gain on settlement of payable

Gain on settlement of payable is primarily related to a gain of $3.9 million resulting from the mutual termination agreement entered into with Valeant during the first quarter of 2016.

Other expense

The following table provides components of other expense:

	Years Ended December 31,	
	2016	2015
	(in thousands)	
Interest expense	$ 3,782	$ 7,817
Interest expense - beneficial conversion feature	45,915	—
Interest paid-in-kind	14,695	11,434
Write-off of deferred financing costs and debt discount	3,820	2,752
Amortization of deferred financing costs and debt discount	4,422	5,157
Loss on extinguishment of debt	11,176	2,934
Change in fair value of financial instruments	(4,380)	(1,494)
Gain on deconsolidation of subsidiary	—	(24,000)
Loss on equity method investment	13,625	2,776
Other income	(46)	(144)
Other expense	**$ 93,009**	**$ 7,232**

For the year ended December 31, 2016, other expense consisted primarily of interest expense and other costs related to our debt of $72.6 million, a loss on extinguishment of debt of $11.2 million related to the June 2016 Exchange Agreements, loss on equity method investment in MeiraGTx of $13.6 and a change in the fair value of financial instruments of $4.4 million.

For the year ended December 31, 2015, other expense consisted primarily of interest expense and other costs related to our debt of $27.2 million, a loss on extinguishment of debt of $2.9 million related to an amendment to our Senior Convertible Term Loan and a loss on equity method investment in MeiraGTx of $2.8 million, partially offset by a $24.0 million gain recognized upon the deconsolidation of MeiraGTx and a change in the fair value of financial instruments of $1.5 million.

Income taxes

Historically we were a limited liability company taxed as a C corporation for federal and state tax purposes. On July 26, 2016, we effected the Corporate Conversion whereby we converted from a Delaware limited liability company to a Delaware corporation pursuant to a statutory conversion. For the year ended December 31, 2016, we recorded income tax expense of $0.3 million related to the $2.0 million milestone payment received from Jinghua. No income tax expense was recorded for the year ended December 31, 2015.

Deemed Dividend

We calculated a deemed dividend on the Class E redeemable convertible units of $13.4 million in August 2016, which equaled a 15% discount to the price per share of our common stock of $12.00 in the IPO upon conversion to common stock at our IPO due to a beneficial conversion feature. The Class E redeemable convertible units converted into common stock at our IPO resulting in no Class E redeemable convertible units outstanding at December 31, 2016.

At our IPO, we issued 30,000 shares of convertible preferred stock which accrues dividends at a rate of 5% and converts into shares of our common stock at a 20% discount to the price per share of our common stock of $12.00 in the IPO. We calculated a deemed dividend on the convertible preferred stock of $7.5 million in August 2016, which equals the 20% discount to the price per share of our common stock in the IPO of $12.00, a beneficial conversion feature. We also accrued dividends on the convertible preferred stock of $0.6 million for the year ended December 31, 2016.

Comparison of the years ended December 31, 2015 and 2014

Revenues

Total revenue decreased by 62.4%, or approximately $59.3 million, to $35.7 million for the year ended December 31, 2015 from $95.0 million for the year ended December 31, 2014. The decrease was mostly attributable to the 2014 launches of novel direct-acting antivirals by other pharmaceutical companies. As a result of these launches, we expect sales of our ribavirin portfolio of products to continue to decrease.

We recognized milestone revenue from our license agreement with AbbVie amounting to $27.0 million for the year ended December 31, 2014, while no such milestone revenue was recognized in 2015. We also recognized previously deferred

revenue from our license and collaboration agreements amounting to $5.4 million and $4.4 million for the years ended December 31, 2015 and 2014, respectively, and service revenue of $1.0 million for the year ended December 31, 2015, while no such service revenue was recognized in 2014.

Cost of sales

Cost of sales decreased by 39.2%, or approximately $2.4 million, to $3.7 million for the year ended December 31, 2015 from $6.1 million for the year ended December 31, 2014. The decrease was a direct result of lower sales of our ribavirin portfolio of products.

Write-down of inventory

We recognized $2.3 million and $4.9 million of inventory write-downs during the years ended December 31, 2015 and 2014, respectively, of our Ribasphere inventory based on our expectation that such inventory will not be sold prior to reaching its product expiration date.

Research and development expenses

Research and development expenses increased by 2.1%, or approximately $0.7 million, to $33.6 million for the year ended December 31, 2015 from $32.9 million for the year ended December 31, 2014, primarily related to the advancement of our clinical product candidates. For the years ended December 31, 2015 and 2014, we recognized $4.6 million and $4.8 million, respectively, in development expenses for tesevatinib; $3.0 million and $2.9 million, respectively, for KD025; $1.0 million and $0.2 million, respectively, for KD034; $2.5 million and $1.6 million, respectively, for other product candidates; and $22.5 million and $23.5 million, respectively, was related to unallocated internal and external costs of developing our product candidates across multiple projects.

In June 2016, research and development expenses, and selling, general and administrative expenses were revised to conform to the current presentation with regard to our method of allocating a portion of facility-related expenses to research and development expenses to more accurately reflect the effort spent on research and development. We reclassified $3.9 million and $3.8 million from selling, general and administrative expense to research and development expense for years ended December 31, 2015 and 2014.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by 17.2%, or approximately $15.4 million, to $104.7 million for the year ended December 31, 2015 from $89.3 million for the year ended December 31, 2014. The increase was primarily related to higher amortization expense related to our Ribasphere intangible asset of $5.6 million, additional rent expense of $1.0 million and an increase of $24.4 million in advisory and consulting fees and legal settlements, $24.0 million of which were non-cash. The increase was partially offset by lower employee costs of $6.6 million as a result of headcount reductions, lower royalty and other sales related expenses of $3.8 million in connection with revenue declines and lower travel, entertainment and other general and administrative expenses of $2.3 million in connection with cost-savings initiatives.

Impairment loss on intangible asset

In September 2015, we reviewed the estimated useful life of the Ribasphere product rights and determined that the actual life of the Ribasphere product rights intangible asset was shorter than the estimated useful life used for amortization purposes in our financial statements due to hepatitis C market conditions. As a result, effective September 30, 2015, we changed the estimate of the useful life of our Ribasphere product rights intangible asset to 1.25 years to better reflect the estimated period during which the asset will generate cash flows. We also determined that the estimated fair value of the Ribasphere product rights was impaired and recorded an impairment loss of $31.3 million in September 2015.

Other expense

The following table provides components of other expense:

	Years Ended December 31,	
	2015	2014
	(in thousands)	
Interest expense	$ 7,817	$ 12,204
Interest paid-in-kind	11,434	13,374
Amortization of deferred financing costs and debt discount	5,157	3,333
Write-off of deferred financing costs and debt discount	2,752	—
Loss on extinguishment of debt	2,934	4,579
Change in fair value of financial instruments	(1,494)	(4,969)
Gain on deconsolidation of subsidiary	(24,000)	—
Loss on equity method investment	2,776	—
Other income	(144)	(2,425)
Other expense	**$ 7,232**	**$ 26,096**

For the year ended December 31, 2015, other expense consisted primarily of interest expense and other costs related to our debt of $27.2 million, a loss on extinguishment of debt of $2.9 million related to an amendment to our Senior Convertible Term Loan and a loss on equity method investment in MeiraGTx of $2.8 million, partially offset by a $24.0 million gain recognized upon the deconsolidation of MeiraGTx and a change in the fair value of financial instruments of $1.5 million.

For the year ended December 31, 2014, other expense consisted primarily of interest expense and other costs related to our debt of $28.9 million and a $4.6 million loss on extinguishment of debt, partially offset by a change in the fair value of financial instruments of $5.0 million and a gain on settlement of obligations of $2.3 million.

Non-GAAP Financial Measures

To supplement our financial results determined in accordance with GAAP, we have also disclosed in the tables below non-GAAP adjusted earnings and non-GAAP adjusted earnings per share for the years ended December 31, 2016 and 2015. These financial measures exclude the impact of certain items and, therefore, have not been calculated in accordance with GAAP. These non-GAAP financial measures exclude beneficial conversion features and deemed dividends recorded in connection with our IPO and Corporate Conversion (comprehensively Adjustment Items). In addition, from time to time in the future there may be other items that we may exclude for the purposes of our non-GAAP financial measures; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of our non-GAAP financial measures. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our operating results because they exclude amounts that management and the board of directors do not consider part of core operating results or that are non-recurring when assessing the performance of the organization. We believe that inclusion of these non-GAAP financial measures provides consistency and comparability with past reports of financial results and provides consistency in calculations by outside analysts reviewing our results. Accordingly, we believe these non-GAAP financial measures are useful to investors in allowing for greater transparency of supplemental information used by management.

We believe that non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, but there are limitations associated with the use of these non-GAAP financial measures. These non-GAAP financial measures are not prepared in accordance with GAAP, do not reflect a comprehensive system of accounting and may not be completely comparable to similarly titled measures of other companies due to potential differences in the exact method of calculation between companies. Adjustment items that are excluded from our non-GAAP financial measures can have a material impact on net earnings. As a result, these non-GAAP financial measures have limitations and should not be considered in isolation from, or as a substitute for, net loss and its components, earnings per share, or other measures of performance prepared in accordance with GAAP. We compensate for these limitations by using these non-GAAP financial measures as supplements to GAAP financial measures and by reconciling the non-GAAP financial measures to their most comparable GAAP financial measure. Investors are encouraged to review the reconciliations of the non-GAAP financial measures to their most comparable GAAP financial measures that are included elsewhere in this Annual Report on Form 10-K.

Reconciliation of GAAP net loss to non-GAAP adjusted earnings are as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2016	2015	2014
		(unaudited)	
Reported GAAP net loss attributable to common stockholders	$ (230,488)	$ (147,082)	$ (64,356)
Interest expense - beneficial conversion feature (1)	45,915	—	—
Deemed dividends (2)	20,931	—	—
Non-GAAP adjusted net loss attributable to common stockholders	$ (163,642)	$ (147,082)	$ (64,356)
Reported GAAP basic and diluted net loss per share of common stock	$ (9.74)	$ (18.10)	$ (8.27)
Impact of Adjustment Items	2.82	—	—
Non-GAAP adjusted basic and diluted net loss per share of common stock	$ (6.92)	$ (18.10)	$ (8.27)
Weighted average basic and diluted shares of common stock outstanding	23,674,512	8,127,781	7,785,637

(1) To exclude the beneficial conversion feature of our debt upon conversion into shares of our common stock on August 1, 2016. This adjustment also includes the beneficial conversion feature of certain outstanding warrants which became exercisable into shares of our common stock on August 1, 2016 (see Note 8, “Financial Instruments,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

(2) To exclude the beneficial conversion feature of our Series E redeemable convertible units upon conversion into shares of our common stock on August 1, 2016 and our convertible preferred stock which converts into shares of our common stock at a 20% discount to the IPO price of $12.00 per share (see Note 4, “Stockholders’ Deficit,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

Liquidity and Capital Resources

Overview

Since inception, we have incurred operating losses and anticipate that we will continue to incur operating losses for the next several years. We expect that our research and development and selling, general and administrative expenses will continue to increase as we develop our product candidates. As a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. As set forth in the second amendment to the 2015 Credit Agreement we are required to maintain certain covenants and to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. At December 31, 2016, we had $36.1 million in cash and cash equivalents and $2.1 million in restricted cash pursuant to leases for our facilities located in New York, New York, and Cambridge, Massachusetts.

In June 2016, we raised $5.5 million in gross proceeds, with no transaction costs, through the issuance of 478,266 Class E redeemable convertible units and we raised $66.0 million, net of underwriting discounts and commissions and offering costs, in our IPO which closed on August 1, 2016. Additionally, in March 2017, we raised $22.7 million in gross proceeds, $21.3 million net of placement agent fees, from the issuance of 6,767,855 shares of our common stock, at a price of $3.36 per share, and warrants to purchase 2,707,138 million shares of our common stock at an initial exercise price of $4.50 per share and a term of 13 months from the date of issuance, which is expected to continue to enable us to advance our planned Phase 2 clinical studies for KD025 and tesevatinib and advance certain of our other pipeline product candidates.

Going Concern

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate our continuation as a going concern. We have not established a source of revenues sufficient to cover our operating costs, and as such, have been dependent on funding operations through the issuance of debt and sale of equity securities. We expect to incur further losses over the next several years as we develop our business. Further, at December 31, 2016, we had working capital of $15.5 million. Our accumulated deficit amounted to $155.7 million and $643.8 million at December 31, 2016 and 2015, respectively. Net cash used in operating activities was $53.0 million, $61.0 million and $8.5 million for years ended December 31, 2016, 2015 and 2014.

We must raise additional capital to fund our continued operations and remain in compliance with our debt covenants. We may not be successful in our efforts to raise additional funds or achieve profitable operations. Amounts raised will be used for further development of our product candidates, to provide financing for marketing and promotion, to secure additional property and equipment, and for other working capital purposes. Even if we are able to raise additional funds through the sale of our equity securities, or loans from financial institutions, our cash needs could be greater than anticipated in which case we could be forced to raise additional capital.

In March 2017, we raised $22.7 million in gross proceeds, $21.3 million net of placement agent fees, from the issuance of 6,767,855 shares of our common stock, at a price of $3.36 per share, and warrants to purchase 2,707,138 million shares of our common stock at an initial exercise price of $4.50 per share and a term of 13 months from the date of issuance. In connection with the offering, we have agreed to file a registration statement to register the shares of common stock underlying the common stock and warrants for resale. Under the agreement, the registration statement must be filed within 30 days of the closing of the financing and declared effective within the timeline provided in the agreement. If the applicable deadlines are not met, monthly liquidated damages of 2.0% of the subscription amount (with an 8.0% cap) will be due to the purchaser. At the present time, we have no commitments for any additional financing, and there can be no assurance that, if needed, additional capital will be available to us on commercially acceptable terms or at all. If we cannot obtain the needed capital, we may not be able to become profitable and may have to curtail or cease our operations. These and other factors raise substantial doubt about our ability to continue as a going concern. The Independent Registered Public Accounting Firm’s Report issued in connection with our audited consolidated financial statements for the year ended December 31, 2016 stated that there is “substantial doubt about our ability to continue as a going concern.” The accompanying financial statements do not include any adjustments or classifications that may result from the possible inability of us to continue as a going concern.

Sources of Liquidity

Since our inception through December 31, 2016, we have raised net proceeds from the issuance of Class A membership units of approximately $272.9 million, proceeds from the issuance of Class E redeemable convertible units of $55.2 million and net proceeds from the issuance of common stock in our IPO of $66.0 million. At December 31, 2016, we had $34.6 million of outstanding loans under the 2015 Credit Agreement. The Senior Convertible Term Loan and Second-Lien Convert were mandatorily converted into shares of our common stock at a conversion price equal to 80% of the IPO price per share of common stock in our IPO, or $9.60 per share.

On November 4, 2016, we executed a second amendment to the 2015 Credit Agreement. Pursuant to this amendment, we deferred further principal payments owed under the 2015 Credit Agreement in the amount of $380,000 per month until August 31, 2017. Additionally, the parties amended various clinical development milestones and added a covenant pursuant to which we are required to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. All other material terms of the 2015 Credit Agreement, including the maturity date, remain the same. This summary of the material terms of the amendment to the 2015 Credit Agreement is qualified in its entirety by reference to the full text of such amendment which is filed as an exhibit to this Annual Report on Form 10-K, which is incorporated by reference herein. As of the date hereof, we are not in default under the terms of the 2015 Credit Agreement. See Note 7, “Debt” of the notes to our audited consolidated financial statements included in this Annual Report on Form 10-K for more information.

The following table sets forth the primary sources and uses of cash and cash equivalents for each period set forth below:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (52,950)	$ (60,977)	$ (8,493)
Investing activities	(539)	(161)	(2,062)
Financing activities	68,084	61,645	(1,241)
Net increase (decrease) in cash and cash equivalents	$ 14,595	$ 507	$ (11,796)

Operating Activities

The net cash used in operating activities was $53.0 million for the year ended December 31, 2016, and consisted primarily of a net loss of $208.8 million adjusted for $157.2 million in non-cash items, including the amortization of intangible assets of $15.2 million, depreciation and amortization of fixed assets of $2.3 million, amortization and write-off of deferred financing costs and debt discount of $8.2 million, loss on extinguishment of debt of $11.2 million, fair value of units issued to third parties to settle obligations of $7.4 million, gain on settlement of payables of $4.1 million, paid-in-kind interest expense of $14.7 million, loss on equity method investment of $13.6 million, beneficial conversion feature expense on convertible debt and warrants of $45.9 million and share-based compensation expense of $47.2 million, as well as, a net decrease in operating assets and liabilities of $1.8 million. The net loss, adjusted for non-cash items, was primarily driven by selling, general and administrative expenses of $36.8 million, research and development expense related to the advancement of our clinical product candidates of $32.8 million and interest paid on our debt of $3.7 million, partially offset by the net sales less cost of sales primarily from our ribavirin portfolio of products of $15.0 million and milestone revenue from our license agreement with Jinghua amounting to $2.0 million.

The net cash used in operating activities was $61.0 million for the year ended December 31, 2015, and consisted primarily of a net loss of $147.1 million adjusted for $96.3 million in non-cash items, including the amortization and impairment of intangible assets of $58.7 million, depreciation of $2.3 million, amortization and write-off of deferred financing costs and debt discount of $7.9 million, gain on deconsolidation of subsidiary of $24.0 million, fair value of units issued to third parties to settle obligations of $13.6 million, accrued legal settlement of $10.4 million, loss on extinguishment of debt of $2.9 million, paid-in-kind interest expense of $11.4 million and share-based compensation expense of $10.3 million, as well as a net decrease in operating assets and liabilities of $10.5 million. The net loss, adjusted for non-cash items, was primarily driven by selling, general and administrative expenses of $42.9 million, research and development expense related to the advancement of our clinical product candidates of $31.4 million and interest paid on our debt of $8.0 million partially offset by the net sales (less cost of sales) of our ribavirin portfolio of products of $25.6 million.

The net cash used in operating activities was $8.5 million for the year ended December 31, 2014, and consisted primarily of a net loss of $64.4 million adjusted for non-cash items, including the amortization of intangible assets of $21.8 million, depreciation of $2.6 million, amortization of deferred financing costs and debt discount of $3.3 million, a loss on extinguishment of debt of $4.6 million, paid-in-kind interest expense of $13.4 million and unit-based compensation expense of $7.6 million, as well as a net increase in operating assets and liabilities of $3.5 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $6.0 million related to prepaid royalties received from AbbVie, an increase in restricted cash of $7.5 million related to our license agreement with AbbVie and a decrease in accounts receivable of $5.8 million due to successful collections from our customers, partially offset by a decrease in deferred revenue of $4.4 million related to the recognition of the $44.0 million upfront payment from the license agreement with AbbVie, a decrease of $13.0 million in accounts payable, accrued expenses, other liabilities and deferred rent primarily resulting from settlement of outstanding payables to our vendors. The net loss, adjusted for non-cash items, was primarily driven by selling,

general and administrative expenses of $54.8 million, research and development expense related to the advancement of our clinical product candidates of $29.1 million and interest paid on our debt of $11.5 million partially offset by the net sales (less cost of sales) of our ribavirin portfolio of products of $57.4 million and milestone revenue from our license agreement with AbbVie amounting to $27.0 million.

Investing Activities

Net cash used in investing activities was $0.5 million for the year ended December 31, 2016 consisting of costs related to leasehold improvements at our clinical office in Cambridge, Massachusetts and the purchase of property and equipment, primarily related to in-house software purchased to support our internal clinical data management group. Net cash used in investing activities was $0.2 million and $2.1 million for the years ended December 31, 2015 and 2014, respectively,consisting of costs related to the purchase of property and equipment, primarily related to in-house software purchased to support our internal clinical data management group.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2016 was $68.1 million, consisting primarily of proceeds from the issuance of common stock in our IPO of $69.8 million, net of underwriting discounts and commissions, and net proceeds from the issuance of Class E redeemable convertible units of $5.5 million, partially offset by payment of offerings costs of $3.3 million and repayment of the related party loan of $3.0 million.

Net cash provided by financing activities for the year ended December 31, 2015 was $61.6 million, consisting of proceeds from the issuance of secured term debt of $35.0 million, proceeds from the issuance of convertible debt of $112.5 million, net proceeds from the issuance of Class A membership units of $15.0 million and net proceeds from the issuance of Class E redeemable convertible units of $10.8 million, partially offset by the repayment of senior secured term debt of $107.2 million and payment of financing costs of $4.1 million.

Net cash used in financing activities for the year ended December 31, 2014 was $1.2 million, consisting of the repayment of senior secured term debt of $43.6 million, partially offset by net proceeds from the issuance of Class E redeemable convertible units of $38.8 million and net proceeds from related party loans of $3.5 million.

Future Funding Requirements

We expect our expenses to increase compared to prior periods in connection with our ongoing activities, particularly as we continue research and development, continue and initiate clinical trials and seek regulatory approvals for our product candidates. In anticipation of regulatory approval for any of our product candidates, we expect to incur significant pre-commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we expect to incur additional costs associated with operating as a public company.

In the second half of 2016, we implemented a number of strategic and operational changes to increase efficiency and to prioritize the continued rapid development of our clinical pipeline and drug discovery efforts. We have streamlined our corporate overhead, reducing headcount as well as fixed costs related to our New York facilities. Since July 2016, we have reduced our workforce by 16 percent, to 118 employees. Furthermore, we have implemented several cost-saving measures in our commercial operation to reduce overall selling, general and administrative expenses. In particular, we have streamlined our product inventory, distribution efforts and marketing expenses for our chronic HCV infection portfolio to align with the evolving treatment landscape and we have focused our field operations on prescribers, specialty pharmacies and payer landscapes while growing our capabilities to coincide with our expanded product portfolio and therapeutic area focus. There is no assurance that we will be able to achieve cost savings and benefits from our efforts to streamline our operations.

The expected use of our cash and cash equivalents at December 31, 2016 and the $22.7 million of gross proceeds raised in March 2017, represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, as well as any additional collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of our existing cash and cash equivalents and the $22.7 million of gross proceeds raised in March 2017. In addition, we plan to raise additional funds from the issuance of additional equity, and our management will retain broad discretion over the allocation of those funds as well.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2016:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Secured term debt	$ 34,620	$ 1,900	$ 32,720	$ —	$ —
Interest expense[1]	5,191	3,612	1,579	—	—
Operating leases[2]	45,005	5,796	11,740	11,083	16,386
Total[3]	$ 84,816	$ 11,308	$ 46,039	$ 11,083	$ 16,386

(1) Interest expense reflects our obligation to make cash interest payments in connection with our 2015 Credit Agreement at a rate of 10.375%.

(2) Operating lease obligations primarily reflect our obligation to make payments in connection with leases for our corporate headquarters and commercial headquarters distribution center.

(3) This table does not include: (a) milestone payments totaling $400.4 million which may become payable to third parties under license agreements as the timing and likelihood of such payments are not known with certainty; (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known with certainty; and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

Off-balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under the SEC rules.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risk and changes in interest rates. As of December 31, 2016, we had cash and cash equivalents of $36.1 million, consisting of cash and money market accounts. Due to the short-term duration of our investment portfolio, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

As of December 31, 2016, we had total debt payable of $30.6 million, which is variable-rate debt. Based on our variable-rate debt outstanding as of December 31, 2016, a 100 basis point change versus the market interest rates available on December 31, 2016 would result in an additional $0.3 million of interest expense annually.

Customer Concentrations

Sales to AbbVie accounted for approximately 27%, 11% and 20% of our aggregate net sales for the years ended December 31, 2016, 2015 and 2014, respectively. Sales to Richmond Pharmaceuticals, Inc. accounted for approximately 14% and 20% of our aggregate net sales for the years ended December 31, 2016 and 2015, respectively. Net accounts receivable from these customers totaled $0.1 million and $0.6 million at December 31, 2016 and 2015, respectively.

Supplier Concentrations

We may be exposed to supplier concentration risk. Due to requirements of the FDA and other factors, we are generally unable to make immediate changes to our supplier arrangements. Manufacturing services related to each of our pharmaceutical products are primarily provided by a single source. Our raw materials are also provided by a single source for each product. Management attempts to mitigate this risk through long-term contracts and inventory safety stock.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear beginning on page 129 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

At December 31, 2016, our management, with the participation of our principal executive officer and principal financial officer, evaluated 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). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, at December 31, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2016 that has materially affected, or is 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

Executive Officers and Directors

The following table sets forth the name, age as of March 8, 2017 and position of the individuals who currently serve as the directors and executive officers of Kadmon Holdings, Inc. The following also includes certain information regarding our directors' and officers' individual experience, qualifications, attributes and skills and brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors. Each executive officer shall serve until his or her successor is elected and qualified.

Name	Age	Position
Executive Officers		
Harlan W. Waksal, M.D.	63	President, Chief Executive Officer and Director
Konstantin Poukalov	33	Executive Vice President, Chief Financial Officer
Lawrence K. Cohen, Ph.D.	63	Executive Vice President, Business Development
Steven N. Gordon, Esq.	49	Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer
John Ryan, Ph.D., M.D.	73	Executive Vice President, Chief Medical Officer
Directors		
Bart M. Schwartz, Esq. (3)(4)	70	Chairman of the Board
Eugene Bauer, M.D. (1)(2)(4)	74	Director
D. Dixon Boardman (1)(2)(3)(4)	71	Director
Alexandria Forbes, Ph.D.	52	Director
Tasos G. Konidaris	50	Director
Steven Meehan (1)	52	Director
Thomas E. Shenk, Ph.D. (4)	70	Director
Susan Wiviott, J.D. (2)(3)(4)	59	Director
Louis Shengda Zan	53	Director

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee
(4) Member of the regulatory and compliance committee

Executive Officers

Harlan W. Waksal, M.D. Dr. Waksal has been our President and Chief Executive Officer since August 2014 and was elected to our board of directors in 2013. Prior to joining Kadmon as an employee, Dr. Waksal served as President and Sole Proprietor of Waksal Consulting LLC from 2003 to 2014. From 2011 to 2014, Dr. Waksal served as Executive Vice President, Business and Scientific Affairs at Acasti Pharma, Inc., a publicly traded biopharmaceutical company, and as a consultant to Neptune Technologies & Bioressources, Inc., a publicly traded life sciences company and the parent company of Acasti. Dr. Waksal co-founded ImClone Systems (ImClone) in 1987, a publicly traded biopharmaceutical company acquired by Eli Lilly and Company in 2008. Dr. Waksal served in senior roles at ImClone, including: President (1987 to 1994); Executive Vice President and Chief Operating Officer (1994 to 2002); and President, Chief Executive Officer and Chief Operating Officer (2002 to 2003). Dr. Waksal also served as a Director of ImClone from 1987 to 2005. Dr. Waksal served on the boards of Oberlin College and Sevion Therapeutics through March 2016 and the boards of Acasti and Neptune through February 2016 and July 2015, respectively. Dr. Waksal received his B.A. from Oberlin College and his M.D. from Tufts University School of Medicine. He completed his training in internal medicine at New England Medical Center and in pathology at Kings County Hospital Center in Brooklyn.

Konstantin Poukalov. Mr. Poukalov has been our Executive Vice President, Chief Financial Officer since 2014. From 2012 to 2014, Mr. Poukalov served as our Vice President, Strategic Operations. Prior to joining Kadmon, Mr. Poukalov was a member of the healthcare investment banking group at Jefferies LLC from 2009 to 2012, focusing on companies across the life-sciences and biotechnology sectors. Prior to Jefferies, Mr. Poukalov was a member of UBS Investment Bank, focusing on the healthcare industry, from 2006 to 2009. Mr. Poukalov serves on the advisory board of Pencils of Promise, a non-profit organization that aims to increase access to quality education in the developing world. Mr. Poukalov received his B.E. from Stony Brook University.

Lawrence K. Cohen, Ph.D. Dr. Cohen has been our Executive Vice President, Business Development since 2014. From 2011 to 2014, Dr. Cohen served as our Senior Vice President, Business Development. Prior to joining Kadmon, Dr. Cohen served as President and Chief Executive Officer of VIA Pharmaceuticals, Inc., a publicly traded biotechnology company, from 2004 to 2011. Prior to joining VIA, Dr. Cohen served in senior roles, including President and Chief Executive Officer, at Zyomyx, Inc., a privately held diagnostics company, from 2001 to 2004. Prior to Zyomyx, Dr. Cohen served as Chief Operating Officer of Progenitor, Inc. from 1997 to 1998. Dr. Cohen also served as Vice President of Research and Development at Somatix Therapy Corporation, a publicly traded gene therapy company, from 1988 to 1997. Dr. Cohen received his B.A. from Grinnell College and his Ph.D. from the University of Illinois. He completed his postdoctoral work in molecular biology at the Dana-Farber Cancer Institute and the Department of Biochemistry at Harvard Medical School.

Steven N. Gordon, Esq. Mr. Gordon, a co-founder of our company, has been our Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer since 2009. Prior to joining Kadmon, Mr. Gordon worked as a prosecutor for the City of New York from 1992 to 1996. From 1997 to 2008, Mr. Gordon practiced law at several law firms and was the principal of his own law firm. Mr. Gordon received his B.A. from Bar Ilan University and his J.D. from Touro College Jacob D. Fuchsberg Law Center.

John Ryan, Ph.D., M.D. Dr. Ryan has been our Executive Vice President, Chief Medical Officer since 2011. Prior to joining Kadmon, Dr. Ryan served as Senior Vice President and Chief Medical Officer of Cerulean Pharma, Inc., a publicly traded pharmaceutical company, from 2009 to 2011. Prior to joining Cerulean, Dr. Ryan was Chief Medical Officer at Aveo Pharmaceuticals, Inc., a publicly traded company, from 2006 to 2009. Prior to joining Aveo, Dr. Ryan served as Senior Vice President of Translational Research at Wyeth, a publicly-traded specialty-pharmaceutical company (formerly Genetics Institute), where he served as head of the Department of Experimental Medicine, from 1995 to 2006. Dr. Ryan also served as an Executive Director of Clinical Research at Merck Research Laboratories from 1989 to 1995 and he previously served on the scientific advisory boards of ArQule, Inc. and Expression Analysis, Inc. Dr. Ryan received his B.S. and his Ph.D. from Yale University. Dr. Ryan received his M.D. from the University of California, San Diego.

Non-Employee Directors

Bart M. Schwartz, Esq. Mr. Schwartz has served as Chairman of our board of directors since 2015. Since 2010, Mr. Schwartz has served as Chairman and Chief Executive Officer of SolutionPoint International, Inc., the parent company of Guidepost Solutions, LLC, a global investigation, security consulting, compliance and monitoring firm where he also serves as Chairman. Mr. Schwartz serves on the board of HMS Holdings Corp., a publicly traded company where he is Chair of its Compliance Committee and a member of its Audit Committee. He also serves on the boards of the Police Athletic League and the Stuyvesant High School Alumni Association. Mr. Schwartz is Founder and former Chief Executive Officer of Decision Strategies, an investigative, compliance and security firm. In October 2015, Mr. Schwartz was appointed independent monitor by the U.S. Department of Justice to oversee General Motors' compliance with its deferred prosecution agreement from its recall of defective ignition switches. Mr. Schwartz served under U.S. Attorney Rudolph Giuliani as the Chief of the Criminal Division in the Southern District of New York. Mr. Schwartz has had numerous additional court and other appointments to monitor the conduct of corporations and has received assignments from or with the approval of the SEC, the U.S. Commodity Futures Trading Commission, the U.S. Attorney's Office for the Southern District of New York, the Manhattan District Attorney's Office, the Attorney General of California, the Attorney General of New York, the New York Organized Crime Task Force, the New York City School Construction Authority and the New York State Department of Environmental Conservation. Mr. Schwartz received his B.S. from the University of Pittsburgh and his J.D. from New York University School of Law.

We believe Mr. Schwartz's extensive legal and compliance experience provides him with the qualifications and skills to serve on our board of directors.

Eugene Bauer, M.D. Dr. Bauer has served as a member of our board of directors since 2010. In 2010, Dr. Bauer co-founded Dermira, a publicly traded specialty biopharmaceutical company, where he serves as Director and Chief Medical Officer. Prior to founding Dermira, Dr. Bauer served as Director, President and Chief Medical Officer of Pelpin, Inc., a publicly traded specialty pharmaceutical company, from 2008 to 2009. Dr. Bauer served as Chief Executive Officer of Neosil, Inc., a specialty pharmaceutical company, from 2006 to 2008, and he co-founded and served as a member of the board of directors at Connetics, a publicly traded specialty pharmaceutical company, from 1990 to 2006. Prior to initiating his career in industry, Dr. Bauer served as Dean of Stanford University School of Medicine and as Chair of the Department of Dermatology at Stanford University School of Medicine from 1995 to 2001. Dr. Bauer is the Lucy Becker Professor Emeritus at Stanford University School of Medicine, a position he has held since 2002. Dr. Bauer was a U.S. National Institutes of Health (NIH)-funded investigator for 25 years and has served on review groups and Councils for the NIH. Dr. Bauer currently serves as a board member for Medgenics, Inc., Cerecor Inc. and First Wave Technologies. He is member of numerous honorific societies, including the National Academy of Medicine. Dr. Bauer received his B.S. from Northwestern University and his M.D. from Northwestern University Medical School.

We believe Dr. Bauer's background of service on the boards of directors of numerous public pharmaceutical companies and his vast industry experience provides him with the qualifications and skills to serve on our board of directors.

D. Dixon Boardman. Mr. Boardman has served as a member of our board of directors since 2010. Mr. Boardman founded Optima Fund Management LLC, an alternative investment firm, in 1988 and currently serves as its Chief Executive Officer. Mr. Boardman is a member of the President's Council of Memorial Sloan Kettering Cancer Center, where he has also served as Chairman of the Special Projects Committee. He is also a member of the Executive Committee of New York Presbyterian-Weill Cornell Council. Mr. Boardman is a Director of Florida Crystals Corporation and an Advisory Board Director of J.C. Bamford Excavators (UK). Mr. Boardman attended McGill University.

We believe Mr. Boardman's financial and business expertise provides him with the qualifications and skills to serve on our board of directors.

Alexandria Forbes, Ph.D. Dr. Forbes has served as a member of our board of directors since 2010. Dr. Forbes has been President and Chief Executive Officer of MeiraGTx, an affiliate of Kadmon, since 2015. Prior to joining MeiraGTx, Dr. Forbes served as Senior Vice President of Strategic Operations and Chief Commercial Officer at Kadmon from 2013 to 2015. Dr. Forbes spent 13 years as a healthcare investor at hedge funds Sivik/Argus Partners and Meadowvale Asset Management. Prior to entering the hedge fund industry, Dr. Forbes was a Human Frontiers/Howard Hughes postdoctoral fellow at the Skirball Institute of Biomolecular Medicine at NYU Langone Medical Center. Prior to this, Dr. Forbes was a research fellow at Duke University and also at Carnegie Institute at Johns Hopkins University. Dr. Forbes received her M.A. from Cambridge University and her Ph.D. from Oxford University.

We believe Dr. Forbes' business and financial expertise as well as her scientific background provides her with the qualifications and skills to serve on our board of directors.

Tasos G. Konidaris. Mr. Konidaris was appointed to our board of directors in February 2017. Mr. Konidaris has served as Executive Vice President and Chief Financial Officer of Alcresta Therapeutics, Inc. since March 2016. Prior to that, he was Senior Vice President and Chief Financial Officer of Ikaria, Inc., a biotherapeutics company, from October 2011 to May 2015. Prior to joining Ikaria, since 2007, Mr. Konidaris served as Senior Vice President and Chief Financial Officer at Dun & Bradstreet (D&B) Corporation, a leading commercial information services company. He was Principal Accounting Officer and led the Global Finance Operations of D&B beginning in 2005. From 2003 to 2005, Mr. Konidaris served as Group Vice President of the Global Pharmaceutical and Global Diversified Products Groups at Schering-Plough Corporation, a pharmaceutical company. Earlier in his career, Mr. Konidaris held senior financial and operational positions of increasing responsibility at the Pharmacia Corporation, Rhone-Poulenc Rorer, Novartis Corporation and Bristol-Myers Squibb Company. Mr. Konidaris currently serves on the board of Pernix Therapeutics Holdings, Inc. Mr. Konidaris was a director of Delcath Systems Inc. from July 2012 until December 2014. Mr. Konidaris holds an MBA from Drexel University, and a BS from Gwynedd Mercy College.

We believe Mr. Konidaris' expertise and financial experience provides him with the qualifications and skills to serve on our board of directors.

Steven Meehan. Mr. Meehan was appointed to our board of directors in 2017. Mr. Meehan brings to the Board over 25 years of investment banking experience. Mr. Meehan was a Partner in the Healthcare Group of Moelis & Company from 2011 through 2016, leading the effort in Life Sciences and Advanced Diagnostics. Additionally, Mr. Meehan was previously the Head of Life Sciences within the Global Healthcare Group in the New York office of UBS Investment Bank (UBS). Mr. Meehan was also part of the team that formed the Healthcare Group at UBS in 1999. During Mr. Meehan's tenure at UBS, he was Chief Executive Officer of UBS Russia and CIS across all businesses including securities, banking and wealth management. Mr. Meehan was also a member of the UBS Group EMEA Management Committee. During his investment banking career, Mr. Meehan also held senior roles in M&A, leveraged finance and capital markets at Salomon Smith Barney, NatWest Securities and Drexel Burnham Lambert.

We believe Mr. Meehan's expertise and financial experience provides him with the qualifications and skills to serve on our board of directors.

Thomas E. Shenk, Ph.D. Dr. Shenk has served as a member of our board of directors since 2014 and he has served as a member of Kadmon's Scientific Advisory Board since December 2013. Dr. Shenk has been the James A. Elkins Jr. Professor of Life Sciences in the Department of Molecular Biology at Princeton University since 1984. Dr. Shenk is a fellow of the American Academy of Arts and Sciences and a member of the U.S. National Academy of Sciences and the National Academy of Medicine. Dr. Shenk serves as the Chairman of the Board of MeiraGTx, an affiliate of Kadmon. He is a past president of the American Society for Virology and the American Society for Microbiology and served on the board of Merck and Company from 2001 to 2012. Dr. Shenk currently serves as a board member of the Hepatitis B Foundation. Dr. Shenk received his B.S. from the University of Detroit and his Ph.D. from Rutgers University.

We believe Dr. Shenk's expertise and experience serving as a director in the pharmaceutical sector and his academic background provides him with the qualifications and skills to serve on our board of directors.

Susan Wiviott, J.D. Ms. Wiviott has served as a member of our board of directors since 2010. Ms. Wiviott has served as the Chief Executive Officer of The Bridge, a non-profit behavioral health treatment and housing agency in New York, since 2014. Prior to joining The Bridge, Ms. Wiviott served as Chief Program Officer at Palladia Inc., a not-for-profit housing and substance abuse treatment provider, from 2012 through 2014. From 1999 through 2012, Ms. Wiviott served as Deputy Executive Vice President of the Jewish Board of Family and Children's Services. Ms. Wiviott began her career as an associate at Sidley Austin LLP. Ms. Wiviott received her B.A. from the University of Wisconsin and her J.D. from Harvard Law School.

We believe Ms. Wiviott's executive and legal experience provides her with the qualifications and skills to serve on our board of directors.

Louis Shengda Zan. Mr. Zan has served as a member of our board of directors since 2014. Mr. Zan founded the Jiangsu Zongyi Group, a conglomerate engaging in investment, new energy, new materials and information technology industries, in 1987 and he currently serves as its Chairman and Chief Executive Officer. Mr. Zan holds an Executive MBA from Tsinghua University.

We believe Mr. Zan's financial expertise and experience provides him with the qualifications and skills to serve on our board of directors.

Corporate Governance

Board of Directors and Committees

The current members of our board of directors have been appointed in accordance with our Second Amended and Restated Limited Liability Company Agreement ("LLC Agreement"). The LLC Agreement provided that our board of directors initially consist of seven members but may be increased from time to time by resolution of the board of directors. Currently, our board of directors is made up of nine members. On the effective date of the Corporate Conversion, the members of the board of managers of Kadmon Holdings, LLC became the members of Kadmon Holdings, Inc.'s board of directors. The LLC Agreement terminated upon the closing of our IPO and, thereafter, our directors will be elected by the vote of our common stockholders. The current directors' term ends at the first annual meeting of our stockholders, which will be held on June 29, 2017.

Pursuant to existing agreements with certain of our investors, GoldenTree Asset Management LP (together with certain of its affiliated entities), Falcon Flight LLC and Alpha Spring Limited had the right to appoint a member of our board of directors. Under the aforementioned rights, GoldenTree Asset Management LP (together with certain of its affiliated entities) appointed Treacy Gaffney and Alpha Spring Limited appointed Louis Shengda Zan to our board of directors. These rights terminated upon the effectiveness of our IPO. Ms. Gaffney resigned from our board of directors effective April 25, 2016.

For so long as affiliates of GoldenTree Asset Management LP collectively own at least 7.5% of our common stock (calculated on an "as if" converted basis and taking into account the exercise of all other options, warrants and other equity-linked securities held by such GoldenTree affiliated entities), GoldenTree Asset Management LP will have the right, at its option, to designate (i) one director to our board of directors and, upon such designation, the board of directors shall recommend to the stockholders to vote for the election of GoldenTree Asset Management LP's designee at any meeting of stockholders convened to elect our directors or (ii) one observer to our board of directors. As of the date of this Annual Report, GoldenTree has not designated a director or observer to our board of directors.

Following closing of or IPO until the dissolution and winding up of Kadmon I, for so long as 72 KDMN Investments, LLC (72 KDMN) owns, directly or indirectly, any membership interests in Kadmon I, then 72 KDMN will have the right, at its option, to designate one director to our board of directors and, upon such designation, the board of directors shall recommend to the stockholders to vote for the election of 72 KDMN's designee at any meeting of stockholders convened to elect our directors. Andrew B. Cohen, a former member of our board of directors, is an affiliate of 72 KDMN. Following the dissolution of Kadmon I on January 23, 2017, for so long as 72 KDMN owns, directly or indirectly, at least 25.0% of our common stock received by 72 KDMN upon the dissolution and winding up of Kadmon I, then 72 KDMN will have the right, at its option, to designate one director to our board of directors and, upon such designation, the board of directors shall recommend to the stockholders to vote for the election of 72 KDMN's designee at any meeting of stockholders convened to elect our directors. In January 2017, Mr. Cohen resigned from our board of directors and we received notice that 72 KDMN forfeited, relinquished and waived any and all rights it has to designate a director to our board of directors.

Director Independence

Prior to the consummation of our IPO, our board of directors undertook a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has determined that each of its members, other than Drs. Harlan W. Waksal, Thomas E. Shenk and Alexandria Forbes, is an "independent director" as defined under the NYSE listing standards.

Audit Committee

The audit committee of our board of directors oversees the quality and integrity of our financial statements and other financial information, accounting and financial reporting processes, internal controls and procedures for financial reporting and internal audit function. It also oversees the audit and other services provided by our independent auditors and is directly responsible for the appointment, independence, qualifications, compensation and oversight of the independent auditor. In addition, our audit committee is responsible for reviewing our compliance with legal and regulatory requirements, and it assists the board of directors in an initial review of recommendations to the board of directors regarding proposed business transactions.

The current members of our audit committee are Mr. D. Dixon Boardman, Dr. Eugene Bauer and Mr. Steven Meehan, with Mr. Boardman serving as the committee's chairman. Our board of directors has determined that Mr. Boardman is an "audit committee financial expert" as defined by SEC rules and regulations. The composition of our audit committee meets the requirements for independence under the rules and regulations of the SEC and the listing standards of the NYSE. A copy of the audit committee's written charter is publicly available on our website at www.kadmon.com.

Compensation Committee

The compensation committee of our board of directors reviews and determines the compensation of all of our executive officers and establishes our compensation policies and programs. Specific responsibilities of our compensation committee will include, among other things, evaluating the performance of our chief executive officer and determining our chief executive officer's compensation. It also determines the compensation of our other executive officers. In addition, our compensation committee administers all equity compensation plans and has the authority to grant equity awards subject to the terms and conditions of such equity compensation plans. Our compensation committee also reviews and approves various other compensation policies and matters. Our compensation committee also reviews and discusses with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings, and it will prepare a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

The current members of our compensation committee are Mr. D. Dixon Boardman, Dr. Eugene Bauer and Ms. Susan Wiviott with Mr. Boardman serving as the committee's chairman. The composition of our compensation committee meets the requirements for independence under the rules and regulations of the SEC and the listing standards of the NYSE. A copy of the compensation committee's written charter is publicly available on our website at www.kadmon.com.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee of our board of directors oversees the nomination of directors, including, among other things, identifying, evaluating and making recommendations of nominees to our board of directors, and evaluates the performance of our board of directors and individual members of our board of directors. When identifying nominees, the nominating and corporate governance committee considers, among other things, a nominee's character and integrity, level of education and business experience, financial literacy and commitment to represent long-term interests of our equity holders. Our nominating and corporate governance committee is also responsible for reviewing developments in corporate governance practices, evaluating the adequacy of our corporate governance practices and making recommendations to our board of directors concerning corporate governance matters.

The current members of our nominating and corporate governance committee are Mr. D. Dixon Boardman, Mr. Bart M. Schwartz and Ms. Susan Wiviott with Mr. Schwartz serving as the committee's chairman. The composition of our nominating and corporate governance committee meets the requirements for independence under the rules and regulations of the SEC and the listing standards of the NYSE. A copy of the nominating and corporate governance committee's written charter is publicly available on our website at www.kadmon.com.

Regulatory and Compliance Committee

The current members of our regulatory and compliance committee are Dr. Eugene Bauer, Mr. D. Dixon Boardman, Mr. Bart M. Schwartz, Dr. Thomas E. Shenk and Ms. Susan Wiviott with Mr. Schwartz serving as the committee's chairman.

The regulatory and compliance committee is responsible for, among other matters:

- reviewing and overseeing our compliance program and the compliance program(s) with respect to companies we acquire and which we exercise a controlling interest;
- reviewing the status of our compliance with relevant laws, regulations and internal procedures;
- reviewing and evaluating internal reports and external data based on criteria developed by the regulatory and compliance committee;
- discussing, in consultation with the compensation committee, an evaluation of whether compensation practices are aligned with our compliance obligations;
- making written recommendations about whether an employee's compensation should be reduced or extinguished if there is a government or regulatory action that has caused significant financial or reputational damage to our company due to the employee's involvement in the conduct at issue; and
- reporting to the board of directors on the state of our compliance functions, relevant compliances issues, potential patterns of non-compliance identified within our company, significant disciplinary actions against any compliance or internal audit personnel, and any other issues that may reflect any systemic or widespread problems in compliance or regulatory matters exposing our company to substantial compliance risk.

A copy of the regulatory and compliance committee's written charter is publicly available on our website at www.kadmon.com.

Risk Oversight

One of the key functions of our board of directors is informed oversight of our business risk management process. The board of directors does not have a standing business risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit and finance committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The nominating and corporate governance committee monitors compliance with legal and regulatory requirements and the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our nominating and corporate governance committee is also responsible for overseeing our risk management efforts generally, including the allocation of risk management functions among our board of directors and its committees. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Our audit and finance committee periodically reviews the general process for the oversight of risk management by our board of directors.

Risk Considerations in Our Compensation Program

We conducted an assessment of our compensation policies and practices for our employees and concluded that these policies and practices are not reasonably likely to have a material adverse effect on us.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and third-party consultants. We have posted a current copy of the code on our website, *www.kadmon.com*. In addition, we intend to post on our website all disclosures that are required by law or the NYSE listing standards concerning any amendments to, or waivers from, any provision of the code. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

Item 11. Executive Compensation

DIRECTOR COMPENSATION

The following table sets forth a summary of the compensation we paid to each non-employee member of our board of directors for the year ended December 31, 2016. Other than as set forth in the table and described more fully below, we did not pay any compensation to, make any equity awards or non-equity awards to, or pay any other compensation to any of the other non-employee member of our board of directors in 2016. Dr. Harlan W. Waksal is a member of our board of directors who also serves as our President and Chief Executive Officer and therefore does not receive any additional compensation for his service as a director.

Name	Fees earned or paid in cash [1]	Option awards [2]	Total
Bart M. Schwartz, Esq.	25,000	27,814	52,814
Eugene Bauer, M.D.	23,000	9,271	32,271
D. Dixon Boardman	31,000	27,814	58,814
Andrew B. Cohen[3]	26,000	9,271	35,271
Alexandria Forbes, Ph.D.	8,000	9,271	17,271
Treacy Gaffney[4]	2,000	—	2,000
Thomas E. Shenk, Ph.D.	20,000	9,271	29,271
Susan Wiviott, J.D.	25,000	9,271	34,271
Louis Shengda Zan	—	9,271	9,271

(1) The amounts reported in this column represent the aggregate dollar amount of all fees earned or paid in cash to each non-employee director in 2016 for their service as a director, including any annual retainer fees, committee and/or chair fees.

(2) The amounts reported in this column represent the grant date fair value calculated in accordance with the provisions of ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 13 to our consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2016.

(3) Mr. Cohen resigned from our board of directors effective January 13, 2017. Mr. Steven Meehan was appointed to replace Mr. Cohen on our board of directors effective January 17, 2017.

(4) For Ms. Gaffney's 2016 board of directors' compensation, payment was issued to GoldenTree Asset Management LP. Ms. Gaffney resigned from our board of directors effective April 25, 2016.

At December 31, 2016, our non-employee directors as of such date held the following outstanding options (in the aggregate):

Name	Shares Subject to Outstanding Options
Bart M. Schwartz, Esq.	26,668
Eugene Bauer, M.D.	16,925
D. Dixon Boardman	23,079
Andrew B. Cohen	16,925
Alexandria Forbes, Ph.D.	23,079
Thomas E. Shenk, Ph.D.	12,308
Susan Wiviott, J.D.	16,925
Louis Shengda Zan	12,308

For the year ended December 31, 2016, our non-employee directors were compensated for their services on our board of directors as follows:

- each non-employee director received an option grant to purchase 3,077 shares of our common stock with an exercise price equal to the closing price of our common stock on the date of grant upon his or her initial election or appointment to our board of directors;
- each non-employee director received an annual, or pro rata portion thereof for each partial year of service, option grant to purchase 3,077 shares of common stock with an exercise price equal to the closing price of our common stock on the date of grant;
- each non-employee director received compensation for each attended regularly scheduled board meeting of $2,000;
- each non-employee director received compensation for each attended special board meeting of $1,000;
- each non-employee director who served as a chairperson of our board or its audit committees received an additional annual option grant to purchase 6,154 shares of our common stock; and
- each non-employee director who served as member of a committee of our board of directors received additional compensation per attended meeting of $1,000.

Beginning January 1, 2017, our non-employee directors will be compensated for their services on our board of directors as follows:

- each non-employee director will receive an annual, or pro rata portion thereof, option grant to purchase 25,000 shares of common stock with an exercise price equal to the closing price of our common stock on the date of grant;
- each non-employee director who serves as a chairperson of our board or its audit committee will receive an annual option grant to purchase 50,000 shares of our common stock with an exercise price equal to the closing price of our common stock on the date of grant;
- each non-employee director will receive $5,000 for each board meeting personally attended and $2,500 for each board meeting attended telephonically;
- each non-employee director who serves as a chairperson of our board will receive an additional $2,500 for each board meeting personally attended and $1,250 for each board meeting attended telephonically;
- each non-employee director who serves as member of a committee of our board of directors will receive $2,500 for each committee meeting personally attended and $1,250 for each committee meeting attended telephonically; and
- each non-employee director who serves as chairperson of a committee of our board of directors will receive an additional $1,000 for each committee meeting personally attended and $500 for each committee meeting attended telephonically.

The stock options granted to our non-employee directors have, or will have, an exercise price equal to the fair market value of our common stock on the date of grant and will expire 10 years after the date of grant. The annual stock options granted to our non-employee directors will, subject to the director’s continued service on our board, vest one year from the grant date. Stock options granted to our non-employee directors will also vest in full upon the occurrence of a change in control of us.

Each member of our board of directors also will continue to be entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee of the board of directors on which he or she serves.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been a current or former officer or employee of Kadmon Holdings, Inc. or had any related person transaction involving Kadmon Holdings, Inc. None of our executive officers serve as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity.

EXECUTIVE COMPENSATION

The following section provides compensation information pursuant to the scaled disclosure rules applicable to "emerging growth companies" under the rules of the SEC.

Named Executive Officers

This section discusses the material components of the executive compensation program for our named executive officers who are named in the "2016 Summary Compensation Table" below. Our named executive officers for the year ended December 31, 2016, which consisted of our principal executive officer and two other most highly-compensated executives, are:

- Harlan W. Waksal, M.D.;
- Konstantin Poukalov; and
- Steven N. Gordon, Esq.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from the currently planned programs summarized in this discussion. See "Forward-Looking Statements."

2016 Summary Compensation Table

The following table sets forth certain information with respect to the compensation paid to the named executive officers for the years ended December 31, 2016 and 2015.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Harlan W. Waksal, M.D.,	2016	500,000	500,000	12,399,395	22,723	13,422,118
President and Chief Executive Officer	2015	500,000	500,000	15,236,944	26,455	16,263,399
Konstantin Poukalov,	2016	400,000	200,000	1,084,536	22,819	1,707,355
Executive Vice President, Chief Financial Officer	2015	315,385	200,000	1,351,005	22,828	1,889,218
Steven N. Gordon, Esq.,	2016	400,000	200,000	774,669	32,699	1,407,368
Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer	2015	350,000	150,000	337,751	499,274 [4]	1,337,025

(1) Bonus includes contractual guaranteed bonus, as well as discretionary annual merit-based awards determined by the compensation committee of the board of directors based on the executive's performance during the year.

(2) This column reflects the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 13, "Share-based Compensation," of the notes to our audited consolidated financial statements appearing in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

(3) Includes premiums we paid with respect to each of our named executive officers for health benefits and for life and disability insurance, as well as other income paid to each individual as further discussed in note 4 below.

(4) Includes contractually obligated reimbursement expenses incurred by Mr. Gordon in connection with the educational welfare of his children of $470,427 and reimbursement of premiums we paid for health benefits and for life and disability insurance of $28,847.

Narrative Disclosure to 2016 Summary Compensation Table

Employment Agreements

We entered into employment agreements with Dr. Harlan W. Waksal, under which he serves as our President and Chief Executive Officer, Mr. Poukalov, under which he serves as our Executive Vice President, Chief Financial Officer and Mr. Gordon under which he serves as our Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer. Under these agreements, Dr. Harlan W. Waksal and Messrs. Poukalov and Gordon are each eligible to receive certain severance benefits in specified circumstances.

Pursuant to Dr. Harlan W. Waksal's employment agreement, he is entitled to a base salary of $500,000 and is guaranteed to receive an annual bonus of $500,000, plus an additional merit-based bonus amount as shall be determined by the Compensation Committee of our board of directors, in its discretion. Pursuant to the terms of their respective employment agreements, Messrs. Poukalov and Gordon are each entitled to a base salary of $400,000 and are guaranteed to receive an annual bonus of $200,000, plus an additional merit-based bonus amount as shall be determined by the Compensation Committee of our board of directors, in its discretion.

Potential Payments upon Termination or Change in Control

In the event that we terminate Dr. Harlan W. Waksal or Messrs. Poukalov or Gordon without cause or if any of the aforementioned resign for good reason, they will be entitled to receive, upon execution and effectiveness of a release of claims, (i) continued payment of their then-current base salary and guaranteed annual bonus for a period of 12 months following termination (or, if sooner, until the executive becomes employed by another entity or individual (and not self-employed)) and (ii) a direct payment by us of the medical, vision and dental coverage premiums due to maintain any COBRA coverage for which he is eligible and has appropriately elected through the earlier of (A) 12 months following termination and (B) the date they become employed by another entity or individual (and not self-employed).

In the event that we terminate Dr. Harlan W. Waksal or Messrs. Poukalov or Gordon with cause or they resign without good reason, then they will not be entitled to receive severance benefits.

We expect that base salaries for the named executive officers will be reviewed periodically by the board of directors and/or the compensation committee, with adjustments expected to be made generally in accordance with the applicable employment agreements, as well as financial and other business factors affecting our company, and to maintain a competitive compensation package for our executive officers.

2016 Annual Performance-Based Compensation and Bonuses

In 2016, Dr. Harlan W. Waksal and Messrs. Poukalov and Gordon earned a guaranteed bonus of $500,000, $200,000 and $200,000, respectively.

In 2014 and 2015, Dr. Harlan W. Waksal, Messrs. Poukalov and Gordon received in aggregate 750, 1,000 and 1,300 equity appreciation rights units (EARs), respectively, under our 2014 Long-Term Incentive Plan with a base price of $6.00 per unit, expiring 10 years from the grant date (Award). Each Award entitles the holder to receive a payment having an aggregate value equal to the product of (i) the excess of (A) the highest fair market value during the period beginning on the applicable vesting date and ending on the date of settlement of one EAR unit over (B) the base price, and (ii) the number of EAR units granted. The number of EAR units granted to each recipient was adjusted in connection with the IPO to stock appreciation rights which equal a certain percentage of our common equity securities determined on a fully diluted basis, assuming exercise of all derivative securities including any convertible debt instruments. Based on the IPO price of $12.00 per share, the number of shares underlying the awards to Dr. Waksal and Messrs. Poukalov and Gordon are 267,543, 356,724 and 463,741 shares, respectively, and such awards may be settled in stock or cash.

The liability and associated compensation expense for these EAR unit awards was recognized upon consummation of our IPO in July 2016. Total compensation expense recorded under the 2014 LTIP during 2016 for Dr. Harlan W. Waksal and Messrs. Poukalov and Gordon was $1.7 million, 2.3 million and $3.0 million, respectively.

2016 Option Awards

On July 13, 2016, the compensation committee of our board of directors approved an option award for Dr. Harlan W. Waksal increasing the number of options (giving effect to the Corporate Conversion) subject to his original option grant. The number of shares subject to this option award shall equal the difference between the 769,231 options originally granted to Dr. Harlan W. Waksal and 5% of our outstanding common equity determined on a fully diluted basis on the IPO date, which amounted to 1,630,536 options. The effective date of the new option award was the IPO date of July 26, 2016. The exercise price per share of common stock subject to the new incremental options awarded was equal to the IPO price per share of common stock at the IPO date of $12.00. The option award is subject to the same vesting schedule applicable to the original option grant such that all options awarded will vest on August 4, 2017. In consideration for the new option award, Dr. Harlan W. Waksal has committed to perform an additional year of service in connection with receipt of the additional option shares. In the event Dr. Harlan W. Waksal voluntarily terminates his employment prior to completion of this additional year of service, Dr. Harlan W. Waksal shall forfeit 25% of the additional options, or 25% of the aggregate additional option gain associated with the additional option shares in the event the options are exercised, as applicable.

Outstanding Equity Awards at December 31, 2016

Although we do not have a formal policy with respect to the grant of equity incentive awards to our named executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executives to remain in our employment during the vesting period. Accordingly, our board of directors will periodically review the equity incentive compensation of our named executive officers and, from time to time, may grant equity incentive awards to them in the form of stock options or other equity awards.

The following table sets forth information concerning outstanding equity awards at December 31, 2016 for each of our named executive officers.

	Option Awards				Stock Awards[1]	
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($/share)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Harlan W. Waksal, M.D.	385	—	$ 12.00	12/19/2023	—	—
	512,847	256,384 (2)	12.00	12/31/2024	—	—
	1,087,024	543,512 (3)	12.00	12/31/2024	—	—
	—	267,543 (4)	6.00	12/31/2024	—	—
Konstantin Poukalov	9,232	—	12.00	12/19/2023	—	—
	—	356,724 (4)	6.00	12/31/2024	—	—
	20,518	41,021 (5)	12.00	12/31/2025	—	—
	—	350,000 (6)	4.66	12/15/2026	—	—
Steven N. Gordon, Esq.	12,308	—	12.00	6/25/2022	—	—
	12,308	—	12.00	12/19/2023	—	—
	—	463,741 (4)	6.00	12/31/2024	—	—
	5,130	10,255 (5)	12.00	12/31/2025	—	—
	—	250,000 (6)	4.66	12/15/2026	—	—

(1) Based on closing price of our common stock on December 31, 2016 ($5.35 per share).

(2) The unvested portion of this option vests on August 4, 2017.

(3) The unvested portion of this option vests on August 4, 2017. In consideration for this option award, Dr. Harlan W. Waksal has committed to perform an additional year of service after this vest date in connection with receipt of the additional option shares. In the event Dr. Harlan W. Waksal voluntarily terminates his employment prior to completion of this additional year of service, Dr. Harlan W. Waksal shall forfeit 25% of the additional options, or 25% of the aggregate additional option gain associated with the additional option shares in the event the options are exercised, as applicable..

(4) Represents shares issuable under the 2014 LTIP.

(5) This option vests in three substantially equal tranches on December 31, 2016, 2017 and 2018.

(6) This option vests in three substantially equal tranches on December 15, 2017, 2018 and 2019.

Equity and Other Incentive Compensation Plans

In this section we describe our 2011 Equity Incentive Plan, as amended to date, or the 2011 Equity Plan, our 2014 Long-Term Incentive Plan, as amended to date, or the 2014 LTIP, our 2016 Equity Incentive Plan, or the 2016 Plan, and our 2016 Employee Stock Purchase Plan. Prior to our IPO, we granted awards to eligible participants under the 2011 Equity Plan and 2014 LTIP. Following the closing of our IPO, we will grant awards to eligible participants under the 2016 Plan.

2011 Equity Incentive Plan

The 2011 Equity Incentive Plan was adopted in July 2011. Under this plan, the board of directors could grant unit-based awards to employees, officers, directors, managers, consultants and advisors. Such unit-based awards included awards entitling recipients to acquire Class A Membership Units, subject to a vesting schedule determined by the board of directors and subject to the right of our company to repurchase all or a portion of such units at their issue price or other stated or formula price, and options to purchase membership units. The plan was amended on December 19, 2013 to authorize the grant of an amount of Class A membership units equal to 7.5% of the outstanding Class A membership units calculated on a fully diluted basis. The board of directors had the authority, in its discretion, to determine the terms and conditions of any option grant, including the vesting schedule. The type of award granted under the 2011 Equity Plan and the terms of such award were set forth in the applicable award agreement.

Pursuant to the terms of the 2011 Equity Plan, our board of directors (or a committee delegated by our board of directors) administered the plan and, subject to any limitations in the plan, selected the recipients of awards and determined:

- the number of units covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of 10 years;
- the exercise price of options, which must be at least equal to the fair market value of our units on the date of grant; and
- the number of units subject to, and the terms of any, restricted unit awards, restricted units or other equity-based awards and the terms and conditions of such awards, including conditions for repurchase, measurement price, issue price and repurchase price.

Effect of certain changes in capitalization

Upon the occurrence of any of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our units other than an ordinary cash dividend, our board of directors could equitably adjust:

- the number and class of securities available under the 2011 Equity Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding restricted unit award; and
- the share and per-share related provisions and the purchase price, if any, of each other equity-based award.

Effect of certain corporate transactions

Upon a merger or other reorganization event (as defined in the 2011 Equity Plan), our board of directors could take any one or more of the following actions (or a combination of such actions) pursuant to the 2011 Equity Plan as to some or all outstanding awards other than restricted unit awards:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's vested but unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of membership units will receive a cash payment for each unit surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (1) the number of units subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such

reorganization event) multiplied by (2) the excess, if any, of the cash payment for each unit surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or

- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors did not need to take the same action with respect to all awards and could take different actions with respect to portions of the same award.

In the case of certain restricted units, no assumption or substitution was permitted, and the restricted units would instead be settled in accordance with the terms of the applicable restricted unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding awards of restricted units would continue for the benefit of the successor company and would, unless the board of directors may otherwise determine, apply to the cash, securities or other property into which our units are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted unit award would automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted unit award.

At any time, our board of directors could, in its sole discretion, provide that any award under the 2011 Equity Plan would become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

On July 13, 2016, the compensation committee of our board of directors approved the amendment of all outstanding option awards, effective upon the date of our IPO, to adjust the exercise price (on a post-Corporate Conversion, post-split basis) to the IPO price per share in our IPO. Upon the effectiveness of the registration statement for our IPO, the 2011 Equity Plan was merged with and into the 2016 Equity Incentive Plan, outstanding awards converted into awards with respect to our common stock and any new awards will be issued under the terms of the 2016 Equity Incentive Plan. Therefore, no future awards may be granted under the 2011 Equity Plan.

2014 LTIP

The 2014 LTIP was adopted in May 2014 and amended in December 2014, July 2015 and February 2016. Under the 2014 LTIP, the board of directors may grant up to 10% of the equity value of our company (determined on a fully diluted basis assuming the exercise of all derivative securities) including the following types of awards:

- Equity Appreciation Rights Units (EAR units) whereby the holder would possess the right to a payment equal to the appreciation in value of the designated underlying equity from the grant date to the determination date. Such value is calculated as the product of the excess of the fair market value on the determination date of one EAR unit over the base price specified in the grant agreement and the number of EAR units specified by the award, or, when applicable, the portion thereof which is exercised.

- Performance Awards which become payable on the attainment of one or more performance goals established by the Plan Administrator. No performance period shall end prior to an IPO or Change in Control. A Change in Control generally includes the acquisition of over 50% of our company's outstanding equity by an unaffiliated or the sale of over 85% of the gross fair market value of our company's assets to an unaffiliated person. *Person* means any individual, entity or group within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (Exchange Act), other than employee benefit plans sponsored or maintained by our company and by entities controlled by our company or an underwriter of the equity interests of our company in a registered public offering. A Change in Control does not include the acquisition of additional equity interests by a person that holds a controlling interest in our company.

The board of directors has the authority, at its discretion, to determine the terms and conditions of any 2014 LTIP grant, including the vesting schedule.

Generally, under the 2014 LTIP, the EAR units vest on the effective date of an IPO or the consummation date of a Change in Control (as defined under the 2014 LTIP) unless otherwise set forth in the grant agreement pertaining to a particular award. The payment amount with respect to the holder's EAR units will be determined using the fair market value of the common stock on the trading day immediately preceding the settlement date. Each payment under an Award will be made in a lump sum and is considered a separate payment. We reserve the right to make payment in the form of common stock following the consummation of an IPO or in connection with a change in control, subject to the terms of the 2014 LTIP. The LTIP Awards

provide that in the event that the Compensation Committee elects to settle the outstanding LTIP awards using our common stock following an IPO, the maximum number of shares of common stock (maximum share allocation) that would be issued in full settlement of any outstanding award is determined by dividing the aggregate cash value of the LTIP award (determined by multiplying the number of EAR units subject to the LTIP award by the difference between an assumed performance vesting price of $20.00 per share and the base price per EAR unit ($6.00) by the assumed performance vesting price per share ($20.00). The actual value of the LTIP award will be determined using the fair market value of the common stock on the trading date immediately preceding the settlement date, subject to the maximum share allocation. The holder has no right to demand a particular form of payment. A total of 9,750 units were granted under the 2014 LTIP at December 31, 2016. Upon the effectiveness of the registration statement for our IPO, the 2014 LTIP was frozen, outstanding awards were converted to stock appreciation rights which may be settled in cash or common stock at the election of the compensation committee and, any new awards will be issued under the 2016 Equity Incentive Plan.

2016 Equity Incentive Plan

Our 2016 Equity Incentive Plan, or the 2016 Equity Plan, was approved by our board of directors and holders of our membership units in July 2016. It is intended to make available incentives that will assist us to attract, retain and motivate employees, including officers, consultants and directors. We may provide these incentives through the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units and other cash-based or stock-based awards.

A total of 6,720,000 shares of our common stock will be initially authorized and reserved for issuance under the 2016 Equity Plan. This reserve will automatically increase on January 1, 2017 and each subsequent anniversary through January 1, 2025, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the board. This reserve will be increased to include any shares issuable upon exercise of options granted under the 2011 Equity Incentive Plan that expire or terminate without having been exercised in full.

Appropriate adjustments will be made in the number of authorized shares and other numerical limits in the 2016 Equity Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the 2016 Equity Plan. The shares available will not be reduced by awards settled in cash or by shares withheld to satisfy tax withholding obligations. Only the net number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under the 2016 Equity Plan.

The 2016 Equity Plan will be generally administered by the compensation committee of our board of directors. Subject to the provisions of the 2016 Equity Plan, the compensation committee will determine in its discretion the persons to whom and the times at which awards are granted, the sizes of such awards and all of their terms and conditions. However, the compensation committee may delegate to one or more of our officers the authority to grant awards to persons who are not officers or directors, subject to certain limitations contained in the 2016 Equity Plan and award guidelines established by the committee. The compensation committee will have the authority to construe and interpret the terms of the 2016 Equity Plan and awards granted under it. The 2016 Equity Plan provides, subject to certain limitations, for indemnification by us of any director, officer or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the 2016 Equity Plan.

Awards may be granted under the 2016 Equity Plan to our employees, including officers, directors or consultants or those of any present or future parent or subsidiary corporation or other affiliated entity. All awards will be evidenced by a written agreement between us and the holder of the award and may include any of the following:

- *Stock options.* We may grant nonstatutory stock options or incentive stock options (as described in Section 422 of the Internal Revenue Code), each of which gives its holder the right, during a specified term (not exceeding 10 years) and subject to any specified vesting or other conditions, to purchase a number of shares of our common stock at an exercise price per share determined by the administrator, which may not be less than the fair market value of a share of our common stock on the date of grant.

- *Stock appreciation rights.* A stock appreciation right gives its holder the right, during a specified term (not exceeding 10 years) and subject to any specified vesting or other conditions, to receive the appreciation in the fair market value of our common stock between the date of grant of the award and the date of its exercise. We may pay the appreciation in shares of our common stock or in cash.

- *Restricted stock.* The administrator may grant restricted stock awards either as a bonus or as a purchase right at such price as the administrator determines. Shares of restricted stock remain subject to forfeiture until vested,

based on such terms and conditions as the administrator specifies. Holders of restricted stock will have the right to vote the shares and to receive any dividends paid, except that the dividends may be subject to the same vesting conditions as the related shares.

- *Restricted stock units.* Restricted stock units represent rights to receive shares of our common stock (or their value in cash) at a future date without payment of a purchase price, subject to vesting or other conditions specified by the administrator. Holders of restricted stock units have no voting rights or rights to receive cash dividends unless and until shares of common stock are issued in settlement of such awards. However, the administrator may grant restricted stock units that entitle their holders to dividend equivalent rights.

- *Performance shares and performance units.* Performance shares and performance units are awards that will result in a payment to their holder only if specified performance goals are achieved during a specified performance period. Performance share awards are rights whose value is based on the fair market value of shares of our common stock, while performance unit awards are rights denominated in dollars. The administrator establishes the applicable performance goals based on one or more measures of business performance enumerated in the 2016 Equity Plan, such as revenue, gross margin, net income or total stockholder return. To the extent earned, performance share and unit awards may be settled in cash or in shares of our common stock. Holders of performance shares or performance units have no voting rights or rights to receive cash dividends unless and until shares of common stock are issued in settlement of such awards. However, the administrator may grant performance shares that entitle their holders to dividend equivalent rights.

- *Cash-based awards and other stock-based awards.* The administrator may grant cash-based awards that specify a monetary payment or range of payments or other stock-based awards that specify a number or range of shares or units that, in either case, are subject to vesting or other conditions specified by the administrator. Settlement of these awards may be in cash or shares of our common stock, as determined by the administrator. Their holder will have no voting rights or right to receive cash dividends unless and until shares of our common stock are issued pursuant to the award. The administrator may grant dividend equivalent rights with respect to other stock-based awards.

In the event of a change in control as described in the 2016 Equity Plan, the acquiring or successor entity may assume or continue all or any awards outstanding under the 2016 Equity Plan or substitute substantially equivalent awards. Any awards which are not assumed or continued in connection with a change in control or are not exercised or settled prior to the change in control will terminate effective as of the time of the change in control. The compensation committee may provide for the acceleration of vesting of any or all outstanding awards upon such terms and to such extent as it determines, except that the vesting of all awards held by members of the board of directors who are not employees will automatically be accelerated in full. The 2016 Equity Plan will also authorize the compensation committee, in its discretion and without the consent of any participant, to cancel each or any outstanding award denominated in shares upon a change in control in exchange for a payment to the participant with respect to each share subject to the cancelled award of an amount equal to the excess of the consideration to be paid per share of common stock in the change in control transaction over the exercise price per share, if any, under the award.

The 2016 Equity Plan will continue in effect until it is terminated by the administrator, provided, however, that all awards will be granted, if at all, within 10 years of its effective date. The administrator may amend, suspend or terminate the 2016 Equity Plan at any time, provided that without stockholder approval, the plan cannot be amended to increase the number of shares authorized, change the class of persons eligible to receive incentive stock options, or effect any other change that would require stockholder approval under any applicable law or listing rule.

2016 Employee Stock Purchase Plan

Our board of directors has adopted and our stockholders have approved our 2016 Employee Stock Purchase Plan, or the 2016 ESPP.

A total of 1,125,000 shares of our common stock are available for sale under our 2016 ESPP. In addition, our 2016 ESPP provides for annual increases in the number of shares available for issuance under the 2016 ESPP on January 1, 2017 and each subsequent anniversary through 2025, equal to the smallest of:

- 750,000 shares;

- 1.5% of the outstanding shares of our common stock on the immediately preceding December 31; or

- such other amount as may be determined by our board of directors.

Appropriate adjustments will be made in the number of authorized shares and in outstanding purchase rights to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to purchase rights which expire or are cancelled will again become available for issuance under the 2016 ESPP.

The compensation committee of our board of directors will administer the 2016 ESPP and have full authority to interpret the terms of the 2016 ESPP. The 2016 ESPP provides, subject to certain limitations, for indemnification by us of any director, officer or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the 2016 ESPP.

All of our employees, including our named executive officers, and employees of any of our subsidiaries designated by the compensation committee are eligible to participate if they are customarily employed by us or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year, subject to any local law requirements applicable to participants in jurisdictions outside the United States. However, an employee may not be granted rights to purchase stock under our 2016 ESPP if such employee:

- immediately after the grant would own stock or options to purchase stock possessing 5.0% or more of the total combined voting power or value of all classes of our capital stock; or

- holds rights to purchase stock under all of our employee stock purchase plans that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year in which the right to be granted would be outstanding at any time.

Our 2016 ESPP is intended to qualify under Section 423 of the Internal Revenue Code (Code) but also permits us to include our non-U.S. employees in offerings not intended to qualify under Section 423 of the Code. The 2016 ESPP will typically be implemented through consecutive six-month offering periods. The offering periods generally start on the first trading day of April and October of each year. The administrator may, in its discretion, modify the terms of future offering periods, including establishing offering periods of up to 27 months and providing for multiple purchase dates. The administrator may vary certain terms and conditions of separate offerings for employees of our non-U.S. subsidiaries where required by local law or desirable to obtain intended tax or accounting treatment.

Our 2016 ESPP permits participants to purchase common stock through payroll deductions of up to 10.0% of their eligible compensation, which includes a participant's regular and recurring straight time gross earnings and payments for overtime and shift premiums, but exclusive of payments for incentive compensation, bonuses and other similar compensation.

Amounts deducted and accumulated from participant compensation, or otherwise funded in any participating non-U.S. jurisdiction in which payroll deductions are not permitted, are used to purchase shares of our common stock at the end of each offering period. The purchase price of the shares will be 85.0% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the last day of the offering period. Participants may end their participation at any time during an offering period and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with us.

Each participant in any offering will have an option to purchase for each full month contained in the offering period a number of shares determined by dividing $2,083 by the fair market value of a share of our common stock on the first day of the offering period or 200 shares, if less, and except as limited in order to comply with Section 423 of the Code. Prior to the beginning of any offering period, the administrator may alter the maximum number of shares that may be purchased by any participant during the offering period or specify a maximum aggregate number of shares that may be purchased by all participants in the offering period. If insufficient shares remain available under the plan to permit all participants to purchase the number of shares to which they would otherwise be entitled, the administrator will make a pro rata allocation of the available shares. Any amounts withheld from participants' compensation in excess of the amounts used to purchase shares will be refunded, without interest.

A participant may not transfer rights granted under the 2016 ESPP other than by will, the laws of descent and distribution or as otherwise provided under the 2016 ESPP.

In the event of a change in control, an acquiring or successor corporation may assume our rights and obligations under outstanding purchase rights or substitute substantially equivalent purchase rights. If the acquiring or successor corporation does not assume or substitute for outstanding purchase rights, then the purchase date of the offering periods then in progress will be accelerated to a date prior to the change in control.

Our 2016 ESPP will remain in effect until terminated by the administrator. The compensation committee has the authority to amend, suspend or terminate our 2016 ESPP at any time.

401(k) retirement plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Code. In general, all of our employees are eligible to participate, beginning on the first day of the third month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, generally equal to $18,000 in 2016, and have the amount of the reduction contributed to the 401(k) plan. Participants who are at least 50 years old also can make "catch-up" contributions, which in 2016 may be up to an additional $6,000 above the statutory limit. We have an obligation to match non-highly compensated employee contributions of up to 6% of deferrals and also have the option to make discretionary matching contributions and profit sharing contributions to the plan annually, as determined by our board of directors. We provided employer matching contributions for Dr. Harlan W. Waksal of $15,900 for the year ended December 31, 2015, which were disbursed during 2016. No other employer matching contributions were made to our named executive officers for the years ended December 31, 2016, 2015 and 2014.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information as of March 8, 2017 regarding the beneficial ownership of our common stock, by:

- each person or group who beneficially owns more than 5.0% of our outstanding shares of common stock;
- each of our executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership for the purposes of the following table is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting of securities, or to dispose or direct the disposition of securities or has the right to acquire such powers within 60 days. For purposes of calculating each person's percentage ownership, common stock issuable pursuant to options exercisable within 60 days are included as outstanding and beneficially owned for that person or group, but are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as disclosed in the footnotes to this table and subject to applicable community property laws, we believe that each beneficial owner identified in the table possesses sole voting and investment power over all common stock shown as beneficially owned by the beneficial owner.

Percentage ownership of our common stock in the table is based on 45,078,666 shares of our common stock issued and outstanding on December 31, 2016. This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and Schedules 13G, if any, filed with the SEC. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o Kadmon Holdings, Inc., 450 East 29th Street, New York, New York 10016.

	Shares of Common Stock Beneficially Owned [1]			
Name of beneficial owner	Common Stock	Securites Exercisable Within 60 Days	Number of Securities Beneficially Owned	Percentage
5.0% Stockholders				
GoldenTree Entities[2]	8,732,624	219,828	8,952,452	19.76%
Third Point Ventures LLC[3]	7,919,650	—	7,919,650	17.57%
3RP Holdings Company, LLC[4]	3,478,840	—	3,478,840	7.72%
Executive Officers and Directors				
Bart M. Schwartz, Esq.[5]	26,511	17,437	43,948	*
Eugene Bauer, M.D.[6]	1,716	13,848	15,564	*
D. Dixon Boardman[7]	45,911	13,848	59,759	*
Alexandria Forbes, Ph.D.[8]	90,816	20,002	110,818	*
Tasos Konidaris[9]	—	—	—	*
Steven Meehan[10]	—	—	—	*
Thomas E. Shenk, Ph.D.[11]	24,616	7,180	31,796	*
Susan Wiviott, J.D.[12]	4,168	13,848	18,016	*
Louis Shengda Zan[13]	2,187,381	9,231	2,196,612	4.87%
Harlan W. Waksal, M.D.[14]	102,040	1,600,256	1,702,296	3.65%
Konstantin Poukalov[15]	4,000	29,750	33,750	*
Lawrence K. Cohen, Ph.D.[16]	—	19,746	19,746	*
Steven N. Gordon, Esq.[17]	232,484	29,746	262,230	*
John Ryan, Ph.D., M.D.[18]	—	15,900	15,900	*
Zhenping Zhu, M.D., Ph.D.[19]	18,462	23,210	41,672	*
All directors and executive officers as a group (14 persons)	2,738,105	1,814,002	4,552,107	9.71%

* Represents ownership of less than 1.0%.

(1) Represents shares of common stock held and options held by such individuals that were exercisable within 60 days of March 8, 2017. Includes shares held in the beneficial owner's name or jointly with others, or in the name of a bank, nominee or trustee for the beneficial owner's account. Reported numbers do not include options that vest more than 60 days after March 8, 2017.

(2) As reported on Schedule 13D filed with the SEC on August 5, 2016, consists of (i) 6,397,332 shares of common stock held by GN3 SIP Limited (GN3), GoldenTree 2004 Trust (G2T), GTNM, LP (GTNM), GoldenTree Insurance Fund Series Interests of the SALI Multi-Series Fund, LP (GTIF), GoldenTree Credit Opportunities, LP (GTCO), GoldenTree Entrust Master Fund SPC (GSPC), GoldenTree Master Fund, Ltd. (GMF), GoldenTree Master Fund II, Ltd. (GMFII), and a separately managed account managed by the GoldenTree Asset Management LP (the "First Managed Account") and a second separately managed account managed by the GoldenTree Asset Management LP (the "Second Managed Account"), (ii) warrants to purchase 219,828 shares of common stock held by GN3, G2T, GTNM, First Management Account, GTIF and GTCO and (iii) 2,115,416 shares of common stock issuable upon the

conversion of preferred stock held by G2T, GTNM, GN3, First Managed Account and Second Managed Account. GoldenTree Asset Management LP acts as investment manager for all of the entities described herein. GoldenTree Asset Management LLC serves as the general partner for GoldenTree Asset Management LP. GoldenTree Asset Management LLC serves as the general partner for GoldenTree Asset Management LP. Steven A. Tananbaum is the managing member of GoldenTree Asset Management LLC and holds sole voting and dispositive power over the securities indirectly held by such entity. By virtue of the relationships described in this footnote, each entity and individual named herein may be deemed to share beneficial ownership of all shares held by the other entities named herein. Each entity and individual named herein expressly disclaims any such beneficial ownership, except to the extent of their individual pecuniary interests therein. The address for the GoldenTree Entities is 300 Park Avenue, 21st Floor, New York, NY 10022.

(3) As reported on Form 4 filed with the SEC on September 16, 2016, consists of 7,919,650 shares of our common stock issued to Third Point LLC. Third Point LLC and Daniel S. Loeb, in his capacity as the chief executive officer of Third Point LLC, have voting and dispositive power over securities held by Third Point Ventures LLC, as nominee for funds managed and/or advised by Third Point LLC. Third Point LLC and Mr. Loeb disclaim beneficial ownership of these securities, except to the extent of any indirect pecuniary interest therein. The address for Third Point Ventures LLC is c/o Third Point LLC, 390 Park Avenue, 19th floor, New York, NY 10022.

(4) As reported on Schedule 13G filed with the SEC on February 9, 2017, consists of 3,478,840 shares of common stock held by 3RP Holdings Company, LLC. Paul F. Fagan, J.D., C.P.A., is the Executive Vice President and General Counsel of 3RP Holdings Company, LLC and as such has voting and dispositive power over the securities held by such entity. By virtue of the relationships described in this footnote, each entity and individual named herein may be deemed to share beneficial ownership of all shares held by the entities named herein. Mr. Fagan expressly disclaims any such beneficial ownership, except to the extent of his individual pecuniary interests therein. The address for 3RP Holdings Company, LLC is 2215-B Renaissance Drive, Suite B, Las Vegas, NV 89119.

(5) Consists of (i) 26,511 shares of common stock and (ii) 17,437 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017.

(6) Consists of (i) 1,716 shares of common stock and (ii) 13,848 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017.

(7) Consists of (i) 45,911 shares of common stock and (ii) 13,848 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017.

(8) Consists of (i) 90,816 shares of common stock , (ii) 20,002 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (iii) 1,000 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR Units awarded under the 2014 LTIP.

(9) Mr. Konidaris was appointed to our board of directors in February 2017 and, as of March 8, 2017, did not beneficially own shares of our common stock..

(10) Mr. Meehan was appointed to our board of directors in January 2017 and, as of March 8, 2017, did not beneficially own shares of our common stock..

(11) Consists of (i) 24,616 shares of common stock and (ii) 7,180 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017.

(12) Consists of (i) 4,168 shares of common stock and (ii) 13,848 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017.

(13) Consists of (i) 2,187,381 shares of our common stock issued to Alpha Spring Limited and (ii) 9,231 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017. Mr. Zan is the sole director of Alpha Spring Limited and, as such, has sole voting and dispositive power over Alpha Spring Limited. Mr. Zan disclaims beneficial ownership of the securities held by Alpha Spring Limited, except to the extent of his pecuniary interest therein, if any.

(14) Consists of (i) 102,040 shares of common stock, (ii) 1,600,256 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (iii) 750 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our

option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR units awarded under the 2014 LTIP.

(15) Consists of (i) 4,000 shares of common stock, (ii) 29,750 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (iii) 1,000 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR units awarded under the 2014 LTIP.

(16) Consists of (i) 19,746 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (ii) 250 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR units awarded under the 2014 LTIP.

(17) Consists of (i) 232,484 shares of common stock, (ii) 29,746 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (iii) 1,300 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR units awarded under the 2014 LTIP. Mr. Gordon disclaims beneficial ownership of the reported securities except to the extent of his pecuniary interest therein.

(18) Consists of (i) 15,900 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017 and (ii) 250 EAR units under the 2014 LTIP. EAR units awarded under the 2014 LTIP are excluded from the amount listed in this table as they may be paid in cash or stock at our option. See “Executive Compensation—Equity and Other Incentive Compensation Plans” for a discussion of EAR units awarded under the 2014 LTIP.

(19) Consists of (i) 18,462 shares of common stock and (ii) 23,210 shares of common stock issuable upon the exercise of stock options within 60 days of March 8, 2017. Dr. Zhu's employment with us ended on January 6, 2017.

Item 13. Certain Relationships and Related Transactions, and Director Independence

We describe below transactions and series of similar transactions, during our last fiscal year, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

Participation in the Private Placement

Certain of our existing institutional investors purchased an aggregate of 1,488,095 shares of our common stock in our private placement that closed on March 13, 2017. Third Point Partners, LLC purchased 1,488,095 shares of our common stock for $5.0 million and also received 595,238 warrants to purchase shares of our common stock with an exercise price of $4.50 and a term of 13 months from the date of issuance. See “Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” for more information about the shares held by these identified entities.

Participation in the IPO

Certain of our existing institutional investors, including investors affiliated with certain of our directors, purchased an aggregate of 2,708,332 shares of our common stock in our IPO at the IPO price of $12.00 per share, for an aggregate purchase price of $32.5 million, and on the same terms as the shares that were sold to the public generally. Perceptive Advisors, LLC, Third Point Partners, LLC. and GoldenTree purchased 1,458,333 shares of our common stock for $17.5 million, 1,041,666 shares of our common stock for $12.5 million and 208,333 shares of our common stock for $2.5 million, respectively. See “Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” for more information about the shares held by these identified entities.

Related Party Agreements

At December 31, 2016, Kadmon I, LLC held approximately 12.1% of the total outstanding common stock of Kadmon Holdings, Inc. Mr. Steven N. Gordon was the managing member of Kadmon I, LLC and is also our Executive Vice President, General Counsel, Chief Administrative, Compliance and Legal Officer. Kadmon I, LLC has no special rights or preferences in connection with its investment in Kadmon Holdings, Inc., and has the same rights as all other holders of Kadmon

Holdings, Inc. common stock. On January 23, 2017, Kadmon I, LLC was dissolved and liquidated. Upon dissolution and liquidation, all assets of Kadmon I, LLC which consists solely of the shares of common stock in Kadmon Holdings, Inc., were distributed to the members of Kadmon I, LLC.

In October 2011, Dr. Samuel D. Waksal, a former employee and our-then Chief Executive Officer, issued an equity instrument to YCMM Funding, LLC, a third party organization, in exchange for certain fundraising services on behalf of and for the benefit of Kadmon Holdings, LLC. The underlying value of the equity instrument is based on 536,065 Class A membership units and was redeemable for cash upon the occurrence of a liquidity event. In accordance with SAB 107, the liability associated with the equity instrument was recognized by Kadmon Holdings, LLC upon Dr. Samuel D. Waksal entering into the arrangement and has subsequently been stated at fair value at each reporting date with the change in value being recognized within the statement of operations. The fair value of this equity instrument was $0 and $69,000 at December 31, 2016 and 2015, respectively. Upon consummation of our IPO on August 1, 2016 with a price per share of $12.00 per share, the fair value of this equity instrument had a fair value of $0, which resulted in no liability owed by us.

In November 2011, we entered into an agreement with SBI Holdings, Inc., an indirect holder of more than 5% of our outstanding membership interests through Kadmon I, LLC, in connection with an investment of $6.5 million for 306,067 of our Class A membership units (the SBI Agreement). Subject to certain terms and conditions contained therein, the SBI Agreement provided SBI Holdings, Inc. with certain consent rights relating to our activities, information rights and rights upon liquidity events, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

In October 2013, we entered into an agreement with Alpha Spring Limited in connection with an investment of $35.0 million by Alpha Spring Limited for 2,679,939 of our Class A membership units (the Alpha Spring Agreement). Subject to certain terms and conditions contained therein, the Alpha Spring Agreement provides Alpha Spring Limited with certain consent rights relating to our activities, most favored nation rights, the right to appoint a member of our board of directors and information rights, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

During 2014, Dr. Harlan W. Waksal, our President and Chief Executive Officer, provided us with a $3.0 million short-term, interest-free loan to meet operating obligations. The $3.0 million related party loan with Dr. Harlan W. Waksal was repaid in full in November 2016.

In September 2015, we entered into an agreement with GoldenTree Asset Management LP and certain of its affiliated entities in connection with (i) a settlement of certain claims alleging breaches of a letter agreement between us and such entities relating to a prior investment by such entities in our securities, which letter agreement was terminated as part of this settlement and (ii) participation by such entities in an aggregate amount of $15.0 million in the 2015 Credit Agreement, including the warrants issued in connection therewith, and the Senior Convertible Term Loan (the GoldenTree Agreement). Subject to certain terms and conditions contained therein, the GoldenTree Agreement provided GoldenTree Asset Management LP and certain of its affiliated entities with certain most favored nation rights, anti-dilution protections including the issuance of additional Class E redeemable convertible membership units with a conversion price equal to any down round price and a right to appoint a member of our board of directors, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

In June 2016, we entered into an agreement with 72 KDMN whereby we agreed to extend certain rights to 72 KDMN which survived the closing of the IPO, including board of director designation rights, see “Item 10. Directors, Executive Officers and Corporate Governance,” and confidentiality rights, subject to standard exceptions. In addition, we agreed to provide 72 KDMN with most favored nation rights which terminated upon the closing of the IPO on August 1, 2016. Andrew B. Cohen, a former member of our board of directors, is an affiliate of 72 KDMN. Following the dissolution of Kadmon I on January 23, 2017, for so long as 72 KDMN owns, directly or indirectly, at least 25.0% of our common stock received by 72 KDMN upon the dissolution and winding up of Kadmon I, then 72 KDMN will have the right, at its option, to designate one director to our board of directors and, upon such designation, the board of directors shall recommend to the stockholders to vote for the election of 72 KDMN’s designee at any meeting of stockholders convened to elect our directors. In January 2017, Mr. Cohen resigned from our board of directors and we received notice that 72 KDMN forfeits, relinquishes and waives any and all rights it has to designate a director to our board of directors.

In June 2016, Dr. Harlan W. Waksal, our President and Chief Executive Officer, certain entities affiliated with GoldenTree Asset Management LP, Bart M. Schwartz, the chairman of our board of directors, 72 KDMN and D. Dixon Boardman, a member of our board of directors, subscribed for 86,957, 43,479, 21,740, 86,957 and 21,740 of our Class E redeemable convertible units, respectively, at a value of $11.50 per unit.

In June 2016, we entered into certain agreements with Falcon Flight LLC and one of its affiliates in connection with a settlement of certain claims alleging breaches of a letter agreement between us and Falcon Flight LLC relating to a prior investment by Falcon Flight LLC and its affiliate in our securities, which letter agreement was amended and restated as part of this settlement, which, together with a supplemental letter agreement, we refer to as the Falcon Flight Agreement. Subject to

certain terms and conditions contained therein, the Falcon Flight Agreement provides Falcon Flight LLC and its affiliate with certain most favored nation rights, information rights, consent rights, anti-dilution protections including the issuance of 1,061,741 additional Class E redeemable convertible membership units with a conversion price equal to any down-round price, a right to designate a member of our board of then managers or observer and notice requirements with respect to any waivers by the underwriters in connection with lock-up agreements, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016, except for indemnification of Falcon Flight LLC's board designee or observer, which survives termination. In addition, we agreed to pay $500,000 to Falcon Flight LLC within one business day following the consummation of the IPO, and $300,000 within sixty days following the consummation of the IPO. We recorded an estimate for this settlement of approximately $10.4 million in September 2015 and recorded an additional expense of $2.6 million in June 2016 based on the excess of the fair value of this settlement over the $10.4 million previously expensed in 2015.

Corporate Conversion

Prior to the IPO, we were a Delaware limited liability company. On July 26, 2016, in connection with the pricing of the IPO, Kadmon Holdings, LLC filed a certificate of conversion, whereby Kadmon Holdings, LLC effected a Corporate Conversion from a Delaware limited liability company to a Delaware corporation and changed its name to Kadmon Holdings, Inc. As required by the Second Amended and Restated Limited Liability Company Agreement of Kadmon Holdings, LLC, the Corporate Conversion was approved by our board of directors. In connection with the Corporate Conversion and holders of our outstanding voting units received 19,585,865 shares of common stock for all units held immediately prior to the Corporate Conversion, holders of options and warrants to purchase units became options and warrants to purchase one share of common stock for every 6.5 Class A units underlying such options or warrants immediately prior to the Corporate Conversion.

Financing Arrangements

August 2015 Secured Term Debt

In August 2015, we entered into the 2015 Credit Agreement in the amount of $35.0 million with two lenders. The interest rate on the loan is LIBOR plus 9.375% with a 1% floor. We incurred a $0.8 million commitment fee in connection with the loan that will be amortized to interest expense over the term of the agreement. The basic terms of the loan required monthly payments of interest only through the first anniversary date of the loan and required us to maintain certain financial covenants requiring us to maintain a minimum liquidity amount and minimum revenue levels beginning after June 30, 2016 through August 1, 2016, the date we consummated our IPO. Beginning on the first anniversary date of the loan, we were required to make monthly principal payments in the amount of $0.4 million. Any outstanding balance of the loan and accrued interest is to be repaid on June 17, 2018. The secured term loan is collateralized by a first priority perfected security interest in all our tangible and intangible property.

In conjunction with the 2015 Credit Agreement, warrants with an aggregate purchase price of $6.3 million to acquire Class A membership units were issued to two lenders, of which $5.4 million was recorded as a debt discount and $0.9 million was recorded as loss on extinguishment of debt in our consolidated financial statements.

Deferred financing costs of $1.3 million were recognized in recording the 2015 Credit Agreement and will be amortized to interest expense over the three year term of the agreement. Additionally, fees paid to one existing lender, inclusive of financial instruments issued of $0.1 million, were charged to loss on extinguishment of debt. There was also $1.5 million of debt discount and $0.4 million of deferred financing cost write-offs charged to loss on extinguishment of debt in connection with this transaction.

We entered into a third waiver agreement to the 2015 Credit Agreement in September 2016 to negotiate the amendment and restatement of certain covenants contained in the 2015 Credit Agreement. In connection with such negotiation, the lenders under the 2015 Credit Agreement had agreed to refrain from exercising certain rights under the 2015 Credit Agreement, including the declaration of a default and to forbear from acceleration of any repayment rights with respect to existing covenants until the parties have consummated the amendment and restatement of such provisions. In addition, certain payments required to be made under the 2015 Credit Agreement had been deferred while the parties negotiated the amendment. The parties executed a second amendment to the 2015 Credit Agreement in November 2016 whereby we deferred further principal payments owed under the 2015 Credit Agreement in the amount of $0.4 million per month until August 31, 2017. Additionally, the parties amended various clinical development milestones and added a covenant pursuant to which we are required to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. All other material terms of the 2015 Credit Agreement, including the maturity date, remain the same. As of the date hereof, we are not in default under the terms of the 2015 Credit Agreement.

We entered into a fourth waiver agreement to the 2015 Credit Agreement in March 2017 under which the lenders under the 2015 Credit Agreement agreed to refrain from exercising certain rights under the 2015 Credit Agreement, including the declaration of a default and to forbear from acceleration of any repayment rights with respect to existing covenants. The

report and opinion of our independent registered public accounting firm, BDO USA, LLP, contains an explanatory paragraph regarding our ability to continue as a going concern, which is an event of default under the 2015 Credit Agreement.

At December 31, 2016, the outstanding balance of the 2015 Credit Agreement was $34.6 million and the interest rate was LIBOR plus 9.375% with a 1% floor. We were in compliance with all covenants under the 2015 Credit Agreement at December 31, 2016 and 2015.

Other Equity Grants

In December 2014, Dr. Samuel D. Waksal received an award of 5,000 EAR units under the 2014 LTIP with a base price of $6.00 per EAR unit. The number of EAR units granted to Dr. Samuel D. Waksal was adjusted to equal 0.75% of our common stock determined on the first trading date following the date of the IPO. Based on the initial public offering price of $12.00 per share, the number of shares underlying Dr. Samuel D. Waksal's LTIP award is 1,783,618. After giving effect to the provisions of our separation agreement dated as of February 3, 2016 with Dr. Samuel D. Waksal discussed below, his EAR units vest upon the earliest of any of the following events: (a) the expiration date of December 16, 2024 if an IPO is consummated on or before December 16, 2024, subject to continuing service through December 16, 2024 (or a termination due to death or disability within one year prior to such date), (b) the date of a Change in Control (excluding an IPO) that occurs after the submission date of a registration statement on Form S-1 to the SEC but prior to December 16, 2024 (subject to continuing service through the date of the Form S-1 submission or, if earlier, the date of any material agreement or filing made in furtherance of the applicable Change in Control transaction), (c) subject to continuing service through the date of the Form S-1 submission, if and when the fair market value of each EAR unit exceeds 333.0% of the $6.00 grant price ($20.00) per share prior to December 16, 2024. In addition, the Administrator retains the discretion to cash out the EAR units upon a Change in Control. Payments are made no later than March 15 of the year following the year in which the award becomes vested. Payment will be made in cash or in common shares at our election with the payment amount determined using the fair market value of the common stock on the trading date immediately preceding the settlement date and any payment in the form of common stock will be limited to a maximum share allocation.

Relationship with MeiraGTx

In April 2015, we executed several agreements which transferred our ownership of Kadmon Gene Therapy, LLC to MeiraGTx, a then wholly-owned subsidiary of our company. As part of these agreements, we also transferred various property rights, employees and management tied to the ongoing development of the intellectual property and contracts identified in the agreements to MeiraGTx.

MeiraGTx subsequently ratified its shareholder agreement and accepted the pending equity subscription agreements, which provided equity ownership to various parties. The execution of these agreements resulted in our 48.0% ownership in MeiraGTx. The estimated fair value of our ownership interest was $24.0 million at the time of the transaction. At December 31, 2016, we maintain a 38.7% ownership in MeiraGTx. At December 31, 2016, Drs. Alexandria Forbes, Thomas E. Shenk and Mr. Steven N. Gordon, each maintain ownership interests of 6.6%, 1.9% and 0.5%, respectively.

MeiraGTx is developing an extensive pipeline of gene therapy products for inherited and acquired disorders, with the first three Phase 1/2 clinical trials initiating in 2016. MeiraGTx is developing therapies for xerostomia following radiation treatment for head and neck cancer; ocular diseases, including rare inherited retinopathies, including LCA2, achromatopsias, X-linked retinitis pigmentosa and dry and wet AMD; and neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS). MeiraGTx is also developing a transformative gene regulation technology platform that allows delivery of any biologic using an oral small molecule.

Relationship with NT Life

Kadmon Corporation, our wholly-owned subsidiary, currently holds 81,591 shares of common stock of Nano Terra, representing less than 1.0% of Nano Terra's issued and outstanding capital stock. Kadmon Corporation, LLC entered into a joint venture with SLx through the formation of NT Life, whereby Kadmon Corporation, LLC contributed $0.9 million at the date of formation in exchange for a 50.0% interest in NT Life and entered into a sub-licensing arrangement with NT Life. Pursuant to the sub-licensing arrangement, Kadmon Corporation was granted a perpetual, worldwide, exclusive license to three clinical-stage product candidates owned by SLx, as well as rights to SLx's drug discovery platform, Pharmacomer Technology, each of which were licensed by SLx to NT Life. One of the two clinical-stage products is being developed by us and is known as KD025. Patents and applications relating to these products were part of the sub-licensing agreement. Know-how related to the Pharmacomer Technology was also part of the sub-licensing agreement.

Executive Compensation and Equity Awards

Please see "Executive Compensation" for information on the compensation of, and equity awards granted to, our directors and executive officers.

On July 13, 2016, the compensation committee of the board of directors approved the amendment of all outstanding option awards under our 2011 Equity Incentive Plan, including with respect to option awards previously granted to our executive officers, effective upon the date of pricing of the IPO, to adjust the exercise price (on a post-Corporate Conversion, post-split basis) to the initial public offering price of $12.00 per share.

Employment Agreements

Please see the section titled "Item 11, Executive Compensation—Employment Agreements" for information on compensation and employment arrangements with our named executive officers.

Separation of Dr. Samuel D. Waksal

Dr. Samuel D. Waksal's Former Roles at Kadmon

Dr. Samuel D. Waksal founded our company in October 2010 and, until August 2014, was the chairman of our then board of managers and our Chief Executive Officer. In August 2014, he stepped down as our Chief Executive Officer and became our Chief of Innovation, Science and Strategy. Concurrently therewith, Dr. Harlan W. Waksal, who is Dr. Samuel D. Waksal's brother, was appointed President and Chief Executive Officer. In July 2015, Dr. Samuel D. Waksal resigned as chairman and as a member of our then board of managers. On August 1, 2015, Mr. Bart M. Schwartz, Esq., joined our board of directors and was elected as its Chairman.

In 2002, Dr. Samuel D. Waksal was charged by the SEC with violating the federal securities laws in connection with trades made in the shares of ImClone Systems, where he served as president, chief executive officer and director. Dr. Samuel D. Waksal was also charged with, and subsequently pled guilty to, securities fraud, bank fraud, wire fraud, obstruction of justice, perjury and related conspiracy charges.

As a result of a negotiated settlement of a civil enforcement action brought by the SEC, Dr. Samuel D. Waksal is subject to a final judgment and order on consent ("Consent Decree"). The Consent Decree permanently restrains and enjoins him from violating, directly or indirectly, laws and rules that prohibit securities fraud, including Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, Section 17(a) of the Securities Act of 1933 and Section 16(a) of the Exchange Act. The Consent Decree also permanently bars Dr. Samuel D. Waksal from acting as an officer or director of any public company.

Separation Agreement with Dr. Samuel D. Waksal

Effective as of February 8, 2016, Dr. Samuel D. Waksal resigned from all positions with us and is no longer employed by us in any capacity. We do not intend for Dr. Samuel D. Waksal to become an employee, provide any ongoing consulting services or rejoin the board of directors.

In connection with his resignation, we entered into a separation agreement with Dr. Samuel D. Waksal terminating his employment with us and providing that he shall perform no further paid or unpaid services for us whether as employee, consultant, contractor or any other service provider. The principal provisions of the separation agreement are summarized below.

Severance and Other Payments

We have agreed to make a series of payments (all subject to withholding taxes) to Dr. Samuel D. Waksal, some of which are contingent, structured as follows:

- a $3.0 million severance payment, of which the first $1.0 million will be payable during the first year after February 8, 2016, with the remaining $2.0 million to be payable during the two years commencing with the first anniversary of the start of payments of the first $1.0 million;

- supplemental conditional payments of up to $6.75 million in the aggregate that are payable in 2017 ($2.25 million), 2018 ($2.25 million) and 2019 ($2.25 million) if specified benchmarks related to the valuation of our company implied by the public offering price per share in the IPO, the net proceeds to us from the IPO and our equity market capitalization on specified dates are achieved and subject to our having cash and cash equivalents less payables of $50.0 million or more on the dates when we make those payments;

- an amount equal to 5.0% (up to a maximum of $15.0 million) of any cash received by us or guaranteed cash payments (as defined below) received by us pursuant to the first three business development programs that we enter into on or before February 8, 2019 to research, develop, market or commercialize our ROCK2 program or our immuno-oncology program. For purposes of the separation agreement, ROCK2 program is defined to mean pathways involving ROCK2 or other pathways effecting autoimmunity, fibrosis, cancer or neurodegenerative diseases; immuno-oncology program is defined to mean antibodies or small molecules involved in inducing the immune system to make an anti-tumor response; and guaranteed cash payments is defined to mean payments to us of cash contractually provided for pursuant to an agreement entered into by us with respect to a business development program, which payments are not subject to our meeting any milestones or thresholds. If the aggregate cash and guaranteed cash payments received by us pursuant to any business development program exceed $800.0 million before the completion of the IPO, the equity market capitalization requirements that must be met for Dr. Samuel D. Waksal to earn the supplemental payments of up to $6.75 million described above shall be deemed fulfilled, regardless of our equity market capitalization at the applicable time.

LTIP Award

With regard to the award of 5,000 EAR units granted to Dr. Samuel D. Waksal in December 2014, the separation agreement provides that:

- by virtue of his separation from service, Dr. Samuel D. Waksal acknowledges that he is no longer entitled to vesting on December 16, 2024 based on the occurrence of an IPO on or before that date and continued service through that date;
- the service component included in the vesting condition related to the occurrence of a change of control after an IPO but before December 16, 2024 is now satisfied;
- the service component included in the vesting condition related to the occurrence of a 333% increase in the fair market value of each EAR unit from the $6.00 grant price per unit before December 16, 2024 is now satisfied; and
- Dr. Samuel D. Waksal's EAR units shall not be subject to forfeiture, termination or recapture for violation of the restrictive covenants contained in the 2014 LTIP.

Lock-up Agreement

Dr. Samuel D. Waksal entered into a 180-day lock-up agreement in connection with the IPO which expired on January 22, 2017. If requested by the managing underwriters in any subsequent offering at the time of which Dr. Samuel D. Waksal owns five percent or more our common stock, he will enter into a lock-up agreement for a period not to exceed 90 days and in the form customarily requested by the managing underwriters for that offering (subject to mutually agreed exceptions), so long as other equityholders enter into substantially similar lock-up agreements. If any of our equityholders that signs a lock-up agreement is released from its provisions by the managing underwriters, Dr. Samuel D. Waksal will also be released from his lock-up agreement.

Covenants

The separation agreement contained customary non-solicitation, non-competition and non-disparagement provisions that continue in effect until February 8, 2019. In addition, Dr. Samuel D. Waksal agreed to make himself available, at our expense, to assist us in protecting our ownership of intellectual property and in accessing his knowledge of scientific and/or research and development efforts undertaken during his employment with us.

Releases

The separation agreement provided for mutual releases by the parties and related persons of all claims arising out of Dr. Samuel D. Waksal's relationship with us as an employee, founder, investor, member, owner, member or Chairman of the Board, Chief Executive Officer, or officer.

Indemnification Agreements

Our bylaws provide that we will indemnify our directors, officers and certain key employees to the fullest extent permitted by the Delaware General Corporation Law (DGCL), subject to certain exceptions contained in our bylaws. In addition, our certificate of incorporation, provides that our directors will not be liable for monetary damages for breach of fiduciary duty.

We entered into indemnification agreements with each of our executive officers and directors. The indemnification agreements provide the executive officers and directors with contractual rights to indemnification, and expense advancement and reimbursement, to the fullest extent permitted under the DGCL, subject to certain exceptions contained in those agreements.

Except as disclosed in ”Item 3. Legal Proceedings,” there is no pending litigation or proceeding naming any of our directors or officers to which indemnification is being sought, and we are not aware of any pending litigation that may result in claims for indemnification by any director or officer.

Policies and Procedures for Related Person Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interests and/or improper valuation (or the perception thereof). Our board of directors adopted a written policy on transactions with related persons that is in conformity with the requirements for issuers having publicly-held common stock that is listed on the NYSE. Under this policy:

- any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by a committee of the board of directors composed solely of independent directors who are disinterested or by the disinterested members of the board of directors; and

- any employment relationship or transaction involving an executive officer and any related compensation must be approved by the compensation committee of the board of directors or recommended by the compensation committee to the board of directors for its approval.

In connection with the review and approval or ratification of a related person transaction:

- management must disclose to the committee or disinterested directors, as applicable, the name of the related person and the basis on which the person is a related person, the material terms of the related person transaction, including the approximate dollar value of the amount involved in the transaction, and all the material facts as to the related person’s direct or indirect interest in, or relationship to, the related person transaction;

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction complies with the terms of our agreements governing our material outstanding indebtedness that limit or restrict our ability to enter into a related person transaction;

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction will be required to be disclosed in our applicable filings under the Securities Act or the Exchange Act, and related rules, and, to the extent required to be disclosed, management must ensure that the related person transaction is disclosed in accordance with such Acts and related rules; and

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction constitutes a “personal loan” for purposes of Section 402 of the Sarbanes-Oxley Act.

In addition, the related person transaction policy provides that the committee or disinterested directors, as applicable, in connection with any approval or ratification of a related person transaction involving a non-employee director or director nominee, should consider whether such transaction would compromise the director or director nominee’s status as an “independent,” “outside,” or “non-employee” director, as applicable, under the rules and regulations of the SEC, the NYSE and the Code.

Item 14. Principal Accounting Fees and Services.

The following table provides information regarding the fees incurred to BDO USA, LLP during the years ended December 31, 2016 and 2015.

	Year Ended December 31,	
	2016	2015
	(In thousands)	
Audit Fees[1]	$ 1,062	$ 679
Tax Fees	93	84
Audit-Related Fees	—	—
All Other Fees	—	—
Total Fees	$ 1,155	$ 763

(1) Audit fees of BDO USA, LLP for the years ended December 31, 2016 and 2015 were for professional services rendered for the audits of our financial statements, including accounting consultation and reviews of quarterly financial statements. Fees for 2016 and 2015 include $0.4 million and $0.2 million, respectively, for services associated with our IPO, which was completed in August 2016

Pre-Approval Policies and Procedures

The Audit Committee or a delegate of the Audit Committee pre-approves, or provides pursuant to pre-approvals policies and procedures for the pre-approval of, all audit and non-audit services provided by its independent registered public accounting firm. This policy is set forth in the charter of the Audit Committee and is available www.kadmon.com.

The Audit Committee approved all of the audit, audit-related, tax and other services provided by BDO USA, LLP and the estimated costs of those services. Actual amounts billed, to the extent in excess of the estimated amounts, are periodically reviewed and approved by the Audit Committee.

Director Independence

The Board has affirmatively determined that all of its directors, other than Drs. Harlan W. Waksal, Thomas E. Shenk and Alexandria Forbes, are independent directors within the meaning of the applicable NYSE listing standards and relevant securities and other laws, rules and regulations regarding the definition of “independent.” There are no family relationships between any director and any of our executive officers.

The Board has determined that each member of the Audit Committee, the Nominating and Corporate Governance Committee and the Compensation Committee meets the applicable NYSE listing standards and relevant securities and other laws, rules and regulations regarding “independence” and that each member is free of any relationship that would impair his individual exercise of independent judgment with regard to our Company.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The financial statements listed in the Index to Financial Statements beginning on page 129 are filed as part of this Annual Report on Form 10-K.

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our financial statements. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Kadmon Holdings, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Kadmon Holdings, Inc.
New York, New York

We have audited the accompanying consolidated balance sheets of Kadmon Holdings, Inc. (the "Company") as of December 31, 2016 and 2015 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2016. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Kadmon Holdings, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations, expects losses to continue in the future, has a deficiency in stockholders' equity and has a contractual obligation to raise $40.0 million of additional equity capital by the end of the second quarter of 2017 pursuant to the second amendment to the 2015 Credit Agreement entered into in November 2016 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP
New York, New York
March 22, 2017

Kadmon Holdings, Inc.
Consolidated balance sheets
(in thousands, except unit and share amounts)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 36,093	$ 21,498
Accounts receivable, net	655	2,410
Accounts receivable from affiliates	555	985
Inventories, net	1,950	3,468
Deferred offering costs	56	890
Prepaid expenses and other current assets	978	3,490
Total current assets	40,287	32,741
Fixed assets, net	5,427	6,938
Intangible assets, net	—	15,223
Goodwill	3,580	3,580
Restricted cash	2,116	2,116
Investment, at cost	3,542	2,300
Investment, equity method	7,599	21,224
Other noncurrent assets	5	15
Total assets	$ 62,556	$ 84,137
Liabilities, Redeemable Convertible Units and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 6,296	$ 5,902
Related party loan	—	3,000
Accrued expenses	12,150	11,843
Other short term liabilities	—	10,377
Deferred revenue	4,400	4,500
Other milestone payable	—	3,875
Fair market value of financial instruments	—	8,289
Secured term debt - current	1,900	1,900
Total current liabilities	24,746	49,686
Deferred revenue	24,017	28,417
Deferred rent	4,377	3,865
Deferred tax liability	1,376	1,349
Fair market value of financial instruments - non current	3,305	—
Other long term liabilities	1,250	3,152
Secured term debt – net of current portion and discount	28,677	26,264
Convertible debt, net of discount	—	183,457
Total liabilities	87,748	296,190
Commitments and contingencies (Note 16 and 17)		
Class E redeemable convertible units: 0 and 4,969,252 units issued and outstanding at December 31, 2016 and 2015, respectively	—	58,856
Stockholders' deficit:		
Class A units, no par value: 0 and 53,946,001 units issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Class B units, no par value: 0 and 1 unit issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Class C units, no par value: 0 and 1 unit issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Class D units, no par value: 0 and 4,373,674 units issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Convertible Preferred Stock, $0.001 par value; 10,000,000 and 0 shares authorized at December 31, 2016 and 2015, respectively; 30,000 and 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	38,302	—
Common Stock, $0.001 par value; 200,000,000 and 0 shares authorized at December 31, 2016 and 2015, respectively; 45,078,666 and 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	45	—
Additional paid-in capital	92,166	372,936
Accumulated deficit	(155,705)	(643,845)
Total stockholders' deficit	(25,192)	(270,909)
Total liabilities, redeemable convertible units, and stockholders' deficit	$ 62,556	$ 84,137

See accompanying notes to consolidated financial statements

Kadmon Holdings, Inc.
Consolidated statements of operations
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Revenues			
Net sales	$ 18,514	$ 29,299	$ 63,530
License and other revenue	7,541	6,420	31,488
Total revenue	26,055	35,719	95,018
Cost of sales	3,485	3,731	6,123
Write-down of inventory	385	2,274	4,916
Gross profit	22,185	29,714	83,979
Operating expenses:			
Research and development	35,840	33,558	32,947
Selling, general and administrative	105,880	104,740	89,321
Impairment of intangible asset	—	31,269	—
Gain on settlement of payable	(4,131)	—	—
Total operating expenses	137,589	169,567	122,268
Loss from operations	(115,404)	(139,853)	(38,289)
Other expense (income):			
Interest income	(38)	(10)	(26)
Interest expense	72,634	27,160	28,911
Loss on extinguishment of debt	11,176	2,934	4,579
Change in fair value of financial instruments	(4,380)	(1,494)	(4,969)
Gain on deconsolidation of subsidiary	—	(24,000)	—
Loss on equity method investment	13,625	2,776	—
Other income	(8)	(134)	(2,399)
Total other expense	93,009	7,232	26,096
Loss before income tax expense	(208,413)	(147,085)	(64,385)
Income tax expense (benefit)	342	(3)	(29)
Net loss	$ (208,755)	$ (147,082)	$ (64,356)
Deemed dividend on convertible preferred stock and Class E redeemable convertible units	21,733	—	—
Net loss attributable to common stockholders	$ (230,488)	$ (147,082)	$ (64,356)
Basic and diluted net loss per share of common stock	$ (9.74)	$ (18.10)	$ (8.27)
Weighted average basic and diluted shares of common stock outstanding	23,674,512	8,127,781	7,785,637

See accompanying notes to consolidated financial statements

Kadmon Holdings, Inc.
Consolidated statements of stockholders' deficit
(in thousands, except share amounts)

	Convertible units		Stockholders' deficit										
	Class E redeemable convertible units		Class A	Class B	Class C	Class D	Preferred stock		Common stock		Additional paid-in	Accumulated	
	Units	Amount	Units	Units	Units	Units	Shares	Amount	Shares	Amount	capital	Deficit	Total
Balance, January 1, 2014	—	$ —	50,399,070	1	1	4,373,674	—	$ —	—	$ —	$ 330,419	$ (432,407)	$(101,988)
Fair value of units issued in settlement of obligation	—	—	467,081	—	—	—	—	—	—	—	4,100	—	4,100
Fair value of units issued to employees as compensation	—	—	8,000	—	—	—	—	—	—	—	56	—	56
Unit-based compensation	—	—	—	—	—	—	—	—	—	—	4,493	—	4,493
Fair value of units transferred to employees as compensation	—	—	—	—	—	—	—	—	—	—	2,976	—	2,976
Issuance of Class A units to employees related to option exercises	—	—	8,505	—	—	—	—	—	—	—	51	—	51
Equity raised through issuance of Class E units, net	3,438,984	39,548	—	—	—	—	—	—	—	—	—	—	—
Fees and expenses related to issuance of Class E units	—	(3,099)	—	—	—	—	—	—	—	—	—	—	—
Accretion of Class E units fee discount and repayment premium	—	603	—	—	—	—	—	—	—	—	(603)	—	(603)
Reclassification of lender warrants from liability to equity	—	—	—	—	—	—	—	—	—	—	447	—	447
Reclassification of lender warrants from equity to liability	—	—	—	—	—	—	—	—	—	—	(596)	—	(596)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(64,356)	(64,356)
Balance, December 31, 2014	3,438,984	$ 37,052	50,882,656	1	1	4,373,674	—	$ —	—	$ —	$ 341,343	$ (496,763)	$(155,420)
Issuance of Class A units to settle obligation	—	—	1,808,334	—	—	—	—	—	—	—	10,541	—	10,541
Issuance of Class E units to non-employee directors	10,435	63	—	—	—	—	—	—	—	—	—	—	—
Issuance of Class E units to settle obligation	574,392	6,606	—	—	—	—	—	—	—	—	—	—	—
Issuance of Class E units, net of transaction costs of $40	945,441	10,833	—	—	—	—	—	—	—	—	—	—	—
Accretion of Class E units fee discount and repayment premium	—	4,302	—	—	—	—	—	—	—	—	(4,302)	—	(4,302)
Issuance of Class A units	—	—	1,250,000	—	—	—	—	—	—	—	15,000	—	15,000
Unit-based compensation	—	—	—	—	—	—	—	—	—	—	10,324	—	10,324
Issuance of Class A units related to option exercises	—	—	5,011	—	—	—	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	—	—	—	—	—	—	(147,082)	(147,082)
Balance, December 31, 2015	4,969,252	$ 58,856	53,946,001	1	1	4,373,674	—	$ —	—	$ —	$ 372,936	$ (643,845)	$(270,909)
Issuance of Class A units to settle obligation	—	—	25,000	—	—	—	—	—	—	—	125	—	125
Issuance of Class E units to settle obligation	1,170,437	13,460	—	—	—	—	—	—	—	—	—	—	—
Equity raised through issuance of Class E units, net	478,266	5,500	—	—	—	—	—	—	—	—	—	—	—
Accretion of Class E units fee discount and repayment premium	—	5,812	—	—	—	—	—	—	—	—	(5,812)	—	(5,812)
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	47,217	—	47,217
Issuance of Class A units related to option exercises	—	—	7,200	—	—	—	—	—	—	—	41	—	41
Issuance of common stock to settle obligation	—	—	—	—	—	—	—	—	208,334	1	2,499	—	2,500
Common stock issued in initial public offering, net of commissions and underwriting discounts	—	—	—	—	—	—	—	—	6,250,000	6	69,744	—	69,750
Initial public offering costs	—	—	—	—	—	—	—	—	—	—	(3,739)	—	(3,739)
Beneficial conversion feature on Class E units	—	—	—	—	—	—	—	—	—	—	13,431	(13,431)	—
Cumulative effect of change in accounting principle - ASU 2016-09 forfeiture adjustment	—	—	—	—	—	—	—	—	—	—	1,990	(1,990)	—
Corporate conversion from Kadmon Holdings, LLC to Kadmon Holdings, Inc.	—	—	—	—	—	—	—	—	—	—	(720,618)	720,618	—
Corporate conversion to common stock	(6,617,955)	(83,628)	(53,978,201)	(1)	(1)	(4,373,674)	—	—	19,585,865	19	83,607	—	83,626
Conversion of convertible debt to common stock	—	—	—	—	—	—	—	—	19,034,467	19	182,712	—	182,731
Beneficial conversion feature on convertible debt	—	—	—	—	—	—	—	—	—	—	45,683	—	45,683
Conversion of convertible debt to convertible preferred stock	—	—	—	—	—	—	30,000	30,000	—	—	—	—	30,000
Beneficial conversion feature on convertible preferred stock	—	—	—	—	—	—	—	7,660	—	—	—	(7,660)	—
Accretion of dividends on convertible preferred stock	—	—	—	—	—	—	—	642	—	—	—	(642)	—
Reclassification of warrants to equity	—	—	—	—	—	—	—	—	—	—	1,716	—	1,716
Beneficial conversion feature on warrants	—	—	—	—	—	—	—	—	—	—	634	—	634
Net loss	—	—	—	—	—	—	—	—	—	—	—	(208,755)	(208,755)
Balance, December 31, 2016	—	$ —	—	—	—	—	30,000	$38,302	45,078,666	$ 45	$ 92,166	$ (155,705)	$ (25,192)

See accompanying notes to consolidated financial statements

Kadmon Holdings, Inc.
Consolidated statements of cash flows
(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (208,755)	$ (147,082)	$ (64,356)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of fixed assets	2,280	2,312	2,617
Amortization of intangible asset	15,223	27,442	21,831
Impairment of intangible asset	—	31,269	—
Write-down of inventory	385	2,274	4,916
Write-down of capitalized computer software development costs	—	62	—
Gain on purchase commitment	—	(243)	(1,640)
Loss on extinguishment of debt / conversion of debt	11,176	2,934	4,579
Write-off of deferred financing costs and debt discount	3,820	2,752	—
Amortization of deferred financing costs	1,304	1,290	1,635
Amortization of debt discount	3,118	3,867	1,698
Accretion of repayment premium on secured term debt	—	(345)	345
Share-based compensation	47,217	10,324	7,588
Gain on settlement of payable	(4,131)	—	(1,015)
Bad debt expense	6	5	66
Gain on deconsolidation of subsidiary	—	(24,000)	—
Change in fair value of financial instruments	(4,380)	(1,494)	(4,969)
Beneficial conversion feature expense on warrants	1,745	—	—
Beneficial conversion feature expense on convertible debt	44,170	—	—
Fair value of units issued to consultants	3,000	—	—
Fair value of shares / units issued in settlement of obligation	4,360	13,647	1,320
Accrued legal settlement	—	10,350	—
Deferred taxes	27	(3)	(29)
Paid-in-kind interest	14,695	11,434	13,374
Loss on equity method investment	13,625	2,776	—
Changes in operating assets and liabilities:			
Restricted cash	—	(89)	7,498
Accounts receivable, net	937	(1,313)	5,794
Inventories, net	1,133	1,930	(367)
Prepaid expenses and other assets	(479)	597	2,019
Accounts payable	530	(4,413)	120
Accrued expenses, other liabilities and deferred rent	534	3,040	(13,117)
Deferred revenue	(4,500)	(10,300)	1,600
Net cash used in operating activities	(52,950)	(60,977)	(8,493)

See accompanying notes to consolidated financial statements

Kadmon Holdings, Inc.
Consolidated statements of cash flows (continued)
(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from investing activities:			
Purchases of fixed assets	(539)	(161)	(2,062)
Net cash used in investing activities	(539)	(161)	(2,062)
Cash flows from financing activities:			
Proceeds from issuance of common stock in IPO, net	69,750	—	—
Payments of initial public offering costs	(3,293)	(445)	—
Payment of financing costs related to debt exchange agreements	(534)	—	—
Proceeds from issuance of secured term debt	—	35,000	—
Proceeds from issuance of convertible debt	—	112,500	—
Payment of financing costs	—	(4,069)	(51)
Principal payments on secured term debt	(380)	(107,204)	(43,563)
Proceeds from related party loans	—	2,000	4,196
Repayment of related party loans	(3,000)	(2,000)	(696)
Proceeds from issuance of Class A units, net	—	15,000	—
Proceeds from issuance of Class E redeemable convertible units, net	5,500	10,833	38,822
Proceeds from exercise of stock options	41	30	51
Net cash provided by (used in) financing activities	68,084	61,645	(1,241)
Net increase (decrease) in cash and cash equivalents	14,595	507	(11,796)
Cash and cash equivalents, beginning of period	21,498	20,991	32,787
Cash and cash equivalents, end of period	$ 36,093	$ 21,498	$ 20,991
Supplemental cash flow disclosures:			
Cash paid for interest	$ 3,723	$ 8,019	$ 11,549
Cash paid for taxes	339	153	104
Non-cash investing and financing activities:			
Settlement of related party loan	—	500	—
Units issued in settlement of obligation	11,725	9,063	2,780
Capitalized lease obligations	230	20	72
Unpaid financing/offering costs	56	1,958	2,373
Equity method investment related to deconsolidation	—	24,000	—
Fee payable to lenders resulting in principal increase of convertible debt	—	—	10,000
Financing costs paid with convertible notes	—	2,260	—
Fair value of warrants issued to lenders	—	6,300	—
Cost method investment in affiliate	1,242	—	—
Beneficial conversion feature on convertible preferred stock	7,660	—	—
Accretion of dividends on convertible preferred stock	642	—	—
Beneficial conversion feature on Class E units	13,431	—	—
Conversion of Class E units into common stock	83,628	—	—
Conversion of convertible debt into common stock	176,615	—	—
Conversion of convertible debt into convertible preferred stock	30,000	—	—
Reclassification of warrants from liability to equity	1,716	—	—
Reclassification of warrants from equity to liability	—	—	149

See accompanying notes to consolidated financial statements

Kadmon Holdings, Inc. and Subsidiaries

Notes to consolidated financial statements

1. Organization

Nature of Business

Kadmon Holdings, Inc. (together with its subsidiaries, "Kadmon" or "Company") is a fully integrated biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address disease areas of significant unmet medical needs. The Company is actively developing product candidates in a number of indications within autoimmune and fibrotic disease, oncology and genetic diseases. The Company leverages its multi-disciplinary research and clinical development team members to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing its small molecule and biologics platforms. By retaining global commercial rights to its lead product candidates, the Company believes that it has the ability to progress these candidates while maintaining flexibility for commercial and licensing arrangements. The Company expects to continue to progress its clinical candidates and have further clinical trial events throughout 2017.

Corporate Conversion, Initial Public Offering and Debt Conversion

On July 26, 2016, in connection with the pricing of the Company's IPO, Kadmon Holdings, LLC filed a certificate of conversion, whereby Kadmon Holdings, LLC effected a corporate conversion from a Delaware limited liability company to a Delaware corporation and changed its name to Kadmon Holdings, Inc. As a result of the corporate conversion, accumulated deficit was reduced to zero on the date of the corporate conversion, and the corresponding amount was credited to additional paid-in capital. In connection with this corporate conversion, the Company filed a certificate of incorporation and adopted bylaws, all of which were previously approved by the Company's board of directors and stockholders. Pursuant to the Company's certificate of incorporation, the Company is authorized to issue up to 200,000,000 shares of common stock $0.001 par value per share and 10,000,000 shares of preferred stock $0.001 par value per share. All references in the audited consolidated financial statements to the number of shares and per-share amounts of common stock have been retroactively restated to reflect this conversion.

On August 1, 2016, the Company completed its IPO whereby it sold 6,250,000 shares of common stock at $12.00 per share. The aggregate net proceeds received by the Company from the offering were $66.0 million, net of underwriting discounts and commissions of $5.3 million and offering expenses of $3.7 million. Upon the closing of the IPO, 45,078,666 shares of common stock were outstanding, which includes 19,034,467 shares of common stock as a result of the conversion of the Company's Senior Convertible Term Loan and Second Lien Convert (Note 7). The shares began trading on the New York Stock Exchange on July 27, 2016 under the symbol "KDMN."

Liquidity

The Company had an accumulated deficit of $155.7 million and working capital of $15.5 million at December 31, 2016. For the year ended December 31, 2016, the Company earned a $2.0 million milestone payment pursuant to a license agreement entered into with Jinghua to develop products using human monoclonal antibodies and raised $5.5 million through the issuance of Class E redeemable convertible units in June 2016. Additionally, the Company raised $66.0 million, net of underwriting discounts and commissions and offering expenses, in its IPO and raised gross proceeds of $22.7 million in March 2017, $21.3 million net of placement agent fees, which is expected to enable the Company to advance its planned Phase 2 clinical studies for KD025 and tesevatinib, complete its planned development for KD034 and advance certain of its other pipeline product candidates.

On November 4, 2016, the Company executed a second amendment to the 2015 Credit Agreement. Pursuant to this amendment, the Company deferred further principal payments owed under the 2015 Credit Agreement in the amount of $380,000 per month until August 31, 2017. Additionally, the parties amended various clinical development milestones and added a covenant pursuant to which the Company is required to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. All other material terms of the 2015 Credit Agreement, including the maturity date, remain the same. The Company maintained cash and cash equivalents of $36.1 million at December 31, 2016.

Management's plans include continuing to finance operations through the issuance of additional equity instruments and securities and increasing the commercial portfolio through the development of the current pipeline or through the acquisition of a third party or license agreement. Any transactions which occur may contain covenants that restrict the ability of management to operate the business or may have rights, preferences or privileges senior to the Company's common stock and may dilute current stockholders of the Company. Engaging in a transaction with a third party is contingent on negotiations

among the parties; therefore, there is no certainty that the Company will enter into such an agreement should the Company so desire.

2. Going Concern

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company has not established a source of revenues sufficient to cover its operating costs, and as such, has been dependent on funding operations through the issuance of debt and sale of equity securities. The Company expects to incur further losses over the next several years as it develops its business.

Further, at December 31, 2016, the Company had working capital of only $15.5 million. The Company's accumulated deficit amounted to $155.7 million and $643.8 million at December 31, 2016 and 2015, respectively. Net cash used in operating activities was $53.0 million, $61.0 million and $8.5 million for years ended December 31, 2016, 2015 and 2014. The Company must raise additional capital to fund its continued operations and remain in compliance with its debt covenants. The Company may not be successful in its efforts to raise additional funds or achieve profitable operations. Amounts raised will be used for further development of the Company's product candidates, to provide financing for marketing and promotion, to secure additional property and equipment, and for other working capital purposes. Even if the Company is able to raise additional funds through the sale of its equity securities, or loans from financial institutions, the Company's cash needs could be greater than anticipated in which case it could be forced to raise additional capital.

In March 2017, the Company raised $22.7 million in gross proceeds, $21.3 million net of $1.4 million in placement agent fees, from the issuance of 6,767,855 shares of its common stock, at a price of $3.36 per share, and warrants to purchase 2,707,138 million shares of its common stock at an initial exercise price of $4.50 per share for a term of 13 months from the date of issuance (See Note 21). At the present time, the Company has no commitments for any additional financing, and there can be no assurance that, if needed, additional capital will be available to the Company on commercially acceptable terms or at all. If the Company cannot obtain the needed capital, it may not be able to become profitable and may have to curtail or cease its operations. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments or classifications that may result from the possible inability of the Company to continue as a going concern.

3. Summary of Significant Accounting Policies

Basis of Presentation

The Company operates in one segment considering the nature of the Company's products and services, class of customers, methods used to distribute the products and the regulatory environment in which the Company operates. Research and development expenses, and selling, general and administrative expenses were revised to conform to the current presentation with regard to the Company's method of allocating a portion of facility-related expenses to research and development expenses to more accurately reflect the effort spent on research and development. For the years ended December 31, 2015 and 2014, the Company reclassified $3.9 million and $3.8 million respectively, from selling, general and administrative expenses to research and development expenses.

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements include the accounts of Kadmon Holdings, Inc. and its domestic and international subsidiaries, all of which are wholly owned.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates.

Company Valuation

To estimate certain expenses and record certain transactions, it was necessary for the Company to estimate the fair value of its membership units. Given the absence of a public trading market prior to the IPO, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its membership units (Note 4).

Revenue Recognition

The Company recognizes sales when the risk of loss has been transferred to the customer. As is typical in the pharmaceutical industry, gross product sales are subject to a variety of deductions, primarily representing rebates, chargebacks, returns, and discounts to government agencies, wholesalers, and managed care organizations. These deductions represent management's best estimates of the related reserves and, as such, judgment is required when estimating the impact of these sales deductions on gross sales for a reporting period. If estimates are not representative of the actual future settlement, results could be materially affected. The Company's product sales were substantially derived from the sale of its ribavirin portfolio of products during the years ended December 31, 2016, 2015 and 2014.

The Company accounts for revenue arrangements that contain multiple deliverables in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 605-25, "Revenue Recognition for Arrangements with Multiple Elements", which addresses the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting. A delivered item within an arrangement is considered a separate unit of accounting only if both of the following criteria are met:

- the delivered item has value to the customer on a stand-alone basis; and

- the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the vendor.

In accordance with FASB ASC Topic 605-25, if both of the criteria above are not met, then separate accounting for the individual deliverables is not appropriate. Revenue recognition for arrangements with multiple deliverables constituting a single unit of accounting is recognized generally over the greater of the term of the arrangement or the expected period of performance, either on a straight-line basis or on a modified proportional performance method.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the receivable is reasonably assured and the Company has no future performance obligations under the license agreement.

The Company may earn contingent payments from third parties based on the achievement of certain clinical and commercial milestones. The Company recognizes milestone revenue as the underlying criteria is achieved in accordance with FASB ASC Topic 605-28, "Revenue Recognition Milestone Method".

The Company reassesses the period of performance over which the Company recognizes deferred upfront license fees and makes adjustments as appropriate in the period in which a change in the estimated period of performance is identified. In the event a licensee elects to discontinue development of a specific product candidate under a single target license, but retains its right to use the Company's technology to develop an alternative product candidate to the same target or a target substitute, the Company would cease amortization of any remaining portion of the upfront fee until there is substantial pre-clinical activity on another product candidate and its remaining period of substantial involvement can be estimated. In the event that a single target license were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination or through the remaining substantial involvement in the wind down of the agreement.

Foreign Revenue

Foreign product sales represented approximately 21.0%, 10.0% and 10% of total product sales for the years ended December 31, 2016, 2015 and 2014, respectively, the majority of which were to Germany and Ireland.

Sales Returns Reserve

Revenue is recognized net of sales returns, which are estimated using the Company's historical experience. The sales returns reserve was $416,000 and $526,000 at December 31, 2016 and 2015, respectively. Actual results could differ from original estimates resulting in future adjustments to revenue.

Reserve for Wholesaler Chargebacks and Rebates

The Company maintains a reserve for wholesaler chargebacks and rebates to properly reflect the realizable value of accounts receivable. A chargeback represents a contractual allowance provided by the Company to its wholesalers for any variances between wholesale and lower retail prices of the Company's pharmaceutical products. The Company estimates the reserve for wholesaler chargebacks based on wholesaler inventory levels, contract prices and historical experience. Rebate reserves represent contractual allowances based on specific customer contracts. The rebate allowance is estimated as a

percentage of specific customer sales. The reserve for wholesaler chargebacks and rebates was $145,000 and $429,000 at December 31, 2016 and 2015, respectively.

Rebates Payable

The Company issues rebates related to various government programs and buying groups. In these instances, the rebates are paid in cash to the party managing the discount buying program. The estimated rebates earned but unpaid was $443,000 and $370,000 at December 31, 2016 and 2015, respectively. Such amounts have been included in accounts payable on the Company's consolidated balance sheets.

Shipping and Handling Costs

Shipping and handling costs for raw materials and finished goods prior to their sale are classified in cost of sales. Freight charges for shipments to customers are not billed to customers and are included in selling, general and administrative expenses when incurred and were $185,000, $254,000 and $465,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Foreign Currencies

The consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. Gains or losses on transactions denominated in a currency other than the Company's functional currency, which arise as a result of changes in foreign currency exchange rates, are recorded in other income on the consolidated statements of operations. The transaction gains were $9,000, $124,000 and $134,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Share-based Compensation Expense

The Company recognizes share-based compensation expense in accordance with FASB ASC Topic 718, "Stock Compensation" ("ASC 718"), for all share-based awards made to employees and board members based on estimated fair values.

ASC 718 requires companies to measure the cost of employee services incurred in exchange for the award of equity instruments based on the estimated fair value of the share-based award on the grant date. The expense is recognized over the requisite service period.

All share-based awards to non-employees are accounted for in accordance with FASB ASC Topic 505-50, "Equity Based Payments to Non-Employees," where the value of unit compensation is based on the measurement date, as determined at either a) the date at which a performance commitment is reached, or b) the date at which the necessary performance to earn the equity instruments is complete.

The Company uses a Black-Scholes option-pricing model to value the Company's option awards. Using this option-pricing model, the fair value of each employee and board member award is estimated on the grant date. The fair value is expensed on a straight-line basis over the vesting period. The option awards generally vest pro-rata annually. The expected volatility assumption is based on the volatility of the share price of comparable public companies. The expected life is determined using the "simplified method" permitted by Staff Accounting Bulletin Numbers 107 and 110 (the midpoint between the term of the agreement and the weighted average vesting term). The risk-free interest rate is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted. The dividend yield is zero, as the Company has never declared a cash dividend.

In the fourth quarter of 2016, the Company adopted ASU 2016-09, "*Compensation—Stock Compensation*". ASU 2016-09 requires that certain other amendments relevant to the Company be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to accumulated deficit as of the beginning of the period in which the guidance is adopted. As a result of adopting ASU 2016-09 during the three months ended December 31, 2016, the Company adjusted accumulated deficit for amendments related to an entity-wide accounting policy election to recognize share-based award forfeitures only as they occur rather than an estimate by applying a forfeiture rate. The Company recorded a $2.0 million charge to accumulated deficit as of January 1, 2016 and an associated credit to additional paid-in capital for previously unrecognized share-based compensation expense as a result of applying this policy election. The Company also recorded $0.8 million in additional share-based compensation expense during the fourth quarter of 2016 as a result of applying estimated forfeitures recorded during the nine months ended September 30, 2016. When the consolidated statement of operations for the three months ended March 31, June 30 and September 30, 2016 is presented in future periods, it will include $0.3 million, $0.3 million and $0.2 million of additional stock compensation expense.

ASU 2016-09 also requires the recognition of the income tax effects of awards in the consolidated statement of operations when the awards vest or are settled, thus eliminating addition paid-in capital pools. The Company elected to adopt

the amendments related to the presentation of excess tax benefits on the condensed consolidated statement of cash flows using a prospective transition method.

Modification of Awards

A change in any of the terms or conditions of the awards is accounted for as a modification of the award. Incremental compensation cost is measured as the excess, if any, of the fair value of the modified award over the fair value of the original award immediately before its terms are modified, measured based on the fair value of the awards and other pertinent factors at the modification date. For vested awards, the Company recognizes incremental compensation cost in the period the modification occurs. For unvested awards, if the award is probable of vesting both before and after the change, the Company recognizes the sum of the incremental compensation cost and the remaining unrecognized compensation cost for the original award on the modification date over the remaining requisite service period. If the fair value of the modified award is lower than the fair value of the original award immediately before modification, the minimum compensation cost the Company recognizes is the cost of the original award.

Research and Development

Innovation is critical to the success of the Company, and drug discovery and development are time-consuming, expensive and unpredictable. The Company has built a pipeline of therapeutic candidates in all stages of development. The focus is on serious diseases where there is a great need and opportunity for innovative medicines. Product candidates and development strategies contemplate both immediate possibilities in medicine, such as reducing toxicity or addressing certain disease resistance and mutation, and future possibilities and medical needs. Included in research and development expense are personnel related costs, expenditures for laboratory equipment and consumables, payments made pursuant to licensing and acquisition agreements, and the cost of conducting clinical trials. Expenses incurred associated with conducting clinical trials include, but are not limited to, dosing of patients with clinical drug candidates, assistance from third party consultants and other industry experts, accumulation and interpretation of data on drug safety and efficacy, and manufacturing of active pharmaceutical ingredients and placebos for use within the clinical trial.

The Company has entered into agreements with third parties to acquire technologies and pharmaceutical product candidates for development (Note 12). Such agreements generally require an initial payment by the Company when the contract is executed, and additional payments upon the achievement of certain milestones. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the pharmaceutical product candidate and achieves a certain sales volume. In accordance with FASB ASC Topic 730-10-55, “Research and Development”, expenditures for research and development, including upfront licensing fees and milestone payments associated with products that have not yet been approved by the FDA, are charged to research and development expense as incurred. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable. Once a product candidate receives regulatory approval, subsequent license payments are recorded as an intangible asset.

Research and development expense was $35.8 million, $33.6 million and $32.9 million during the years ended December 31, 2016, 2015 and 2014, respectively.

Income Taxes

The Company accounts for income taxes in accordance with the asset and liability method of accounting for income taxes prescribed by FASB ASC Topic 740, “Accounting for Income Taxes” (“ASC 740”). Under the asset and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to the taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment dates.

The Company follows FASB ASC Topic 740-10, “Accounting for Uncertainty in Income Taxes”, which prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. At December 31, 2016 and 2015, the Company had no material uncertain tax positions to be accounted for in the financial statements. The Company recognizes interest and penalties, if any, related to unrecognized tax benefits in interest expense.

Under ASU 2016-09, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) should be recognized as income tax expense or benefit in the statement of operations. The tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity also should

recognize excess tax benefits regardless of whether the benefits reduce tax payable in the current period. The Company made an early adoption on the ASU 2016-09 effect in the fourth quarter of 2016. There is no cumulative impact as the federal and state excess deductions would be offset by a corresponding change to the valuation allowance.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. At times, cash balances deposited at major financial banking institutions exceed the federally insured limit. The Company regularly monitors the financial condition of the institutions in which it has depository accounts and believes the risk of loss is minimal.

Restricted Cash

The Company has a lease agreement for the premises it occupies in New York. A secured letter of credit in lieu of a lease deposit totaling $2.0 million is secured by restricted cash in the same amount at December 31, 2016 and 2015. The secured letter of credit will remain in place for the life of the related lease, expiring in October 2024 (Note 16). The Company also has a lease agreement for the premises it occupies in Massachusetts. A secured letter of credit in lieu of a lease deposit totaling $91,000 was established during the third quarter of 2015 and is secured by restricted cash in the same amount at December 31, 2016 and 2015. The secured letter of credit will remain in place for the life of the related lease, expiring in April 2023 (Note 16).

Allowance for Doubtful Accounts

The Company reviews the collectability of accounts receivable based on an assessment of historical experience, current economic conditions, and other collection indicators. The Company has recorded an allowance for doubtful accounts of $0.7 million at both December 31, 2016 and 2015. Adjustments to the allowance for doubtful accounts are recorded to selling, general and administrative expenses, and amounted to $6,000, $5,000, and $66,000 for the years ended December 31, 2016, 2015 and 2014, respectively. When accounts are determined to be uncollectible they are written off against the reserve balance and the reserve is reassessed. When payments are received on reserved accounts they are applied to the customer's account and the reserve is reassessed.

Inventories

Inventories are stated at the lower of cost or market (on a first-in, first-out basis) using standard costs. Standard costs include an allocation of overhead rates, which include those costs attributable to managing the supply chain and are evaluated regularly. Variances are expensed as incurred.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. If the equity financing is no longer considered probable of being consummated, the deferred offering costs would be expensed immediately to operating expenses in the statement of operations. There were $0.1 million and $0.9 million of deferred offering costs capitalized at December 31, 2016 and 2015, respectively.

Investments

The Company follows FASB ASC Topic 323, "Investments—Equity Method and Joint Ventures" ("ASC 323"), in accounting for its investment in a joint venture. In the event the Company's share of the joint venture's net losses reduces the Company's investment to zero, the Company will discontinue applying the equity method and will not provide for additional losses unless the Company has guaranteed obligations of the joint venture or is otherwise committed to provide further financial support for the joint venture. If the joint venture subsequently reports net income, the Company will resume applying the equity method only after its share of that net income equals the share of net losses not recognized during the period the equity method was suspended.

The Company follows FASB ASC Topic 325, "Investments—Other" ("ASC 325"), in accounting for its investment in the stock of another company. In the event further contributions or additional shares are purchased, the Company will increase the basis in the investment. In the event distributions are made or indications exist that the fair value of the investment has decreased below the carrying amount, the Company will decrease the value of the investment as considered appropriate.

The Company's total investment balance totaled $11.1 million and $23.5 million at December 31, 2016 and 2015, respectively.

For all non-consolidated investments, the Company will continually assess the applicability of FASB ASC Topic 810, "Consolidation" ("ASC 810"), to determine if the investments qualify for consolidation. At December 31, 2016 and 2015, no such investments qualified for consolidation (Note 12).

Fixed Assets

Fixed assets are recorded at cost and depreciated over their estimated useful lives. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term, using the straight-line method. Construction-in-progress and software under development are stated at cost and not depreciated. These items are transferred to fixed assets when the assets are placed into service.

Intangible Assets

Intangible assets are stated at cost, less accumulated amortization. The Company accounts for the purchases of intangible assets in accordance with FASB ASC Topic 350 "Intangibles—Goodwill and Other". Intangible assets are recognized based on their acquisition cost. The assets will be tested for impairment at least once annually, if determined to have an indefinite life, or whenever events or changes in circumstances indicate that the carrying amount may no longer be recoverable. If any of the Company's intangible or long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value. Applicable long-lived assets, including intangible assets with definitive lives, are amortized or depreciated over the shorter of their estimated useful lives, the estimated period that the assets will generate revenue, or the statutory or contractual term in the case of patents. Estimates of useful lives and periods of expected revenue generation are reviewed periodically for appropriateness and are based upon management's judgment.

Goodwill

The Company's goodwill relates to the 2010 acquisition of Kadmon Pharmaceuticals, a Pennsylvania limited liability company that was formed in April 2000. Goodwill is not amortized, but rather is assessed for impairment annually or upon the occurrence of an event that indicates impairment may have occurred, in accordance with FASB ASC Topic 350 "Intangibles—Goodwill and Other". No impairment to goodwill was recorded during the years ended December 31, 2016, 2015 and 2014.

Impairment of Long-Lived Assets

Long-lived assets, such as intangible assets (other than goodwill) and fixed assets, are evaluated for impairment periodically, or when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When any such impairment exists, a charge is recorded in the statement of operations to adjust the carrying value of the related assets.

The Company performed a trigger analysis over all other long-lived assets at the lowest identifiable level of cash flows and determined that an impairment existed during the year ended December 31, 2015 (Note 11) and no impairment triggers existed during the years ended December 31, 2016 and 2014. An impairment of $31.3 million was recognized during the year ended December 31, 2015, while no such impairment was recognized during the years ended December 31, 2016 and 2014 (Note 11).

Accounting for Leases

The Company recognizes rent expense for operating leases as of the earlier of the possession date or the lease commencement date. Rental expense, inclusive of rent escalations, rent holidays, concessions and tenant allowances are recognized over the lease term on a straight-line basis. See Note 16 for a further discussion of operating leases.

The Company has entered into capital lease agreements for information technology and laboratory equipment. As a result of these leases, the Company capitalized $230,000, $20,000 and $72,000 as office equipment and furniture during the years ended December 31, 2016, 2015 and 2014, respectively. The unamortized portion of capital leases totaled $191,000 and $54,000 at December 31, 2016 and 2015, respectively.

Accounting for Contingencies

The Company follows the guidance of FASB ASC Topic 450, "Contingencies" ("ASC 450"), in accounting for contingencies. If some amount within a range of loss is probable and appears at the time to be a better estimate than any other amount within the range, that amount shall be expensed. If a loss is probable, and no amount within the range is a better estimate than any other amount, the estimated minimum amount in the range shall be expensed.

Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, “Fair Value Measurements and Disclosures” (“ASC 820”). This pronouncement defines fair value, establishes a framework for measuring fair value under GAAP and requires expanded disclosures about fair value measurements. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and defines fair value as the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). These valuation techniques are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company’s market assumptions. ASC 820 utilizes a fair value hierarchy that prioritizes inputs to fair value measurement techniques into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices for identical assets or liabilities in active markets.

- Level 2: Observable inputs other than quoted prices that are directly or indirectly observable for the asset or liability, including quoted prices for similar assets or liabilities in active markets; quoted prices for similar or identical assets or liabilities in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

- Level 3: Unobservable inputs that reflect the reporting entity’s own assumptions.

The fair value of cash and cash equivalents, accounts receivable, accounts payable and other milestone payable approximate their carrying amounts due to their short term nature (Note 8).

Loan Modifications and Extinguishments

The Company follows the provisions of FASB ASC Subtopic 470-50 “Debt Modifications and Extinguishments” (“ASC 470-60”) and ASC Subtopic 470-60, “Troubled Debt Restructurings by Debtors” (“ASC 470-60”). Under ASC 470-50, an exchange of debt instruments between or a modification of a debt instrument by a debtor and a creditor in a nontroubled debt situation is deemed to have been accomplished with debt instruments that are substantially different if the present value of the cash flows under the terms of the new debt instrument is at least 10 percent different from the present value of the remaining cash flows under the terms of the original instrument. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is less than 10 percent, the debt instruments are not considered to be substantially different, except in the following two circumstances:

- A modification or an exchange affects the terms of an embedded conversion option, from which the change in the fair value of the embedded conversion option (calculated as the difference between the fair value of the embedded conversion option immediately before and after the modification or exchange) is at least 10 percent of the carrying amount of the original debt instrument immediately before the modification or exchange.

- A modification or an exchange of debt instruments adds a substantive conversion option or eliminates a conversion option that was substantive at the date of the modification or exchange.

Under ASC 470-60, a restructuring of a debt constitutes a troubled debt restructuring for purposes of this Subtopic if the creditor for economic or legal reasons related to the debtor’s financial difficulties grants a concession to the debtor that it would not otherwise consider.

Warrants and Derivative Liabilities

The Company accounts for its derivative financial instruments in accordance with FASB ASC Topic 815, “Derivatives and Hedging” (“ASC 815”). The Company does not have derivative financial instruments that are hedges. ASC 815 establishes accounting and reporting standards requiring that derivative instruments, both freestanding and embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value each reporting period. ASC 815 also requires that changes in the fair value of derivative instruments be recognized currently in the results of operations unless specific criteria are met. For embedded features that are not clearly and closely related to the host instrument, are not carried at fair value, and are derivatives, the feature will be bifurcated and recorded as an asset or liability as noted above, unless the exceptions below are not met. Freestanding instruments that do not meet these exceptions will be accounted for in the same manner.

ASC 815 provides an exception—if an embedded derivative or freestanding instrument is both indexed to the company’s own units and classified in members’ units, it can be accounted for in members’ unit. If at least one of the criteria is

not met, the embedded derivative or warrant is classified as an asset or liability and recorded to fair value each reporting period through the income statement.

The Company assesses classification of our warrants, other freestanding derivatives, and embedded features at each reporting date to determine whether a change in classification is required. The Company's accounting for its embedded features, the warrants and the success fee, are explained further in Note 8.

Recent Accounting Pronouncements

In November 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-18, "*Statement of Cash Flows (Topic 230): Restricted Cash*". This ASU requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total amounts on the balance sheet and disclose the nature of the restrictions. The Company does not expect the standard to have a significant impact on its consolidated financial statements as the Company's restricted cash balances are immaterial.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation—Stock Compensation". This ASU simplifies 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. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2016, with early adoption permitted. The Company early adopted this standard during 2016 which resulted in a $2.0 million charge to accumulated deficit as of January 1, 2016 and an associated charge to additional paid-in capital for previously unrecognized share-based compensation expense as a result of applying this policy election. The Company also recorded $0.8 million in additional share-based compensation expense during 2016 as a result of applying this policy election.

In March 2016, the FASB issued ASU No. 2016-08, "*Revenue from Contracts with Customers*". This ASU amends the existing accounting guidance for principal versus agent considerations when recognizing revenue from contracts with customers. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2017, with early adoption permitted. In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers.*" Under this guidance, an entity is required to recognize revenue upon transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. As such, an entity will need to use more judgment and make more estimates than under the current guidance. The adoption of these standards will not have a significant impact its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-06, "*Derivatives and Hedging*". This ASU clarifies the requirements for assessing whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2016, with early adoption permitted. An entity should apply the amendments in this ASU on a modified retrospective basis to existing debt instruments as of the beginning of the fiscal year for which the amendments are effective. The Company does not expect the standard to impact its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases*". This ASU amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2018, with early adoption permitted. The Company evaluated the impact of adopting the standard on its consolidated financial statements and determined that upon adoption it will have to record a right of use asset and offsetting liability on the Company's balance sheet.

In July 2015, the FASB issued ASU No. 2015-11, "*Inventory (Topic 330)*" which simplifies the subsequent measurement of inventory. It replaces the current lower of cost or market test with a lower of cost or net realizable value test. The standard is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods therein. Early adoption is permitted. The new guidance must be applied prospectively. The Company does not expect the standard to impact its consolidated financial statements.

4. Stockholders' Deficit

Conversion Event

The Class B, C and D units were required to automatically convert into Class A units pursuant to the Company's Second Amended and Restated Limited Liability Company Operating Agreement, as amended (the "Operating Agreement") upon certain defined conversion events including, but not limited to, dissolution of the Company or an underwritten IPO of the Company's equity (each, a "Conversion Event"). The Conversion Event occurred on August 1, 2016, upon consummation of the Company's IPO. The valuation of the Company at the Conversion Event was greater than $45.8 million, which resulted in

the Class B and C units receiving $41.7 million of the proceeds of the Conversion Event in the form of equivalent Class A units. The Class D units converted into Class A units such that the holders thereof received $4.2 million of such proceeds. The proceeds in excess of $45.8 million were shared ratably by the other holders of Class A units.

Class A Units

Class A units represent the Company's common stock equivalents. At December 31, 2016 Kadmon I, LLC ("Kadmon I") held approximately 12.1% of the total outstanding common stock of the Company and at December 31, 2015 Kadmon I held approximately 66% of the total outstanding Class A units. Kadmon I is a Delaware limited liability company that was formed in August 2009 and is an affiliate of the Company (Note 19). Kadmon I's funds were raised through a private offering of 80% of Kadmon I's total membership interests, the other 20% being owned by certain other members, including members of the Company's board of directors and an executive officer at the time of such offering.

Once each Kadmon I investor has received aggregate distributions equal to four times the amount of their initial investment, their collective ownership percentage in additional distributions would have decreased from 80% to 50%, and the collective ownership percentage for the members of the Company's board of directors, an executive officer and members in Kadmon I, and certain other members who received units would have increased from 20% to 50%. The change in ownership percentages would have required the Company to evaluate whether such changes would result in additional compensation expense. As of December 31, 2016 and 2015, the Kadmon I investors had not received any distributions. Accordingly, no additional compensation expense was recognized. On January 23, 2017, Kadmon I, LLC was dissolved and liquidated. Upon dissolution and liquidation, all assets of Kadmon I, LLC which consists solely of the shares of common stock in Kadmon Holdings, Inc., were distributed to the members of Kadmon I, LLC.

During the year ended December 31, 2015, the Company raised $15.0 million in net proceeds through the issuance of 1,250,000 Class A units. The Company also issued 1,500,000 Class A units pursuant to an advisory agreement entered into in April 2015. The Company recorded a deferred charge of $9.0 million related to the issuance of these units which was classified as a prepaid expense on the Company's balance sheet and was expensed over the one year term in the advisory agreement. The Company expensed $6.0 million during the year ended December 31, 2015 related to the advisory agreement. The Company issued 5,011 Class A units as the result of stock option exercises during 2015. The Company also issued 308,334 Class A units to settle third party obligations, for which the Company expensed $1.5 million related to these settlements during the year ended December 31, 2015.

During the year ended December 31, 2016, the Company issued 25,000 Class A units to settle third party obligations, for which the Company expensed $0.1 million related to these settlements during the year ended December 31, 2016 and issued 7,200 Class A units as the result of stock option exercises. The Company also recorded an expense of $3.0 million during the year ended December 31, 2016 related to the 1,500,000 Class A units issued in an advisory agreement entered into in April 2015.

There were 53,946,001 Class A units outstanding at December 31, 2015. The Class A units converted into common stock at the Conversion Event resulting in no Class A units outstanding at December 31, 2016.

Class B Unit

The Class B unit did not participate in distributions from the Company, did not have any preferences in relation to the Class A units, was non-voting, and was non-redeemable. The only right afforded to the Class B unit was the right to convert into Class A units pursuant to the Company's Operating Agreement (see "Conversion Event"). One Class B unit was issued and outstanding at December 31, 2015. The Class B unit converted into common stock at the Conversion Event resulting in no Class B units outstanding at December 31, 2016.

Class C Unit

The Class C unit did not participate in distributions from the Company, does not have any preferences in relation to the Class A units, is non-voting, and is non-redeemable. The only right afforded to the Class C unit was the right to convert into Class A units pursuant to the Operating Agreement (see "Conversion Event"). One Class C unit was issued and outstanding at December 31, 2015. The Class C unit converted into common stock at the Conversion Event resulting in no Class C units outstanding at December 31, 2016.

Class D Units

The Class D units did not participate in distributions from the Company, did not have any preferences in relation to the Class A units, were non-voting, and were non-redeemable. The only right afforded to the Class D unit was the right to convert into Class A units pursuant to the Company's Operating Agreement (see "Conversion Event"). There were 4,373,674 Class D

units issued and outstanding at December 31, 2015. The Class D units converted into common stock at the Conversion Event resulting in no Class D units outstanding at December 31, 2016.

Class E Redeemable Convertible Units

One series of Class E redeemable convertible units, the Class E Series E-1 units (the "Class E redeemable convertible units"), was authorized. The Company was able to issue Class E redeemable convertible units with an aggregate Class E original issue price of up to $85 million, calculated in accordance with the terms of the Operating Agreement, of any series without being subject to preemptive rights. The Class E redeemable convertible units had voting rights and powers equal to the Class A units on an as-if converted basis, had a liquidation preference for liquidating distributions and participated in distributions from the Company on an as-converted basis on non-liquidating distributions. In the case of a qualified IPO, the Class E redeemable convertible units automatically converted into Class A units at a conversion price of the lower of 85% of the value of Class A units (or the price per share of common stock of the corporate successor to the Company) or $11.50 per unit. Prior to a qualified IPO, the Class E redeemable convertible units could be converted at $11.50 per unit. A qualified IPO was defined as an offering of the Company's equity interests with gross proceeds to the Company of at least $75 million. At any time after December 31, 2017, Class E redeemable convertible units were redeemable for cash at the option of the holders of at least 80% of all Class E redeemable convertible units at a redemption price equal to 125% of the liquidation preference. After January 1, 2016 all Class E redeemable convertible units began to accrue a liquidation preference (payable in connection with such liquidating distribution from the Company) at a rate of 5% per annum, compounding annually, with such liquidation preference rate increasing by 100 basis points every six months to a maximum of 10%. Redemption was subject to the Company's ability to make such payment under then-existing debt obligations.

Based on the terms of the Class E redeemable convertible units, the fair value of the Class E redeemable convertible units issued was classified as mezzanine capital on the Company's consolidated balance sheet. The Company accreted changes in the redemption value of the Class E redeemable convertible units to paid-in capital using the interest method, as the Company did not have available retained earnings, from the date of issuance to the earliest redemption date.

During the year ended December 31, 2015, the Company raised $10.9 million in gross proceeds, $10.8 million net of $40,000 in transaction costs, through the issuance of 945,441 Class E redeemable convertible units. The Company raised $10.0 million through the issuance of Class E redeemable convertible units in October 2015 pursuant to a license agreement entered into with Jinghua to develop products using human monoclonal antibodies (Note 12) and $0.9 million through the issuance of Class E redeemable convertible units to other third party investors. The Company also issued 574,392 Class E redeemable convertible units to settle certain obligations totaling $6.6 million, of which $6.1 million was expensed in the third quarter of 2015 and $500,000 related to the settlement of a related party loan entered into in 2014 (Note 19).

During the year ended December 31, 2016, the Company raised $5.5 million in gross proceeds, with no transaction costs, through the issuance of 478,266 Class E redeemable convertible units. Dr. Harlan W. Waksal, the Company's President and Chief Executive Officer, certain entities affiliated with GoldenTree Asset Management LP, Bart M. Schwartz, Esq., the Company's Chairman of the board of directors, and D. Dixon Boardman, a member of the Company's board of directors subscribed for 86,957, 43,479, 21,740 and 21,740 Class E redeemable convertible units, respectively.

The Company calculated a deemed dividend on the Class E redeemable convertible units of $13.4 million in August 2016, which equals a 15% discount to the IPO price of the Company's common stock of $12.00 per share upon conversion to common stock at the Conversion Event, a beneficial conversion feature. There were 4,969,252 Class E redeemable convertible units issued and outstanding at December 31, 2015. The Class E redeemable convertible units converted into common stock at the Conversion Event resulting in no Class E redeemable convertible units outstanding at December 31, 2016.

5% Convertible Preferred Stock

Our certificate of incorporation permitted the Company's board of directors to issue up to 10,000,000 shares of preferred stock from time to time in one or more classes or series. Concurrently with the closing of the Company's IPO and pursuant to the terms of the exchange agreement entered into with the holders of the Company's Senior Convertible Term Loan, the Company issued to such holders 30,000 shares of 5% convertible preferred stock, designated as the convertible preferred stock. Each share of convertible preferred stock was issued for an amount equal to $1,000 per share, which is referred to as the original purchase price. Shares of convertible preferred stock with an aggregate original purchase price and initial liquidation preference of $30.0 million were issued to the holders of the Senior Convertible Term Loan in exchange for an equivalent principal amount of the Senior Convertible Term Loan pursuant to the terms of an exchange agreement dated as of June 8, 2016, between the Company and those holders, which is referred to as the exchange agreement.

The shares of convertible preferred stock are entitled to receive dividends, when and as declared by the board of directors and to the extent of funds legally available for the payment of dividends, at an annual rate of 5% of the sum of the original purchase price per share of convertible preferred stock plus any dividend arrearages. Dividends on the convertible

preferred stock shall, at the Company's option, either be paid in cash or added to the stated liquidation preference amount for purposes of calculating dividends at the 5% annual rate (until such time as the Company declares and pays the missed dividend in full and in cash, at which time that dividend will no longer be part of the stated liquidation preference amount). Dividends shall be payable annually on June 30 of each year and shall be cumulative from the most recent dividend payment date on which the dividend has been paid or, if no dividend has ever been paid, from the original date of issuance of the convertible preferred stock and shall accumulate from day to day whether or not declared until paid.

The convertible preferred stock converts into shares of the Company's common stock at a 20% discount to the price per share of common stock in the IPO. The Company calculated a deemed dividend on the convertible preferred stock of $7.5 million in August 2016, which equals the 20% discount to the IPO price of the Company's common stock of $12.00 per share, a beneficial conversion feature. The convertible preferred stock, inclusive of accrued and unpaid dividends, is convertible into 3,191,843 shares of common stock at December 31, 2016. The Company accrued dividends on the convertible preferred stock of $0.6 million for the year ended December 31, 2016. The Company also calculated a deemed dividend of $0.2 million on the $0.6 million of accrued dividends, a beneficial conversion feature, for the year ended December 31, 2016.

Common Stock

Prior to the IPO, there were no shares outstanding of the Company's common stock, par value $0.001 per share, and no stockholders of record. The Company's certificate of incorporation authorizes the issuance of up to 200,000,000 shares of the Company's common stock. On August 1, 2016, the Company completed its IPO whereby it sold 6,250,000 shares of common stock at $12.00 per share. The aggregate net proceeds received by the Company from the offering were $66.0 million, net of underwriting discounts and commissions of $5.3 million and offering expenses of $3.7 million. At December 31, 2016, 45,078,666 shares of common stock were outstanding, which includes 19,034,467 shares of common stock issued upon the conversion of the Company's Senior Convertible Term Loan and Second Lien Convert (Note 7).

Valuation

Prior to the IPO, to estimate certain expenses and record certain transactions, it was necessary for the Company to estimate the fair value of its membership units. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation," the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its membership units. Factors considered included:

- recent equity financings and the related valuations;
- the estimated present value of the Company's future cash flows;
- industry information such as market size and growth;
- market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and
- macroeconomic conditions.

The Company updated the valuation of Class A units as of September 30, 2015 using a methodology consistent with prior valuations. At the time of the valuation, the Company had issued $92.0 million in second-lien convertible debt, and it was deemed appropriate to place additional weighting on this consideration, as compared to prior valuations. The Company also considered equity raised through the issuance of $15.0 million in Class A units during 2015. The Company assigned no value to the Ribasphere products to reflect changes in market conditions that have resulted in lower sales of the Ribasphere products. As a result of the revised inputs to the analysis, the estimated fair value of each Class A unit was decreased from $39.00 to $32.50 as of September 30, 2015.

5. Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding for the period. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	Years Ended December 31,		
	2016	2015	2014
Numerator – basic and diluted:			
Net loss attributable to common stockholders	$ (230,488)	$ (147,082)	$ (64,356)
Denominator – basic and diluted:			
Weighted average common stock outstanding used to compute basic and diluted net loss per share	23,674,512	8,127,781	7,785,637
Net loss per share, basic and diluted	**$ (9.74)**	**$ (18.10)**	**$ (8.27)**

The amounts in the table below were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

	Years Ended December 31,		
	2016	2015	2014
Convertible preferred stock	3,191,843	3,191,843	3,191,843
Options to purchase common stock	6,437,515	1,685,248	706,460
Warrants to purchase common stock	1,328,452	1,328,452	710,801
Total shares of common stock equivalents	**10,957,810**	**6,205,543**	**4,609,104**

6. Commercial Partnership

On June 17, 2013, the Company entered into a series of agreements with a commercial partner AbbVie Inc. (“AbbVie”), related to our ribavirin products. Pursuant to an asset purchase agreement, as amended, we sold marketing authorizations and related assets for ribavirin in certain countries outside the United States. The Company received upfront payments totaling $64.0 million, and could receive additional contingent payments totaling $51.0 million based on the achievement of certain milestones. The Company earned and recognized $27.0 million of such milestones during 2014. The Company did not earn any such milestones during the years ended December 31, 2016 and 2015.

Of the $64.0 million upfront payment, $44.0 million was considered allocable to the domestic licensing arrangement and was recorded as deferred revenue to be recognized over the 10 year term of the agreement. The Company will recognize the upfront payment to revenue on a straight-line basis over the life of the agreement. The Company recognized $4.4 million of the upfront consideration as license revenue during each of the years ended December 31, 2016, 2015 and 2014. At December 31, 2016 and 2015, $28.4 million and $32.8 million were recorded as deferred revenue, respectively, of which $4.4 million was short-term.

In April 2014, the Company received a payment of $3.0 million upon obtaining the regulatory approval of ribavirin in Germany, which was recognized as milestone revenue. As the milestones meet the criteria defined in ASC 605-28, we will consider this guidance in assessing associated revenue recognition. Additionally, we will continually assess the applicability of the guidance for each milestone.

In May 2014, the Company entered into an amendment with AbbVie and a third party whereby AbbVie was granted a non-exclusive, royalty-free sublicense to develop and commercialize ribavirin. The Company evaluated the terms of the amendment to its license agreement to the entire arrangement and determined the amendment to be a material modification to the original license agreement. In analyzing this material modification, the Company determined that there were no undelivered elements remaining from the original agreement as of the effective date of the amendment. The Company received an upfront payment totaling $5.0 million which was recorded as milestone revenue as this component of the agreement represents the delivery of an executed sublicense agreement and not an upfront fee related to an ongoing servicing arrangement.

In October 2014, the Company entered into a series of amendments with AbbVie whereby the parties agreed to eliminate all potential future unearned and unpaid milestones and also agreed to a revised royalty structure for the sale of

ribavirin products under the domestic license agreement. The Company received upfront payments of $6.0 million in consideration of future royalties payable resulting from the resale of certain ribavirin products by AbbVie during 2015 and 2016. At the time of receipt the balance was recorded to deferred revenue, $3.0 million of which was recorded as short-term as it related to prepaid royalties for 2015 and $3.0 million of which was recorded as long-term as it related to prepaid royalties for 2016. The Company will recognize portions of the deferred revenue to income as ribavirin is sold by AbbVie. The Company is entitled to receive additional compensation from AbbVie for any royalties earned in excess of the annual prepayment. If royalties earned do not exceed the annual prepayment, the Company is required to refund the excess to AbbVie.

Since the royalties earned from the resale of ribavirin products by AbbVie under the domestic license agreement did not exceed the $3.0 million annual prepayment in 2015, the Company refunded approximately $2.0 million of the prepaid royalty to AbbVie as a credit against future purchases during the year ended December 31, 2016. The Company had recorded this amount as an accrued expense at December 31, 2015. Furthermore, the Company expects to refund approximately $2.2 million of the prepaid royalty to AbbVie resulting from the resale of ribavirin products by AbbVie during 2016. Therefore, the Company has recorded this amount as an accrued expense at December 31, 2016 and other long term liability at December 31, 2015, as the refund is payable in March 2017.

The Company has a continuing obligation to supply ribavirin products, maintain the marketing authorizations for certain ribavirin products and maintain the intellectual property for Ribasphere and RibaPak through the term of the agreements ending December 31, 2020.

7. Debt

Concurrent with the closing of the IPO on August 1, 2016, the Company's Senior Convertible Term Loan and Second Lien Convert converted into 19,034,467 shares of common stock.

The Company is a party to three credit agreements in the following amounts (in thousands):

	December 31,	
	2016	2015
Senior convertible term loan due June 17, 2018 (A)	$ —	$ 58,500
Secured term debt due June 17, 2018 (B)	34,620	35,000
Second-lien convertible debt due August 28, 2019 (C)	—	114,760
Total debt before fees, interest and debt discount	34,620	208,260
Paid-in-kind interest	—	18,726
Less: Deferred financing costs	(737)	(5,861)
Debt discount	(3,306)	(9,504)
Total debt payable	**$ 30,577**	**$ 211,621**
Debt payable, current portion	$ 1,900	$ 1,900
Debt payable, long-term	$ 28,677	$ 209,721

A. Senior Convertible Term Loan

In August 2015, the Company entered into the Third Amended and Restated Convertible Credit Agreement ("Senior Convertible Term Loan"), pursuant to which the Company was permitted to enter into the 2015 Credit Agreement (defined below) and a Second-Lien Convert (defined below). Most of the reporting and financial covenants pertaining to the Company that were previously required were removed so that the Company only needed to maintain a minimum liquidity amount. Beginning after June 30, 2016, the Company also had to meet a minimum revenue requirement. In August 2015, the Company further amended the terms of the Third Amended and Restated Convertible Credit Agreement to provide for, among other things, a $69.1 million term loan which was scheduled to mature on June 17, 2018. As consideration for the amendment, if a qualified IPO, defined as a public offering of the Company's equity interests with gross proceeds to the Company of at least $75.0 million, had not been completed on or prior to March 31, 2016, the Company agreed to pay an amendment fee equal to $1.3 million to be allocated among the lenders. This fee was paid in April 2016 through the issuance of 108,696 Class E redeemable convertible units, as the Company did not complete a qualified IPO by this date. As a result of this amendment, $1.3 million was recorded as a debt discount at September 30, 2015 and was amortized to interest expense over the remaining term of the agreement as the amendment was deemed a modification in accordance with ASC 470.

June 2016 Exchange Agreements

In June 2016, the Company entered into an exchange agreement with all holders of the approximately $75.0 million in aggregate principal amount of the Senior Convertible Term Loan. Under the exchange agreement, (i) $30.0 million in aggregate principal amount of the Senior Convertible Term Loan was exchanged for 30,000 shares of a newly created class of capital stock that is designated as convertible preferred stock and subject to a lock-up agreement; (ii) as to $25.0 million in aggregate principal amount of the Senior Convertible Term Loan, the Company converted 100% of that principal amount into shares of the Company's common stock at a conversion price equal to 80% of the price per share of common stock in the IPO; and (iii) as to $20.0 million in aggregate principal amount of the Senior Convertible Term Loan, the Company converted 125% of that principal amount into shares of the Company's common stock at a conversion price equal to the price per share of common stock in the IPO. In addition, the Company paid a make-whole fee amounting to $8.0 million. The make-whole fee was paid through the issuance of shares of the Company's common stock at an issue price equal to 80% of the price per share of common stock in the IPO. During the third quarter of 2016, the Company incurred a $20.7 million charge as a result of a beneficial conversion feature included in the exchange agreement, since the conversion price was equal to a 20% discount to the price per share of common stock in the IPO.

B. Secured Term Debt

August 2015 Secured Term Debt

In August 2015, the Company entered into a secured term loan in the amount of $35.0 million with two lenders ("2015 Credit Agreement"). The interest rate on the loan is LIBOR plus 9.375% with a 1% floor. The Company incurred and paid a $788,000 commitment fee in connection with the loan that will be amortized to interest expense over the term of the agreement. The basic terms of the loan required monthly payments of interest only through the first anniversary date of the loan and require the Company to maintain certain financial covenants requiring the Company to maintain a minimum liquidity amount and minimum revenue levels beginning after June 30, 2016 through August 1, 2016, the date the Company consummated its IPO. Beginning on the first anniversary date of the loan, the Company is required to make monthly principal payments in the amount of $380,000. Any outstanding balance of the loan and accrued interest is to be repaid on June 17, 2018. The secured term loan is collateralized by a first priority perfected security interest in all the tangible and intangible property of the Company.

In conjunction with the 2015 Credit Agreement, warrants to purchase $6.3 million of Class A units were issued to two lenders, of which $5.4 million was recorded as a debt discount and $900,000 was recorded as loss on extinguishment of debt (Note 8). The debt discount is being amortized over the life of the outstanding term loan using the effective interest method.

Deferred financing costs of $1.3 million were recognized in recording the 2015 Credit Agreement and will be amortized to interest expense over the three year term of the agreement. Additionally, a fee paid to one existing lender of $113,000 was charged to loss on extinguishment of debt in accordance with ASC 470. There was also $1.5 million of debt discount and $390,000 of deferred financing cost write-offs charged to loss on extinguishment of debt in accordance with ASC 470 in connection with this transaction. Unamortized deferred financing costs were $0.7 million and $1.1 million at December 31, 2016 and 2015, respectively. Approximately $0.4 million and $0.4 million were charged to interest expense during the years ended December 31, 2016 and 2015, respectively.

The Company entered into a third waiver agreement to the 2015 Credit Agreement in September 2016 to negotiate the amendment and restatement of certain covenants of the Company contained in the 2015 Credit Agreement. In connection with such negotiation, the lenders under the 2015 Credit Agreement had agreed to refrain from exercising certain rights under the 2015 Credit Agreement, including the declaration of a default and to forbear from acceleration of any repayment rights with respect to existing covenants until the parties have consummated the amendment and restatement of such provisions. In addition, certain payments required to be made under the 2015 Credit Agreement had been deferred while the parties negotiated the amendment. The parties executed a second amendment to the 2015 Credit Agreement in November 2016 whereby the Company deferred further principal payments owed under the 2015 Credit Agreement in the amount of $380,000 per month until August 31, 2017. Additionally, the parties amended various clinical development milestones and added a covenant pursuant to which the Company is required to raise $40.0 million of additional equity capital by the end of the second quarter of 2017. All other material terms of the 2015 Credit Agreement, including the maturity date, remain the same. As of the date hereof, the Company is not in default under the terms of the 2015 Credit Agreement.

The Company entered into a fourth waiver agreement to the 2015 Credit Agreement in March 2017 under which the lenders under the 2015 Credit Agreement agreed to refrain from exercising certain rights under the 2015 Credit Agreement, including the declaration of a default and to forbear from acceleration of any repayment rights with respect to existing covenants. The report and opinion of the Company's independent registered public accounting firm, BDO USA, LLP, contains an explanatory paragraph regarding the Company's ability to continue as a going concern, which is an event of default under the 2015 Credit Agreement.

C. Second-Lien Convertible Debt

In August 2015, in conjunction with the 2015 Credit Agreement, the Company incurred indebtedness pursuant to its offering of second-lien convertible PIK notes ("Second-Lien Convert"), to a syndicate of lenders, including the same two parties as the 2015 Credit Agreement. The Second-Lien Convert has a four year term under which the initial borrowings were $94.3 million, including $2.3 million in third-party fees that was settled through the issuance of Second-Lien Convert. In October 2015 and November 2015, the Company borrowed an additional $5.5 million and $15.0 million, respectively, and incurred $0.4 million in transaction costs under the Second-Lien Convert to three additional lenders, bringing the total borrowings under the Second-Lien Convert to $114.8 million, including $2.3 million in third-party fees. Interest is calculated at a rate of 13.0% and payable-in-kind semi-annually as an increase of principal. If the Company had not consummated an IPO of not less than $50.0 million and listed on a national stock exchange ("Qualified IPO") on or before March 31, 2016, the interest rate was to automatically increase on April 1, 2016 by an additional 3.0% and by an additional 3.0% on each October 1 and April 1 until the interest rate equaled 21.0% per annum, which would have remained the applicable interest rate so long as the Second-Lien Convert remained outstanding. The Company did not consummate a Qualified IPO until August 1, 2016; therefore the additional 3% interest was applied from April 1, 2016 through August 1, 2016, the date on which the Second-Lien Convert converted into the Company's common stock. The debt was collateralized by the tangible and intangible property of the Company.

Holders of the Second-Lien Convert could elect to convert any portion of principal to Class A units at any time following the Company's consummation of a Qualified IPO. The conversion price would have been equal to the product of (x) 90% and (y) the price per Class A unit of the Company offered in a Qualified IPO provided, however, that the conversion price would have been capped at $12.00. The Company could have redeemed the Second-Lien Convert at its option, in whole or in part, at any time on or after the later of (x) the first anniversary of the issue date and (y) the date of the consummation of a Qualified IPO, at a redemption price of 150.0% of the principal amount, plus accrued and unpaid interest payable (at the Company's option) in cash or Class A units. In addition, on or after the later of (x) the third anniversary of the issue date and (y) the date of the consummation of a Qualified IPO, the Company could have redeemed the Second-Lien Convert at its option, in whole or in part, at a redemption price in cash of 110.0% of the principal amount, plus accrued and unpaid interest.

Deferred financing costs of $4.2 million were recognized in recording the Second-Lien Convert and were being amortized to interest expense over the four year term of the agreement. There were no unamortized deferred financing costs at December 31, 2016 and $3.9 million of unamortized deferred financing costs at December 31, 2015. Approximately $0.7 million and $0.3 million were charged to interest expense during the years ended December 31, 2016 and 2015, respectively. The Company incurred $0.1 million in debt issuance costs to new creditors in August 2015, which was recorded as a debt discount and was being amortized to interest expense over the four year term.

The Company considered ASC 480, "Distinguishing Liabilities from Equity," and determined that the Second-Lien Convert does not contain any of the criteria under this guidance. In accordance with ASC 815, the Company determined that the interest rate increase and put/redemption feature do not require bifurcation since the embedded interest rate increase, if freestanding, would not qualify as a derivative. The Second-Lien Convert represented the host contract and the option to convert the debt into the Company's Class A units represented the embedded conversion option. Since the conversion option meets the criteria under ASC 815, the conversion option does not require bifurcation and is not accounted for as a derivative under ASC 815.

Pursuant to an amendment and restatement of the terms of the Second-Lien Convert in June 2016, 100% of the outstanding balance under the outstanding Second-Lien Convert was mandatorily converted into shares of the Company's common stock at a conversion price equal to 80% of the price per share of common stock in the IPO. During the third quarter of 2016, the Company incurred a $32.4 million charge as a result of the beneficial conversion feature included in this agreement since the conversion price is equal to a 20% discount to the price per share of common stock in the IPO.

The minimum payments required on the outstanding balances of the 2015 Credit Agreement at December 31, 2016 are (in thousands):

	2015 Credit Agreement
2017	$ 1,900
2018	32,720
	$ 34,620

The following table provides components of interest expense and other related financing costs (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Interest expense and other financing costs	$ 3,782	$ 7,817	$ 12,204
Interest expense - beneficial conversion feature	45,915	—	—
Interest paid-in kind	14,695	11,434	13,374
Write-off of deferred financing costs and debt discount	3,820	2,752	—
Amortization of deferred financing costs and debt discount	4,422	5,157	3,333
Interest expense	**$ 72,634**	**$ 27,160**	**$ 28,911**

8. Financial Instruments

Success Fee

In October 2011, an executive officer and member of Kadmon Holdings, LLC issued an equity instrument for which the underlying value is based on 536,065 Class A units. The intrinsic value of the instrument is redeemable for cash upon certain defined liquidity or distribution events (“Success Fee”).

A liability was recorded based on the instrument’s fair value of $0 and $69,000 at December 31, 2016 and December 31, 2015, respectively. As a result of marking to market this instrument, the Company recorded ($0.1) million, ($0.2) million and ($0.9) million to change in fair value of financial instruments for the years ended December 31, 2016, 2015 and 2014, respectively. Upon consummation of the Company’s IPO on August 1, 2016 with a price per share of $12.00 per share, the fair value of this equity instrument had a fair value of $0, which resulted in no Success Fee owed by the Company.

As there were no quoted prices for identical or similar instruments prior to the IPO, the Company had utilized a Black-Scholes calculation to value this instrument at December 31, 2015 and 2014, based on the following assumptions:

Input	December 31, 2015	December 31, 2014
Unit price	$32.50	$39.00
Strike price	$74.17	$74.17
Volatility	79.18%	79.09%
Risk-free interest rate	0.49%	0.19%
Expected life	.50 Years	.75 Years
Expected dividend yield	0%	0%

Equity issued pursuant to Credit Agreements

In connection with the incurrence of the Senior Convertible Term Loan, the Company issued three tranches of warrants as fees to the lenders that were redeemable for Class A units. The aggregate fair value of the warrants was $1.7 million and $1.9 million at December 31, 2016 and December 31, 2015, respectively. The change in fair value of the warrants was ($0.2) million, ($1.3) million and $4.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. Upon consummation of the Company’s IPO on August 1, 2016 with a price per share of common stock in the IPO of $12.00, the warrants to purchase Class A units issued to lenders in the Senior Convertible Term Loan were exchanged for 351,992 warrants with a strike price of $10.20 per share to purchase the same number of shares of the Company’s common stock. Since the strike price was determined at IPO, the aggregate fair value of these warrants totaling $1.7 million was reclassified from liability to equity at December 31, 2016.

At December 31, 2015 the Company utilized a binomial model to measure all three warrant tranches. Due to the uncertainty of the strike price of the warrants, the Company performed each calculation multiple times using a weighted number of units exercisable based on the Company's best estimate of how many units would be issuable. The inputs used in the calculations to measure all three warrant tranches at December 31, 2015 and December 31, 2014 are as follows:

Input	December 31, 2015	December 31, 2014
Unit price	$32.50	$39.00
Strike price	$61.75	$61.75
Volatility	79.18%	79.09%
Risk-free interest rate	0.49%	0.19%
Expected life	.50 Years	.75 Years
Expected dividend yield	0%	0%

In connection with the 2015 Credit Agreement, the Company issued warrants as fees to the lenders to purchase an aggregate of $6.3 million of the Company's Class A units. The strike price of the warrants was 85% of the price per unit in an IPO or, if before an IPO, 85% of the deemed per unit equity value as defined in the 2015 Credit Agreement. The warrants were exercisable as of the earlier of an IPO or July 1, 2016. Since these warrants are also redeemable at the option of the holder after the 51st month from the issue date, they are recorded as a non-current liability of $3.3 million and $6.3 million at December 31, 2016 and December 31, 2015, respectively. Upon entry into the agreement in August 2015, the warrants issued to an existing lender was recorded to loss on extinguishment of debt of $900,000 and the warrants issued to the new lender was recorded as a debt discount of $5.4 million and will be amortized over the three year term (Note 7) in accordance with ASC 470.

Upon consummation of the Company's IPO on August 1, 2016 with a price per share of common stock in the IPO of $12.00, the warrants to purchase Class A units issued to lenders under the 2015 Credit Agreement were exchanged for 617,651 warrants with a strike price of $10.20 per share to purchase the same number of shares of the Company's common stock. The decline in fair value of the warrants was ($4.3) million for the year ended December 31, 2016, while there was no change in fair value of financial instruments for the years ended December 31, 2015 and 2014. None of these instruments have been exercised at December 31, 2016 or December 31, 2015.

Other Warrants

On April 16, 2013, the Company issued warrants with an estimated fair value of $1.4 million for the purchase of 30,000 Class A units at a strike price of $21.24 as consideration for fundraising efforts performed. Upon consummation of the Company's IPO on August 1, 2016 and Corporate Conversion, these warrants to purchase Class A units were exchanged for 46,163 warrants to purchase the same number of shares of the Company's common stock at a strike price of $138.06. None of these warrants have been exercised at December 31, 2016.

Fair Value of Long-term Debt

At December 31, 2016 the Company maintained a long-term secured term debt balance of $28.7 million. At December 31, 2015 the Company maintained long-term secured term debt and long-term convertible debt balances of $26.3 million and $183.5 million, respectively. The underlying agreements for these balances were negotiated with parties that included fully independent third parties, at an interest rate which is considered to be in line with over-arching market conditions. Based on these factors management considers the carrying value of the debt to approximate fair value at December 31, 2016.

Fair Value Classification

The Company held certain liabilities that are required to be measured at fair value on a recurring basis. Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The table below represents the values of the Company's financial instruments at December 31, 2016 and December 31, 2015 (in thousands):

		Fair Value Measurement Using:	
Description	December 31, 2015	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrants	$ 8,220	$ —	$ 8,220
Success Fee	69	—	69
Total	**$ 8,289**	**$ —**	**$ 8,289**

Description	December 31, 2016	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrants	$ 3,305	$ 3,305	$ —
Total	**$ 3,305**	**$ 3,305**	**$ —**

The table below represents a rollforward of the Level 2 and Level 3 financial instruments from January 1, 2015 to December 31, 2016 (in thousands).

	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Balance as of January 1, 2015	**$ —**	**$ 3,483**
Change in fair value of financial instruments	—	(1,494)
Fair value of warrants issued in connection with 2015 credit agreement	—	6,300
Balance as of December 31, 2015	**$ —**	**$ 8,289**
Transfer of warrants from Level 3 to Level 2	6,300	(6,300)
Change in fair value of financial instruments	(4,107)	(273)
Beneficial conversion feature recognized on warrants issued in connection with 2015 credit agreement	1,112	—
Reclassification of warrants to APIC in connection with IPO	—	(1,716)
Balance as of December 31, 2016	**$ 3,305**	**$ —**

The Level 2 inputs used to value our financial instruments were determined using prices that can be directly observed or corroborated in active markets. In August 2016, the warrants issued in connection with the 2015 Credit Agreement were transferred from Level 3 to Level 2 as the Company's securities began trading on the New York Stock Exchange. Although the fair value of this obligation is calculated using the observable market price of Kadmon Holdings Inc. common stock, an active market for this financial instrument does not exist and therefore the Company has classified the fair value of this liability as a Level 2 liability in the table above.

9. Inventories

Inventories are stated at the lower of cost or market (on a first-in, first-out basis) using standard costs. Standard costs include an allocation of overhead rates, which include those costs attributable to managing the supply chain and are evaluated regularly. Variances are expensed as incurred.

The Company regularly reviews the expiration date of its inventories and maintains a reserve for inventories that are probable to expire before shipment. Inventories recorded on the Company's consolidated balance sheets are net of a reserve for expirable inventory of $4.9 million and $5.4 million at December 31, 2016 and 2015, respectively. The Company expensed Ribasphere inventory that it believes will not be sold prior to reaching its product expiration date totaling $0.4 million, $2.3 million and $4.9 million during the years ended December 31, 2016, 2015 and 2014, respectively. If the amount and timing of future sales differ from management's assumptions, adjustments to the estimated inventory reserves may be required.

Inventories are comprised of the following (in thousands):

	December 31, 2016	December 31, 2015
Raw materials	$ 1,153	$ 1,905
Finished goods, net	797	1,563
Total inventories	**$ 1,950**	**$ 3,468**

10. Fixed Assets

Fixed assets consisted of the following (in thousands):

	Useful Lives (Years)	December 31, 2016	December 31, 2015
Leasehold improvements	4-8	$ 10,274	$ 10,019
Office equipment and furniture	3-15	2,193	2,060
Machinery and laboratory equipment	3-15	3,255	3,082
Software	1-5	3,581	3,409
Construction-in-progress	–	44	9
		19,347	18,579
Less accumulated depreciation and amortization		(13,920)	(11,641)
Fixed assets, net		$ 5,427	$ 6,938

Depreciation and amortization of fixed assets totaled $2.3 million, $2.3 million and $2.6 million in each of the years ended December 31, 2016, 2015 and 2014, respectively. The construction-in-progress balance was related to costs of unimplemented software still under development. Unamortized computer software costs were $0.8 million and $1.3 million at December 31, 2016 and 2015, respectively. The amortization of computer software costs amounted to $0.7 million, $0.7 million and $0.3 million during the years ended December 31, 2016, 2015 and 2014, respectively.

11. Goodwill and Other Intangible Assets

The changes in the carrying amount of goodwill and other amortizable intangible assets at December 31, 2016 and 2015 are as follows (in thousands):

	Balance as of December 31, 2014	Amortization	Impairment	Balance as of December 31, 2015	Remaining Useful Life as of December 31, 2015
Ribasphere product rights	$ 73,934	$ (27,442)	$ (31,269)	$ 15,223	1.0
Goodwill	$ 3,580	$ —	$ —	$ 3,580	—

	Balance as of December 31, 2015	Amortization	Impairment	Balance as of December 31, 2016	Remaining Useful Life as of December 31, 2016
Ribasphere product rights	$ 15,223	$ (15,223)	$ —	$ —	—
Goodwill	$ 3,580	$ —	$ —	$ 3,580	—

In September 2015, the Company reviewed the estimated useful life of the Ribasphere product rights and determined that the actual lives of the Ribasphere product rights intangible asset was shorter than the estimated useful lives used for amortization purposes in the Company's financial statements due to the continued growth of competitor products that do not necessitate the use of Ribasphere as a complement in treating the hepatitis C infection. As a result, effective September 30, 2015, the Company changed its estimate of the useful life of its Ribasphere product rights intangible asset to 1.25 years to better reflect the estimated period during which the remaining asset will generate cash flows. The Company also determined that the carrying value of the Ribasphere product rights exceeded its fair value and recorded an impairment loss of $31.3 million in September 2015.

In October 2015, the Company determined that the proportional performance method of amortization was more appropriate than straight-line amortization. The amortization of the Ribasphere product rights intangible asset based on the consumption of the economic benefit (Ribasphere gross profit), became a reliably determinable method of amortization due to the remaining asset useful life being only 1.25 years and the ability to more accurately forecast the Ribasphere market. Accordingly, Kadmon amortized the remaining book value of the intangible asset utilizing the proportional performance method starting October 1, 2015 and ending December 31, 2016.

Amortization expense is included within selling, general and administrative expenses on the Company's consolidated statements of operations. The Company recorded amortization expense related to the intangible asset of $15.2 million, $27.4 million and $21.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. The accumulated amortization of the intangible asset was $140.7 million and $125.5 million at December 31, 2016 and 2015, respectively.

12. License Agreements

Yale University

On February 4, 2011, the Company entered into a license agreement with Yale University, whereby the Company obtained the worldwide exclusive license and right to make, use, sell, import and export PHY906, a development stage botanical compound, and the related technology. In April 2016, the Company entered into a mutual termination agreement with Yale University. All rights and licenses granted under the agreement were immediately terminated and reverted to the party granting such rights.

Symphony Evolution, Inc.

In August 2010, the Company entered into a license agreement with Symphony Evolution, Inc. (Symphony), under which Symphony granted to the Company an exclusive, worldwide, royalty-bearing, sublicensable license under certain Symphony patents, copyrights and technology to develop, make, use, sell, import and export XL647 and the related technology in the field of oncology and non-oncology.

The Company is the licensee of granted patents in Australia, Canada, Europe, Japan and the United States. The patents claim tesevatinib as a composition-of-matter, as well as use of tesevatinib to treat certain cancers. A pending U.S. application supports additional composition-of-matter claims and methods of synthesis. The last to expire U.S. patent in this family has a term that ends in May 2026 based on a calculated Patent Term Adjustment (PTA) and without regard to any potential Patent Term Extension (PTE), which could further extend the term by an additional five years.

The Company is the licensee of a second family of granted patents in China and Europe, as well as applications in Canada, Eurasia, Japan, Taiwan and the United States. These patents and applications disclose the use of tesevatinib to treat PKD. The last to expire U.S. patent in this family would have a term that ends in 2031, though this term could be extended by obtaining a PTA and/or PTE.

The license agreement includes a series of acquisition and worldwide development milestone payments totaling up to $218.4 million, and $14.1 million of these payments and other fees have been paid as of December 31, 2016. Additionally, the license agreement includes commercial milestone payments totaling up to $175.0 million, none of which have been paid as of December 31, 2016, contingent upon the achievement of various sales milestones, as well as single-digit sales royalties. The royalty term expires with the last to expire patent.

The agreement with Symphony will expire upon the expiration of the last to expire patent within the licensed patents. The Company may terminate the agreement at any time upon six months written notice to Symphony. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. Symphony may terminate the agreement if the Company challenges the licensed patents. Either party may terminate the agreement upon the bankruptcy or insolvency of the other party.

On June 11, 2014 the Company and Symphony executed an additional amendment to the amended and restated agreement, whereby the $1.1 million payment due on June 1, 2014 was extended to September 30, 2014. This amendment increased the payment to $1.2 million to include fees for deferral of the payment. The Company expensed $200,000 to research and development expense for these additional fees during 2014.

On September 30, 2014 the Company and Symphony executed an additional amendment to the amended and restated agreement, whereby the $1.2 million payment due on September 30, 2014 was extended to November 30, 2014. This amendment increased the payment to $1.4 million to include fees for deferral of the payment. The Company expensed $200,000 to research and development expense for these additional fees during 2014. In November 2014, the Company made payment to Symphony for $1.4 million in settlement of this obligation.

All other contingent payments will be expensed as research and development as incurred.

Valeant Pharmaceuticals North America LLC

On February 25, 2014, the Company entered into an agreement with Valeant for the co-promotion of Syprine®, a chelation therapy indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. In February 2016, the Company entered into a mutual termination agreement with Valeant. Upon termination, neither party shall have any rights or obligation including any and all past, present and future payments. Additionally, all rights and licenses granted under the agreement were immediately terminated and reverted to the party granting such rights. As a result of the termination, in February 2016 the Company recorded a gain on settlement of the $3.9 million other milestone payable to Valeant in connection with the acquisition of the drug Infergen.

Vivus, Inc.

In June 2015, the Company entered into an agreement with Vivus Inc. ("Vivus") for the co-promotion of Qsymia®, a combination of phentermine and topiramate extended-release indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults. In November 2016, the Company notified Vivus that it will not renew this agreement and therefore the agreement terminated on December 31, 2016. No meaningful revenue was generated from this agreement as of December 31, 2016 and 2015.

Princeton University

On December 8, 2010, the Company entered into a license agreement with Princeton University ("Princeton") whereby the Company obtained from Princeton a worldwide exclusive license and right to make, use and sell products identified by Princeton's Flux technology ("Princeton License"). The Company was obligated to pay Princeton an annual license fee of $60,000, which was recorded as a research and development expense. In addition, the Princeton License required the Company to make payments contingent on the achievement of certain development milestones totaling $31.0 million, such as receiving certain government approvals. Upon commercial sale, the Company was obligated to pay a low single digit royalty based on net sales levels. No development milestones or sales were achieved as of December 31, 2016 and 2015. In February 2017, the Company entered into a mutual termination agreement with Princeton. All rights and licenses granted under the agreement were immediately terminated and shall revert to the party granting such rights.

MeiraGTx Limited

In April 2015, the Company executed several agreements which transferred its ownership of Kadmon Gene Therapy, LLC to MeiraGTx Limited ("MeiraGTx"), a then wholly-owned subsidiary of the Company. As part of these agreements, the Company also transferred various property rights, employees and management tied to the intellectual property and contracts identified in the agreements to MeiraGTx. At a later date, MeiraGTx ratified its shareholder agreement and accepted the pending equity subscription agreements, which provided equity ownership to various parties. The execution of these agreements resulted in a 48% ownership in MeiraGTx by the Company. After MeiraGTx was deconsolidated or derecognized, the retained ownership interest was initially recognized at fair value and a gain of $24.0 million was recorded based on the fair value of this equity investment. The Company's investment is being accounted for under the equity method at zero cost with an estimated fair value at the time of the transaction of $24.0 million. This value was determined based upon the implied value established by the cash raised by MeiraGTx in exchange for equity interests by third parties.

The Company assessed the applicability of ASC 810 to the aforementioned agreements and based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, determined that MeiraGTx is a variable interest entity, however consolidation is not required as the Company is not the primary beneficiary based upon the voting and managerial structure of the entity.

MeiraGTx, a limited company organized under the laws of England and Wales, was established to focus on the development of novel gene therapy treatments for a range of inherited and acquired disorders. MeiraGTx is developing therapies for ocular diseases, including rare inherited blindness, as well as xerostomia following radiation treatment for head and neck cancer. MeiraGTx is also developing an innovative gene regulation platform that has the potential to expand the way that gene therapy can be applied, creating a new paradigm for biologic therapeutics in the biopharmaceutical industry.

The summarized financial information for MeiraGTx as of and for the years ended December 31, 2016 and 2015 is as follows (amounts in thousands):

	2016	2015
Balance Sheet Data:		
Cash	$ 17,486	$ 14,543
Other current assets	1,756	453
Noncurrent assets	2,921	245
Current liabilities	4,967	4,728
Noncurrent liabilities	261	12
Total stockholders' equity	16,935	10,501
Statement of Operations Data:		
General and administrative expense	$ 5,162	$ 3,318
Research and development expense	13,823	16,124
Net loss attributable to non-controlling interest in subsidiary and other comprehensive loss	(456)	4,477
Net loss and comprehensive loss	(19,149)	(14,942)

As part of a transition services agreement with MeiraGTx, the Company recognized $1.0 million of service revenue to license and other revenue during each of the years ended December 31, 2016 and 2015. During April 2016, the Company received 230,000 shares of MeiraGTx's convertible preferred Class C shares as a settlement for $1.2 million in receivables from MeiraGTx. Under ASC 323, the Class C shares of MeiraGTx do not qualify as common stock or in-substance common stock and the $1.2 million was recorded as a cost method investment. The Company also received cash payments of $0.2 million for service revenue earned during 2016.

The Company assessed the recoverability of both the cost method and equity method investment in MeiraGTx at December 31, 2016 and 2015 and identified no events or changes in circumstances that may have a significant adverse impact on the fair value of this investment. For the years ended December 31, 2016 and 2015, the Company recorded its share of MeiraGTx's net loss of $13.6 million and $2.8 million, respectively, inclusive of adjustments related to MeiraGTx's 2015 financial statements that resulted in the Company recording a loss on equity method investment of $3.9 million for the year ended December 31, 2016. The Company maintains a 38.7% ownership in MeiraGTx at December 31, 2016. The Company's maximum exposure associated with MeiraGTx is limited to its initial investment of $24.0 million.

Nano Terra, Inc.

On April 8, 2011, the Company entered into a series of transactions with Nano Terra, Inc. ("Nano Terra"), pursuant to which the Company (i) paid $2.3 million for Nano Terra's Series B Preferred Stock, (ii) entered into a joint venture with Surface Logix, Inc. ("Surface Logix") (Nano Terra's wholly-owned subsidiary) through the formation of NT Life Sciences, LLC ("NT Life"), whereby the Company contributed $900,000 at the date of formation in exchange for a 50% interest in NT Life and (iii) entered into a sub-licensing arrangement with NT Life. Pursuant to the sub-licensing arrangement, the Company was granted a perpetual, worldwide, exclusive license to three clinical-stage product candidates owned by Surface Logix, as well as rights to Surface Logix's drug discovery platform, Pharmacomer™ Technology, each of which were licensed by Surface Logix to NT Life. In December 2014, the Company received one share of Nano Terra's Common Stock for every 100 shares of Series B Preferred Stock held by the Company, resulting in approximately a 1% holding in Nano Terra as of December 31, 2016 and 2015. In accordance with ASC 325, "Investments—Other", the Company continues to account for the investment under the cost method.

The primary product candidates are currently in early to mid-stage clinical development for a variety of diseases and target several novel pathways of disease by inhibiting the activity of specific enzymes.

Nano Terra and NT Life are research and development companies, each of which independently maintains intellectual property for the purpose of pursuing medical discoveries. The Company is a minority shareholder of Nano Terra and thereby is unable to exercise significant influence with regard to the entity's daily operations. The Company is represented on the Board of Managers of NT Life and is a party to decisions which influence the direction of the organization.

Since inception, the Company has continuously assessed the applicability of ASC 810, based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, and determined that Nano Terra and NT Life are not variable interest entities and not subject to consolidation. On April 8, 2011 the Company recorded its $2.3 million investment in Nano Terra in accordance with ASC 325, and its investment of $900,000 in NT Life in accordance with ASC 323, of which was $450,000 was recorded as a loss on equity investment and $450,000 was recorded as an

impairment loss in 2011. In accordance with ASC 325-20-35, the Company assessed the recoverability of the investment in Nano Terra as of December 31, 2016 and 2015 and identified no events or changes in circumstances that may have a significant adverse impact on the fair value of this investment. There was no activity of the joint venture during the years ended December 31, 2016, 2015 and 2014 which resulted in income or loss to the Company. The Company's maximum exposure associated with Nano Terra and NT Life is limited to cash contributions made.

Additionally, future licensing and royalty fees to NT Life and Surface Logix are based on the achievement of certain milestones relative to achieving ANDA approvals, net sales and sublicense revenues. No milestones or sales were achieved as of December 31, 2016 and 2015.

Dyax Corp.

On July 22, 2011 the Company entered into a license agreement with Dyax Corp. ("Dyax") for the rights to use the Dyax Antibody Libraries, Dyax Materials and Dyax Know-How (collectively "Dyax Property"). Unless otherwise terminated, the agreement is for a term of four years. The agreement includes the world-wide, non-exclusive, royalty-free, non-transferable license to use the Dyax Property to be used in the research field, without the right to sublicense. Additionally, the Company has the option to obtain a sublicense for use in the commercial field if any research target is obtained. The Company was required to pay Dyax $600,000 upon entering into the agreement and $300,000 annually to maintain the agreement. The initial payment was deferred and recorded as prepaid expense; $300,000 of which will be amortized over the term of the agreement, and $300,000 of which was amortized in a manner consistent with that of the annual payments. All subsequent annual payments will be and have been recorded as prepaid expense and amortized over the applicable term of one year.

On September 13, 2012 the Company entered into a separate license agreement with Dyax whereby the Company obtained from Dyax the exclusive, worldwide license to use research, develop, manufacture and commercialize DX-2400 in exchange for a payment of $500,000. All payments associated with this agreement were recorded as research and development expense at the time the agreement was executed.

The DX-2400 license requires the Company to make additional payments contingent on the achievement of certain development milestones (such as receiving certain regulatory approvals and commencing certain clinical trials) and sales targets. None of these targets have been achieved and, as such, no assets or liabilities associated with the milestones have been recorded in the accompanying consolidated financial statements for the year ended December 31, 2016. The DX-2400 license also includes royalty payments commencing on the first commercial sale of any licensed product, which had not occurred as of December 31, 2016 and 2015.

Chiromics

On November 18, 2011 the Company entered into a non-exclusive, royalty free license agreement with Chiromics LLC ("Chiromics") for access to two chemical compound libraries for the research, discovery and development of biological and/or pharmaceutical products. The Company was required to pay $200,000 upon execution of the agreement and $150,000 following the delivery of each of the chemical compounds included within the related library. The Company was additionally required to make quarterly payments of $200,000 for the eight quarters following delivery of all compounds; such payments were expensed to research and development expense in those quarters. The payable balance associated with these agreements was $500,000 at December 31, 2015, which was settled in October 2016.

Concordia

On December 16, 2011, the Company purchased certain intellectual property rights and associated contractual rights and obligations from Concordia Pharmaceuticals, LLC. ("Concordia") for $500,000. In May 2016, the Company entered into a mutual termination agreement with Concordia. All rights and licenses granted under the agreement were immediately terminated and reverted to the party granting such rights.

EffRx

On March 12, 2014 the Company entered into a development and license agreement with EffRx Pharmaceuticals S.A. ("EffRx") for the development of effervescent formulations of certain pharmaceutical products. This agreement was mutually terminated on April 6, 2016.

Zydus

In June 2008, the Company entered into an asset purchase agreement with Zydus Pharmaceuticals USA, Inc. ("Zydus") and Cadila Healthcare Limited where the Company purchased all of Zydus' rights, title and interest to high dosages of ribavirin. Under the terms of the agreement, the Company paid a one-time purchase price of $1.1 million. The Company was

required to pay a royalty based on net sales of products in the low twenty percents, subject to specified reductions and offsets. In April 2013, the Company entered into an amendment to the asset purchase agreement with Zydus which reduced the royalty payable on net sales of products from the low twenty percents to the mid-teens percents.

In June 2008, the Company also entered into a non-exclusive patent license agreement with Zydus, under which Zydus granted to the Company a non-exclusive, royalty free, fully paid up, non-transferable license under certain Zydus patent rights related to ribavirin. This agreement will expire upon the expiration or termination of a specific licensed patent. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period or upon the bankruptcy or insolvency of the other party.

The Company recorded royalty expense of $1.2 million, $2.7 million and $6.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Jinghua

In November 2015, the Company entered into a license agreement with Jinghua Pharmaceutical Group Co., Ltd. (“Jinghua”). Under this agreement, the Company granted to Jinghua an exclusive, royalty-bearing, sublicensable license under certain of its intellectual property and know-how to use, develop, manufacture, and commercialize certain monoclonal antibodies in China, Hong Kong, Macau and Taiwan.

In partial consideration for the rights granted to Jinghua under the agreement, the Company received an upfront payment of $10.0 million in the form of an equity investment in Class E redeemable convertible units of the Company. The Company is eligible to receive from Jinghua a royalty equal to a percentage of net sales of product in the territory in the low ten percents. In addition to such payments, the Company is eligible to receive milestone payments for the achievement of certain development milestones, totaling up to $40.0 million. The Company earned a $2.0 million milestone payment in March 2016, which was recorded as license and other revenue during the year ended December 31, 2016. The Company is also eligible to receive a portion of sublicensing revenue from Jinghua ranging from the low ten percents to the low thirty percents based on the development stage of a product. No such revenue was earned during the years ended December 31, 2016, 2015 and 2014. The Company earned a $2.0 million milestone payment in January 2017, which was received in February 2017, and will be recorded as license and other revenue.

The Company’s agreement with Jinghua will continue on a product-by-product and country-by-country basis until the later of ten years after the first commercial sale of the product in such country or the date on which there is no longer a valid claim covering the licensed antibody contained in the product in such country. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period or upon the bankruptcy or insolvency of the other party. No patents were licensed to the Company under this agreement.

Camber Pharmaceuticals, Inc.

Tetrabenazine

In February 2016, the Company entered into a supply and distribution agreement with Camber Pharmaceuticals, Inc. (“Camber”) for the purposes of marketing, selling and distributing tetrabenazine, a medicine that is used to treat the involuntary movements (chorea) of Huntington’s disease. The initial term of the agreement is twelve months. Under the agreement, the Company will obtain commercial supplies of tetrabenazine and will distribute tetrabenazine through its existing sales force and commercial network. The Company will pay Camber a contracted price for supply of tetrabenazine and will retain 100% of the revenue generated from the sale of tetrabenazine. The Company recognized revenue of $0.6 million during the year ended December 31, 2016. No revenue was generated from sales of tetrabenazine in 2015 and 2014.

Valganciclovir

In May 2016, the Company amended its agreement with Camber to include the marketing, selling and distributing of valganciclovir, a medicine that is used for the treatment of cytomegalovirus (CMV) retinitis, a viral inflammation of the retina of the eye, in patients with acquired immunodeficiency syndrome (AIDS) and for the prevention of CMV disease, a common viral infection complicating solid organ transplants, in kidney, heart and kidney pancreas transplant patients. The Company will pay Camber a contracted price for supply of valganciclovir and will retain 100% of the revenue generated from the sale of valganciclovir. The Company recognized revenue of $0.9 million during the year ended December 31, 2016. No revenue was generated from sales of valganciclovir in 2015 and 2014.

Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine.

In August 2016, the Company amended its agreement with Camber to include the marketing, selling and distributing of Abacavir tablets, USP, a medicine that is used in combination with other antiretroviral agents for the treatment of human

immunodeficiency virus type-1 (HIV-1) infection; Entecavir, a medicine that is used for the treatment of chronic hepatitis B virus (HBV) infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease; Lamivudine tablets, a nucleoside analogue medicine used in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection; Lamivudine tablets (HBV), a medicine that is used for the treatment of chronic hepatitis B virus (HBV) infection associated with evidence of hepatitis B viral replication and active liver inflammation; and Lamivudine and Zidovudine tablets, USP, a combination of two nucleoside analogue medicines, used in combination with other antiretrovirals for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. The Company will pay Camber a contracted price for supply of these products and will retain 100% of the revenue generated from the sale of these products. No meaningful revenue was generated from sales of these products for the years ended December 31, 2016, 2015 and 2014.

13. Share-based Compensation

2011 Equity Incentive Plan—Options

The 2011 Equity Incentive Plan was adopted in July 2011. Under this plan, the Company's board of directors was able to grant unit-based awards to certain employees, officers, directors, managers, consultants and advisors. The plan was amended on November 7, 2013 to authorize the grant of a number of options to purchase Class A units equal to 7.5% of the outstanding Class A units calculated on a fully diluted basis. The Company's board of directors had the authority, in its discretion, to determine the terms and conditions of any option grant, including the vesting schedule. Effective July 26, 2016, no award may be granted under the 2011 Equity Plan. The 2011 Equity Plan was merged with and into the 2016 Equity Incentive Plan, outstanding awards were converted into awards with respect to our common stock and any new awards will be issued under the terms of the 2016 Equity Incentive Plan.

2016 Equity Incentive Plan

The Company's 2016 Equity Incentive Plan (the "2016 Equity Plan"), was approved by the Company's board of directors and holders of the Company's membership units in July 2016. It is intended to make available incentives that will assist the Company to attract, retain and motivate employees, including officers, consultants and directors. The Company may provide these incentives through the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units and other cash-based or stock-based awards.

A total of 6,720,000 shares of the Company's common stock was initially authorized and reserved for issuance under the 2016 Equity Plan. At December 31, 2016 the number of additional shares available for grant was 282,485. This reserve will automatically increase on January 1, 2017 and each subsequent anniversary through January 1, 2025, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the board of directors. This reserve was increased to include any shares issuable upon exercise of options granted under the Company's 2011 Equity Incentive Plan that expire or terminate without having been exercised in full.

Appropriate adjustments will be made in the number of authorized shares and other numerical limits in the 2016 Equity Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in the Company's capital structure. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the 2016 Equity Plan. The shares available will not be reduced by awards settled in cash or by shares withheld to satisfy tax withholding obligations. Only the net number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under the 2016 Equity Plan.

The 2016 Equity Plan will be generally administered by the compensation committee of the Company's board of directors. Subject to the provisions of the 2016 Equity Plan, the compensation committee will determine, in its discretion, the persons to whom and the times at which awards are granted, the sizes of such awards and all of their terms and conditions. However, the compensation committee may delegate to one or more of our officers the authority to grant awards to persons who are not officers or directors, subject to certain limitations contained in the 2016 Equity Plan and award guidelines established by the compensation committee. The compensation committee will have the authority to construe and interpret the terms of the 2016 Equity Plan and awards granted under it. The 2016 Equity Plan provides, subject to certain limitations, for indemnification by the Company of any director, officer or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the 2016 Equity Plan.

Awards may be granted under the 2016 Equity Plan to the Company's employees, including officers, directors or consultants or those of any present or future parent or subsidiary corporation or other affiliated entity. All awards will be evidenced by a written agreement between the Company and the holder of the award and may include any of the following:

- *Stock options.* The Company may grant nonstatutory stock options or incentive stock options as described in Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), each of which gives its holder the right, during a specified term (not exceeding 10 years) and subject to any specified vesting or other conditions, to purchase a number of shares of our common stock at an exercise price per share determined by the administrator, which may not be less than the fair market value of a share of the Company's common stock on the date of grant.

- *Stock appreciation rights.* A stock appreciation right gives its holder the right, during a specified term (not exceeding 10 years) and subject to any specified vesting or other conditions, to receive the appreciation in the fair market value of the Company's common stock between the date of grant of the award and the date of its exercise. The Company may pay the appreciation in shares of the Company's common stock or in cash.

- *Restricted stock.* The administrator may grant restricted stock awards either as a bonus or as a purchase right at such price as the administrator determines. Shares of restricted stock remain subject to forfeiture until vested, based on such terms and conditions as the administrator specifies. Holders of restricted stock will have the right to vote the shares and to receive any dividends paid, except that the dividends may be subject to the same vesting conditions as the related shares.

- *Restricted stock units.* Restricted stock units represent rights to receive shares of the Company's common stock (or their value in cash) at a future date without payment of a purchase price, subject to vesting or other conditions specified by the administrator. Holders of restricted stock units have no voting rights or rights to receive cash dividends unless and until shares of common stock are issued in settlement of such awards. However, the administrator may grant restricted stock units that entitle their holders to dividend equivalent rights.

- *Performance shares and performance units.* Performance shares and performance units are awards that will result in a payment to their holder only if specified performance goals are achieved during a specified performance period. Performance share awards are rights whose value is based on the fair market value of shares of the Company's common stock, while performance unit awards are rights denominated in dollars. The administrator establishes the applicable performance goals based on one or more measures of business performance enumerated in the 2016 Equity Plan, such as revenue, gross margin, net income or total stockholder return. To the extent earned, performance share and unit awards may be settled in cash or in shares of our common stock. Holders of performance shares or performance units have no voting rights or rights to receive cash dividends unless and until shares of common stock are issued in settlement of such awards. However, the administrator may grant performance shares that entitle their holders to dividend equivalent rights.

- *Cash-based awards and other stock-based awards.* The administrator may grant cash-based awards that specify a monetary payment or range of payments or other stock-based awards that specify a number or range of shares or units that, in either case, are subject to vesting or other conditions specified by the administrator. Settlement of these awards may be in cash or shares of our common stock, as determined by the administrator. Their holder will have no voting rights or right to receive cash dividends unless and until shares of our common stock are issued pursuant to the award. The administrator may grant dividend equivalent rights with respect to other stock-based awards.

In the event of a change in control as described in the 2016 Equity Plan, the acquiring or successor entity may assume or continue all or any awards outstanding under the 2016 Equity Plan or substitute substantially equivalent awards. Any awards which are not assumed or continued in connection with a change in control or are not exercised or settled prior to the change in control will terminate effective as of the time of the change in control. The compensation committee may provide for the acceleration of vesting of any or all outstanding awards upon such terms and to such extent as it determines, except that the vesting of all awards held by members of the board of directors who are not employees will automatically be accelerated in full. The 2016 Equity Plan also authorizes the compensation committee, in its discretion and without the consent of any participant, to cancel each or any outstanding award denominated in shares upon a change in control in exchange for a payment to the participant with respect to each share subject to the cancelled award of an amount equal to the excess of the consideration to be paid per share of common stock in the change in control transaction over the exercise price per share, if any, under the award.

The 2016 Equity Plan will continue in effect until it is terminated by the administrator, provided, however, that all awards will be granted, if at all, within 10 years of its effective date. The administrator may amend, suspend or terminate the 2016 Equity Plan at any time, provided that without stockholder approval, the plan cannot be amended to increase the number of shares authorized, change the class of persons eligible to receive incentive stock options, or effect any other change that would require stockholder approval under any applicable law or listing rule.

Total unrecognized compensation expense related to unvested options granted under the Company's share-based compensation plan was $21.7 million and $18.6 million at December 31, 2016 and 2015, respectively. That expense is expected to be recognized over a weighted average period of 1.7 years and 2.1 years as of December 31, 2016 and 2015, respectively. The Company recorded share-based option compensation expense under the 2011 Equity Incentive Plan and 2016 Equity Plan of $24.6 million, $10.3 million and $4.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

In January 2015, the compensation committee of the Company's board of directors approved the amendments of all outstanding option awards under the 2011 Equity Incentive Plan that have an exercise price above $6.00 per unit to adjust the exercise price per unit to $6.00 per unit (Note 4), the estimated fair value of the Company's Class A units as of October 31, 2014. The awarded options have the same vesting schedule as the original award. The amendment to the option awards resulted in a modification charge of $1.1 million, of which $668,000 was expensed immediately during the first quarter of 2015 and the remaining amount will be recognized over the vesting periods of each award. These vesting periods range from one to two years.

On July 13, 2016, the compensation committee of the Company's board of directors approved the amendment of all outstanding option awards issued under the Company's 2011 Equity Incentive Plan whereby, effective upon pricing of the Company's IPO, the exercise price (on a post-Corporate Conversion, post-split basis) was adjusted to equal the price per share of the Company's common stock in the IPO. The amendment was made to the awards as the original exercise price was substantially higher than the price of the Company's common stock in the IPO as a result of changes in the Company's capital structure that occurred upon IPO. Options to purchase an aggregate of approximately 1.6 million shares of the Company's Class A units were modified. Following this modification, the previously granted options will have the same vesting schedule as the original award and are modified on a one-for-one basis. The modification resulted in a $4.0 million charge, of which the incremental value of the previously vested portion of the awards totaling $1.8 million was expensed immediately during the third quarter of 2016 and the remaining $2.2 million will be recognized over the remaining vesting periods of each award. These vesting periods range from one to three years.

The following table summarizes information about unit options outstanding at December 31, 2016 and 2015:

	Options Outstanding				Options Exercisable	
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)	Number of Options	Weighted Average Exercise Price
Balance, December 31, 2014	706,460	$ 52.15	8.63	$ —	266,518	$ 50.50
Granted	1,154,394	37.44				
Exercised	(772)	38.70				
Forfeited	(174,834)	57.68				
Balance, December 31, 2015	1,685,248	$ 37.38	8.72	$ —	381,072	$ 36.29
Granted	4,858,460	7.12				
Exercised	(1,109)	36.63				
Forfeited	(105,084)	32.09				
Balance, December 31, 2016	6,437,515	$ 8.32	9.28	$ 2,227,268	2,181,810	$ 12.00

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value calculated as the difference between the fair value of the Company's common stock at December 31, 2016 ($5.35 per share) and the exercise price, multiplied by the related in-the-money options that would have been received by the option holders had they exercised their options at the end of the fiscal year. This amount changes based on the fair value of the Company's common stock. There were 1,109 options exercised during the year ended December 31, 2016 that were not in-the-money. There were 772 options exercised during 2015 that were in-the-money, with an aggregate intrinsic value at time of exercise of $4,800.

During the year ended December 31, 2016, 1,630,536 options were granted to the Company's Chief Executive Officer and 3,227,924 options were granted to the Company's employees and directors. The weighted-average fair value of the stock option awards granted to employees, officers, directors and advisors was $7.12, $20.67 and $28.15 during the years ended December 31, 2016, 2015 and 2014, respectively, and was estimated at the date of grant using the Black-Scholes option-pricing model and the assumptions noted in the following table:

	Year Ended		
	December 31, 2016	December 31, 2015	December 31, 2014
Weighted average fair value of grants	$7.12	$20.67	$28.15
Expected volatility	74.98% - 79.35%	77.23% - 93.85%	58.70% - 93.94%
Risk-free interest rate	1.15% - 2.20%	1.54% - 1.93%	1.73% - 1.81%
Expected life	5.0 - 6.0 years	5.2 - 6.0 years	5.5 - 6.0 years
Expected dividend yield	0%	0%	0%

In December 2014, the Company's board of directors approved an option grant to the Chief Executive Officer with an exercise price of $39.00 to purchase a number of units equal to 5% of the total issued and outstanding units of the Company (after, in the event of an IPO, giving effect to the exercise and conversion of certain exercisable and convertible securities and after giving effect to consummating the IPO) calculated on the earliest to occur of 1) a sale of the Company, 2) the date on which the Company consummates an IPO and 3) the date the key employee ceases to be a service provider to the Company. This option grant was issued in March 2015 when the terms of the agreement were finalized. Since the grant was contingent on a liquidity event, a grant date had not been established and therefore no compensation expense was initially recorded.

In December 2015, the option agreement entered into with the Company's Chief Executive Officer was replaced in its entirety by an option agreement dated December 31, 2015 so that the number of units is set to 769,231 unit options valued at $15.2 million which will be recognized as compensation expense over the vesting term. These units under this option agreement were issued outside of the 2011 Equity Incentive Plan. The Company expensed $7.2 million and $5.1 million during the year ended December 31, 2016 and fourth quarter of 2015, respectively, and the remaining amount will be recognized ratably through August 2017. The options vest 1/3 at the grant date, 1/3 in August 2016 and 1/3 in August 2017. While the awards vest over this term they are not exercisable until the occurrence of the Calculation Date. The Calculation Date is defined as the earliest to occur of 1) a sale of the Company (as defined in the Company's second amended and restated limited liability company agreement dated as of June 27, 2014), 2) the date on which the Company consummates an IPO and 3) the date the key employee ceases to be a service provider to the Company.

On July 13, 2016, the compensation committee of the Company's board of directors approved an option award for Dr. Harlan W. Waksal increasing the number of options (giving effect to the Corporate Conversion) subject to his original option grant. The number of shares subject to this option award shall equal the difference between the 769,231 options originally granted to Dr. Harlan W. Waksal and 5% of the Company's outstanding common equity determined on a fully diluted basis on the IPO date, which amounted to 1,630,536 options. The effective date of the new option award was the IPO date of July 26, 2016. The exercise price per share of common stock subject to the new incremental options awarded was equal to the IPO price per share of common stock at the IPO date of $12.00. The option award was subject to the same vesting schedule applicable to the original option grant such that all options awarded will vest on August 4, 2017. In consideration for the new option award, Dr. Harlan W. Waksal has committed to perform an additional year of service in connection with receipt of the additional option shares. In the event Dr. Harlan W. Waksal voluntarily terminates his employment prior to completion of this additional year of service, Dr. Harlan W. Waksal shall forfeit 25% of the additional options, or 25% of the aggregate additional option gain associated with the additional option shares in the event the options are exercised, as applicable. This modification resulted in a $12.4 million charge, of which the incremental value of the previously vested portion of the awards totaling $8.3 million was expensed during the third quarter of 2016 and the remaining amount of the unvested portion totaling $4.1 million will be recognized over the additional two years of service.

2014 Long-term Incentive Plan ("LTIP")

The LTIP was adopted in May 2014 and amended in December 2014. Under the LTIP, the Company's board of directors may grant up to 10% of the equity value of the Company including the following types of awards:

- Equity Appreciation Rights Units ("EAR units") whereby the holder would possess the right to a payment equal to the appreciation in value of the designated underlying equity from the grant date to the determination date. Such value is calculated as the product of the excess of the fair market value on the determination date of one EAR unit over the base price specified in the grant agreement and the number of EAR units specified by the award, or, when applicable, the portion thereof which is exercised.

- Performance Awards which become payable on the attainment of one or more performance goals established by the Plan Administrator. No performance period shall end prior to an IPO or Change in Control (the "Determination Date").

The Company's board of directors has the authority, at its discretion, to determine the terms and conditions of any LTIP grant, including vesting schedule.

Certain key employees were granted a total of 1,250 EAR units and 8,500 EAR units with a base price of $6.00/unit, expiring 10 years from the grant date (the "Award") during 2015 and 2014, respectively. Each unit entitles the holder to a payment amount equal to 0.001% of the fair market value of all of the outstanding equity in the Company on a fully diluted basis assuming the exercise of all derivative securities as of the Determination Date. The number of EAR units shall be adjusted to equal a certain percentage of the Company's outstanding common equity securities determined on the first trading date following the Determination Date.

The EAR units vest based on the earlier of (a) the expiration date if an IPO is consummated on or before that date or (b) the date of a change in control that occurs after the submission date of a Form S-1 registration statement to the SEC but prior to the expiration date. The EAR units also vest upon achieving certain predetermined stock price targets subject to continuing service through the date of the Form S-1 submission. The payment amount with respect to the holder's EAR units will be determined using the fair market value of the common stock on the trading date immediately preceding the settlement date. Each payment under the Award will be made in a lump sum and is considered a separate payment. The Company reserves the right to make payment in the form of common stock following the consummation of an IPO or in connection with a change in control, subject to the terms of the LTIP. Any settlement in the form of common stock will be limited to a maximum share allocation. The holder has no right to demand a particular form of payment.

A total of 9,750 units were granted under the LTIP at December 31, 2016 and 2015. The liability and associated compensation expense for this award was recognized upon consummation of the Company's IPO on August 1, 2016. No compensation expense had been recorded prior to this date. The Company utilized a Monte-Carlo simulation to determine the fair value of the awards granted under the LTIP of $22.6 million, which was recorded as shared-based compensation during the third quarter of 2016 as these awards are not forfeitable.

2016 Employee Stock Purchase Plan ("2016 ESPP")

The Company's board of directors has adopted and the Company's stockholders have approved the 2016 ESPP. A total of 1,125,000 shares of the Company's common stock are available for sale under the 2016 ESPP. In addition, the 2016 ESPP provides for annual increases in the number of shares available for issuance under the 2016 ESPP on January 1, 2017 and each subsequent anniversary through 2025, equal to the smallest of:

- 750,000 shares;

- 1.5% of the outstanding shares of the Company's common stock on the immediately preceding December 31; or

- such other amount as may be determined by the Company's board of directors.

Appropriate adjustments will be made in the number of authorized shares and in outstanding purchase rights to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in the Company's capital structure. Shares subject to purchase rights which expire or are cancelled will again become available for issuance under the 2016 ESPP.

The compensation committee of the Company's board of directors will administer the 2016 ESPP and have full authority to interpret the terms of the 2016 ESPP. The 2016 ESPP provides, subject to certain limitations, for indemnification by the Company of any director, officer or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the 2016 ESPP.

All of the Company's employees, including the Company's named executive officers, and employees of any of the Company's subsidiaries designated by the compensation committee are eligible to participate if they are customarily employed by the Company or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year, subject to any local law requirements applicable to participants in jurisdictions outside the United States. However, an employee may not be granted rights to purchase stock under the 2016 ESPP if such employee:

- immediately after the grant would own stock or options to purchase stock possessing 5.0% or more of the total combined voting power or value of all classes of the Company's capital stock; or

- holds rights to purchase stock under all of the Company's employee stock purchase plans that would accrue at a rate that exceeds $25,000 worth of the Company's stock for each calendar year in which the right to be granted would be outstanding at any time.

The 2016 ESPP is intended to qualify under Section 423 of the Code but also permits us to include our non-U.S. employees in offerings not intended to qualify under Section 423. The 2016 ESPP will typically be implemented through consecutive six-month offering periods. The offering periods generally start on the first trading day of April and October of each year. The administrator may, in its discretion, modify the terms of future offering periods, including establishing offering periods of up to 27 months and providing for multiple purchase dates. The administrator may vary certain terms and conditions of separate offerings for employees of the Company's non-U.S. subsidiaries where required by local law or desirable to obtain intended tax or accounting treatment.

The 2016 ESPP permits participants to purchase common stock through payroll deductions of up to 10.0% of their eligible compensation, which includes a participant's regular and recurring straight time gross earnings and payments for overtime and shift premiums, but exclusive of payments for incentive compensation, bonuses and other similar compensation.

Amounts deducted and accumulated from participant compensation, or otherwise funded in any participating non-U.S. jurisdiction in which payroll deductions are not permitted, are used to purchase shares of the Company's common stock at the end of each offering period. The purchase price of the shares will be 85.0% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last day of the offering period. Participants may end their participation at any time during an offering period and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with the Company.

Each participant in any offering will have an option to purchase for each full month contained in the offering period a number of shares determined by dividing $2,083 by the fair market value of a share of the Company's common stock on the first day of the offering period or 200 shares, if less, and except as limited in order to comply with Section 423 of the Code. Prior to the beginning of any offering period, the administrator may alter the maximum number of shares that may be purchased by any participant during the offering period or specify a maximum aggregate number of shares that may be purchased by all participants in the offering period. If insufficient shares remain available under the plan to permit all participants to purchase the number of shares to which they would otherwise be entitled, the administrator will make a pro rata allocation of the available shares. Any amounts withheld from participants' compensation in excess of the amounts used to purchase shares will be refunded, without interest.

A participant may not transfer rights granted under the 2016 ESPP other than by will, the laws of descent and distribution or as otherwise provided under the 2016 ESPP.

In the event of a change in control, an acquiring or successor corporation may assume the Company's rights and obligations under outstanding purchase rights or substitute substantially equivalent purchase rights. If the acquiring or successor corporation does not assume or substitute for outstanding purchase rights, then the purchase date of the offering periods then in progress will be accelerated to a date prior to the change in control.

The 2016 ESPP will remain in effect until terminated by the administrator. The compensation committee has the authority to amend, suspend or terminate the 2016 ESPP at any time.

Warrants

The following table summarizes information about warrants outstanding at December 31, 2016 and 2015:

	Warrants	Weighted Average Exercise Price
Balance, December 31, 2014	710,801	$ 46.64
Balance, December 31, 2015	710,801	$ 46.64
Granted	617,651	10.20
Exercised	—	—
Forfeited	—	—
Balance, December 31, 2016	1,328,452	$ 29.70

In conjunction with 2015 Credit Agreement, warrants to purchase $6.3 million of Class A units were issued to two lenders at 85% of the price per share of common stock in the IPO. Upon consummation of the Company's IPO on August 1, 2016 with a price per share of common stock in the IPO of $12.00, these warrants to purchase Class A units were exchanged for 617,651 warrants at a strike price of $10.20 to purchase the same number of shares of the Company's common stock (Note 8).

14. Accrued Expenses and Other Short Term Liabilities

Short-term accrued expenses at December 31, 2016 and 2015 include the following (in thousands):

	December 31, 2016	December 31, 2015
Commission payable	$ 2,395	$ 2,820
Accrued bonus	245	362
Severance	1,744	578
Other compensation and benefits	709	956
Financing/Offering Costs	56	1,250
Threatened litigation	—	10,377
Royalty arrangements	2,502	2,777
Other	4,499	3,100
Total Accrued Expenses	$ 12,150	$ 22,220

Commission Payable

In November 2015, the Company entered into an agreement with a lender whereby the Company borrowed $15.0 million under the Second-Lien Convert and incurred a $600,000 commission fee to a third party, which was accrued for at December 31, 2015, of which $300,000 is payable in cash and was still in accounts payable at December 31, 2016 and $300,000 was payable in Class A units with a fair value of $125,000, which was settled through the issuance of 25,000 Class A units in February 2016.

During 2015, the Company raised $873,000 in gross proceeds, $833,000 net of $40,000 in transaction costs, through the issuance of 75,875 Class E redeemable convertible units. At December 31, 2016 and 2015, $40,000 remains in accrued liabilities relating to commissions to third parties for Class E redeemable convertible raises during 2015.

During 2014, the Company raised $39.5 million in gross proceeds, $36.4 million net of $3.1 million in transaction costs, through the issuance of 3,438,984 Class E redeemable convertible units. Of the $3.1 million in transaction costs, $2.4 million remains in accrued liabilities at December 31, 2016 and 2015 relating to commissions to third parties for Class E redeemable convertible raises during 2014.

Accrued Bonus

Accrued bonus balances represent anticipated bonus compensation to be paid to employees resulting from past services performed.

Severance

Severance balances represent contractual compensation to be paid to former employees, a significant portion of which relates to the separation agreement with Dr. Samuel D. Waksal. Effective as of February 8, 2016, Dr. Samuel D. Waksal

resigned from all positions with the Company and is no longer employed by the Company in any capacity. At December 31, 2016, accrued severance payable to Dr. Samuel D. Waksal totaled $2.2 million, of which $1.0 million is recorded as accrued expense and $1.2 million is recorded as other long-term liabilities. The separation agreement with Dr. Samuel D. Waksal contains certain supplement conditional payments, none of which have been met at December 31, 2016. The Company has not recorded any expense related to these conditional payments at December 31, 2016 and will continue to evaluate the probability of these conditional payments.

Separation Agreement with Dr. Samuel D. Waksal

Dr. Samuel D. Waksal founded the Company in October 2010 and, until August 2014, was the chairman of the Company's board of directors and the Company's Chief Executive Officer. In August 2014, he stepped down as the Company's Chief Executive Officer and became the Company's Chief of Innovation, Science and Strategy. In July 2015, Dr. Samuel D. Waksal resigned as chairman of the Company's board of directors.

Effective as of February 8, 2016, Dr. Samuel D. Waksal resigned from all positions with the Company and is no longer employed by the Company in any capacity. The Company does not intend for Dr. Samuel D. Waksal to become an employee, provide any ongoing consulting services or rejoin the board of directors.

In connection with his resignation, the Company entered into a separation agreement with Dr. Samuel D. Waksal terminating his employment with the Company and providing that he shall perform no further paid or unpaid services for the Company whether as employee, consultant, contractor or any other service provider. The principal provisions of the separation agreement are summarized below.

Severance and Other Payments

The Company has agreed to make a series of payments (all subject to withholding taxes) to Dr. Samuel D. Waksal, some of which are contingent, structured as follows:

- a $3.0 million severance payment, of which the first $1.0 million will be payable during the first year after February 8, 2016, with the remaining $2.0 million to be payable during the two years commencing with the first anniversary of the start of payments of the first $1.0 million. Severance expense totaling $3.1 million, including the cost of Company-paid medical benefits, was recorded during the first quarter of 2016 as these payments are probable and estimable;

- supplemental conditional payments of up to $6.75 million in the aggregate that are payable in 2017 ($2.25 million), 2018 ($2.25 million) and 2019 ($2.25 million) if specified benchmarks related to the valuation of the Company implied by the public offering price in the IPO, the net proceeds to the Company from the IPO and the Company's equity market capitalization on specified dates are achieved and subject to the Company having cash and cash equivalents less payables of $50 million or more on the dates when the Company makes those payments. These conditional payments, although estimable, are not probable at December 31, 2016 as the Company is not able to determine if or when these benchmarks related to the valuation of the Company will be achieved. The Company has not recorded any expense related to these conditional payments at December 31, 2016 and will continue to evaluate the probability of these conditional payments;

- an amount equal to five percent (up to a maximum of $15 million) of any cash received by the Company or guaranteed cash payments (as defined below) payable to the Company pursuant to the first three business development programs that the Company enters into on or before February 8, 2019 to research, develop, market or commercialize the Company's ROCK2 program or the Company's immuno-oncology program. For purposes of the separation agreement, ROCK2 program is defined to mean pathways involving ROCK2 or other pathways effecting autoimmunity, fibrosis, cancer or neurodegenerative diseases; immunooncology program is defined to mean antibodies or small molecules involved in inducing the immune system to make an anti-tumor response; and guaranteed cash payments is defined to mean payments to the Company of cash contractually provided for pursuant to an agreement entered into by the Company with respect to a business development program, which payments are not subject to the Company's meeting any milestones or thresholds. If the aggregate cash and guaranteed cash payments received by the Company pursuant to any business development program exceed $800 million before the completion of the IPO, the equity market capitalization requirements that must be met for Dr. Samuel D. Waksal to earn the supplemental payments of up to $6.75 million described above shall be deemed fulfilled, regardless of the Company's equity market capitalization at the applicable time. These conditional payments are not estimable or probable at December 31, 2016 as the Company is not able to determine if or when the Company will enter into these business development programs. The Company has not recorded any expense related to these conditional payments at December 31, 2016 and will continue to evaluate the probability of these conditional payments.

LTIP Award

With regard to the award of 5,000 EAR units granted to Dr. Samuel D. Waksal in December 2014, the separation agreement provides that:

- by virtue of his separation from the Company, Dr. Samuel D. Waksal acknowledges that he is no longer entitled to vesting at December 16, 2024 based on the occurrence of an initial public offering on or before that date and continued service through that date;
- the service component included in the vesting condition related to the occurrence of a change of control after an initial public offering but before December 16, 2024 is now satisfied;
- the service component included in the vesting condition related to the occurrence of a 333% increase in the fair market value of each EAR unit from the $6.00 grant price per unit before December 16, 2024 is now satisfied; and
- Dr. Samuel D. Waksal's EAR units shall not be subject to forfeiture, termination or recapture payment for violation of the restrictive covenants contained in the 2014 LTIP.

The liability and associated compensation expense for this award was recognized upon consummation of the Company's IPO on August 1, 2016. No compensation expense had been recorded prior to this date. The Company utilized a Monte-Carlo simulation to determine the fair value of the award granted under the LTIP of $11.6 million, which was recorded during the third quarter of 2016 as this award is not forfeitable.

Lock-up Agreement

Dr. Samuel D. Waksal has agreed to enter into a 180-day lock-up agreement in connection with the IPO. If requested by the managing underwriters in any subsequent offering at the time of which Dr. Samuel D. Waksal owns five percent or more the Company's common stock, he will enter into a lock-up agreement for a period not to exceed 90 days and in the form customarily requested by the managing underwriters for that offering (subject to mutually agreed exceptions), so long as other equityholders enter into substantially similar lock-up agreements. If any of our equityholders that signs a lock-up agreement is released from its provisions by the managing underwriters, Dr. Samuel D. Waksal will also be released from his lock-up agreement.

Covenants

The separation agreement contains customary non-solicitation, non-competition and non-disparagement provisions that continue in effect until February 8, 2019. In addition, Dr. Samuel D. Waksal agrees to make himself available, at the Company's expense, to assist the Company in protecting its ownership of intellectual property and in accessing his knowledge of scientific and/or research and development efforts undertaken during his employment with the Company.

Releases

The separation agreement provides for mutual releases by the parties and related persons of all claims arising out of Dr. Samuel D. Waksal's relationship with the Company as employee, founder, investor, member, owner, member or Chairman of the Board, Chief Executive Officer, or officer.

Financing Costs

As consideration for the amendment to the Company's 2013 convertible debt, if a qualified IPO, defined as a public offering of the Company's equity interests with gross proceeds to the Company of at least $75.0 million, had not been completed on or prior to March 31, 2016, the Company agreed to pay an amendment fee equal to $1.3 million to be allocated among the lenders. This fee was accrued at December 31, 2015, and subsequently paid in April 2016 through the issuance of 108,696 Class E redeemable convertible units, as the Company did not complete a qualified IPO by March 31, 2016.

Threatened Litigation

During 2015, the Company received a demand for the issuance of additional equity under a letter agreement with Falcon Flight LLC that was entered into in November 2014. In June 2016, the Company entered into an agreement with Falcon Flight LLC and one of its affiliates in connection with a settlement of certain claims alleging breaches of a letter agreement between the Company and Falcon Flight LLC relating to a prior investment by Falcon Flight LLC and its affiliate in the Company's securities, which letter agreement was amended and restated as part of this settlement, which the Company refers to as the Falcon Flight Agreement. Subject to certain terms and conditions contained therein, the Falcon Flight Agreement provides Falcon Flight LLC and its affiliate with certain information rights, consent rights, and anti-dilution protections

including the issuance of 1,061,741 additional Class E redeemable convertible membership units with a conversion price equal to any down-round price and a right to designate a member of the Company's board of directors or observer, among other rights. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016, except for indemnification of Falcon Flight LLC's board designee or observer, which survives termination. In addition, the Company agreed to provide Falcon Flight LLC with most favored nation rights which terminated upon the closing of the IPO on August 1, 2016 and to pay $800,000 in cash to Falcon Flight LLC. The Company recorded an estimate for this settlement of approximately $10.4 million in September 2015 and recorded an additional expense of $2.6 million in June 2016 based on the excess of the fair value of this settlement over the $10.4 million previously expensed in 2015.

Royalty Arrangements

The Company has contracts with third parties, which require the Company to make royalty payments based on the sales revenue of the products specified in the contract. The Company records royalty expense as the associated sales are recognized, and classifies such amounts as selling, general and administrative expenses in the accompanying consolidated statements of operations. Royalty payable was $2.5 million and $2.8 million at December 31, 2016 and 2015, respectively. These royalties are generally paid quarterly. Royalty expense was $1.2 million, $2.7 million and $6.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. Approximately $2.2 million and $2.0 million at December 31, 2016 and 2015, respectively, of the royalty payable is the prepaid royalty that will have to be refunded to the Company's commercial partner (Note 6).

15. 401(k) Profit-Sharing Plan

In October 2011, the Company began sponsoring a qualified Tax Deferred Savings Plan (401(k)) for all eligible employees of the Company and its subsidiaries. Participation in the plan is voluntary. Participating employees may defer up to 75% of their compensation up to the maximum prescribed by the Internal Revenue Code. The Company has an obligation to match non-highly compensated employee contributions of up to 6% of deferrals and also has the option to make discretionary matching contributions and profit sharing contributions to the plan annually, as determined by the Company's board of directors. The plan's effective date is October 1, 2011 and incorporates funds converted from the Kadmon Pharmaceuticals Profit Sharing Plan.

The Company expensed employer matching contributions of $0.3 million, $0.3 million and $0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. The Company made disbursements of $0.3 million and $0.4 million for the years ended December 31, 2016 and 2015, respectively. The Company typically disburses employer matching contributions during the first quarter following the plan year.

16. Commitments

Lease Commitments

The Company has three primary operating locations which are occupied under long-term leasing arrangements. In October 2010, Kadmon Corporation, LLC entered into a corporate headquarters and laboratory lease in New York, New York, expiring in February 2021 and opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $2.0 million. Since inception there have been four amendments to this lease agreement, which have altered office and laboratory capacity and extended the lease term through October 2024. Rental expense for this lease amounted to $6.4 million, $6.2 million and $5.5 million for each of the years ended December 31, 2016, 2015 and 2014. During future years, the base rent amount associated with these premises will increase 3.5% annually. The Company has the ability to extend portions of the lease on the same terms and conditions as the current lease, except that the base rent will be adjusted to the fair market rental rate for the building based on the rental rate for comparable space in the building at the time of extension.

The Company is party to an operating lease in Warrendale, Pennsylvania (the Company's specialty-focused commercial operation), which expires on September 30, 2019, with a five-year renewal option. Rental payments under the renewal period will be at market rates determined from the average rentals of similar tenants in the same industrial park. Rental expense for this lease was $0.6 million for each of the years ended December 31, 2016, 2015 and 2014, respectively.

In August 2015, the Company entered into an office lease agreement in Cambridge, Massachusetts (the Company's new clinical office) effective January 2016 and expiring in April 2023. The Company opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $91,000. Rental expense for this lease was $0.3 million for the year ended December 31, 2016. No rental expense was incurred for this lease during the year ended December 31, 2015.

Future minimum rental payments under noncancellable leases are as follows (in thousands) at December 31, 2016:

Year ending December 31,	Amount
2017	$ 5,796
2018	5,912
2019	5,828
2020	5,449
2021	5,634
Thereafter	16,386
Total	**$ 45,005**

Licensing Commitments

The Company has entered into several license agreements for products currently under development (Note 12). The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory, and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent milestone payments aggregate to $400.4 million at December 31, 2016. Any payments made prior to FDA approval will be expensed as research and development. Payments made after FDA approval will be capitalized.

Further, under the terms of certain licensing agreements, the Company may be obligated to pay commercial milestones contingent upon the realization of sales revenues and sublicense revenues. Due to the long-range nature of such commercial milestones, they are neither probable at this time nor predictable, and consequently are not included in the additional contingent milestone payment amount.

Employment Agreements

Two former employees of the Company received $1.25 million each upon the consummation of the IPO, which the Company settled through the issuance of an aggregate of 208,334 shares of its common stock on August 1, 2016. The amount of compensation due to another former employee as a result of this event is contingent upon the valuation of the Company at the time of the transaction, which was not achieved upon consummation of the IPO on August 1, 2016. Certain employment agreements also provide for routine severance compensation. The Company has recorded a liability for such agreements of $2.9 million, which is primarily attributable to the severance expense recognized in connection with the resignation of Dr. Samuel D. Waksal, and $0.6 million at December 31, 2016 and 2015, respectively (Note 14).

17. Contingencies

The Company is subject to various legal proceedings that arise from time to time in the ordinary course of its business. Although the Company believes that the various proceedings brought against it are without merit, and that it has adequate product liability and other insurance to cover any claims, litigation is subject to many factors which are difficult to predict and there can be no assurance that the Company will not incur material costs in the resolution of legal matters. Should the Company determine that any future obligations will exist, the Company will record expense equal to the amount which is deemed probable and estimable.

Legal Proceedings

The Rosenfeld Litigation

On February 3, 2014, Steven Rosenfeld commenced a lawsuit in the New York State Supreme Court, for the county of New York, against Joel Schreiber, Samuel D. Waksal and certain Kadmon entities alleging that he and co-defendant Schreiber were engaged to raise funds for a new venture involving Kadmon. Rosenfeld alleges that he was responsible for raising funds but that he was not compensated. A Third Amended Complaint was filed in or about August 2016 adding new corporate entities and adding an alleged breach of an exclusivity agreement, again seeking an amount to be determined at trial, but believed by Rosenfeld to be no less than $150 million dollars. In October 2016, the Company filed a motion to dismiss the action and a motion to stay certain discovery pending resolution of the motion to dismiss. Briefing on both motions was completed in January 2017. The Company believes that the claims have no merit and intends to vigorously defend this action.

The Belesis Litigation

On June 29, 2015, Anastasios Thomas Belesis and ATB Holding Company, LLC (together "Belesis") filed a lawsuit in the U.S. District Court for the Southern District of New York against the Company, our subsidiaries, Samuel D. Waksal and Steven N. Gordon alleging that they are owed equity or a monetary amount for services allegedly performed. The lawsuit asserted 12 claims, ranging from federal securities fraud to breach of contract and a variety of other common law causes of action and sought an order compelling specific performance of the conveyance of 1,000,000 shares of "Kadmon stock" or compensatory damages in the amount of at least $15,000,000 and punitive damages in an amount to be determined by the Court, with pre- and post-judgment interest thereon, attorney's fees, all taxable costs and disbursements. The Company filed a motion to dismiss in September 2015 and the claims were dismissed without prejudice in September 2016. On November 8, 2016, Belesis filed a motion for leave to file a second amended complaint. Defendants filed opposition papers to plaintiffs' motion on November 30, 2016 and plaintiffs filed their reply brief on December 6, 2016. The parties are awaiting the court's decision. The Company believes that the claims have no merit and intends to vigorously defend this action.

The Glodek Litigation

On July 25, 2016, Kevin Glodek filed and served a Summons with Notice against Kadmon Holdings, LLC and Kadmon Holdings, Inc. in the New York State Supreme Court, for the county of New York, for an amount of no less than $2.8 million with interest, plus costs and disbursements. Company counsel demanded a complaint and that complaint was served and filed on September 6, 2016. In the complaint, Glodek alleges fraud, misrepresentation, breach of contract, breach of the implied covenant of good faith and fair dealing, and unjust enrichment, for amounts to be determined at trial, but in no event less than $4 million with interest, plus costs and disbursements. Glodek's claims arise out of a 2015 settlement agreement, in which he released all claims he had against Kadmon Holdings, LLC and Kadmon Holdings, Inc. On September 21, 2016, Glodek filed an Amended Summons and an Amended Complaint adding Steven N. Gordon and Mr. Poukalov as named defendants. All defendants moved (i) to dismiss the Amended Complaint and (ii) for sanctions or, in the alternative, to disqualify Glodek's counsel. Argument on the motions was conducted on January 24, 2017 before the Honorable Anil Singh and the parties are awaiting the court's decision. All defendants believe that the settlement agreement and its broad release are binding; they deny all of the allegations and believe that they are entirely without merit; and they intend to vigorously defend themselves against this action.

18. Concentrations

Major Customers

Sales to two major customers aggregate to approximately 41% and 31% of the Company's net sales for the years ended December 31, 2016 and 2015, respectively. Net accounts receivable from these customers totaled $0.1 and $0.6 million at December 31, 2016 and 2015, respectively. Sales to one major customer aggregated to approximately 20% of the Company's net sales for the year ended December 31, 2014.

Major Suppliers

Due to requirements of the U.S. Food and Drug Administration and other factors, the Company is generally unable to make immediate changes to its supplier arrangements. Manufacturing services related to each of the Company's pharmaceutical products are primarily provided by a single source. The Company's raw materials are also provided by a single source for each product. Management attempts to mitigate this risk through long-term contracts and inventory safety stock.

19. Related Party Transactions

At December 31, 2016 Kadmon I held approximately 12.1% of the total outstanding common stock of Kadmon Holdings and at December 31, 2015 Kadmon I held approximately 66% of the total outstanding Class A units of Kadmon Holdings (Note 4). The sole manager of Kadmon I was an executive officer of the Company. Kadmon I has no special rights or preferences in connection with its investment into Kadmon Holdings, and had the same rights as all other holders of Kadmon Holdings Class A units. On January 23, 2017, Kadmon I, LLC was dissolved and liquidated. Upon dissolution and liquidation, all assets of Kadmon I, LLC which consists solely of the shares of common stock in Kadmon Holdings, Inc., were distributed to the members of Kadmon I, LLC.

In October 2011, Dr. Samuel D. Waksal, a former employee of the Company, issued an equity instrument for which the underlying value is based on Class A units and is redeemable for cash upon the occurrence of a liquidity event. The liability was recorded based on fair value of the instrument on the issuance date and was subsequently marked to market using a Black-Scholes calculation. The total liability for this instrument was $0 and $69,000 at December 31, 2016 and 2015, respectively (Note 8). Upon consummation of the Company's IPO on August 1, 2016 with a price per share of $12.00 per share, the fair value of this equity instrument had a fair value of $0, which resulted in no liability owed by the Company

In November 2011, the Company entered into an agreement with SBI Holdings, Inc., an indirect holder of more than 5% of the Company's outstanding membership interests through Kadmon I, LLC, in connection with an investment of $6.5 million for 306,067 of the Company's Class A membership units (the SBI Agreement). Subject to certain terms and conditions contained therein, the SBI Agreement provided SBI Holdings, Inc. with certain consent rights relating to the Company's activities, information rights and rights upon liquidity events, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

In October 2013, the Company entered into an agreement with Alpha Spring Limited in connection with an investment of $35.0 million by Alpha Spring Limited for 2,679,939 of the Company's Class A membership units (the Alpha Spring Agreement). Subject to certain terms and conditions contained therein, the Alpha Spring Agreement provides Alpha Spring Limited with certain consent rights relating to the Company's activities, most favored nation rights, the right to appoint a member of the Company's board of directors and information rights, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

During 2014 the Chief Executive Officer and member, a family member of the Chief Executive Officer and member and an executive officer provided the Company with short-term, interest-free loans to meet operating obligations. During this time the maximum amount which was outstanding in the aggregate was $3.5 million and was recorded as a related party loan on the Company's balance sheet. The $500,000 related party loan with a family member of the Chief Executive Officer and member was settled in January 2015 through the issuance of 43,478 Class E redeemable convertible units. At December 31, 2015, the $3.0 million related party loan with the Chief Executive Officer and director was still outstanding and was repaid in full during the fourth quarter of 2016.

In April 2015, the Company executed several agreements which transferred the Company's ownership of KGT to MeiraGTx, a then wholly-owned subsidiary of the Company. The execution of all these agreements resulted in a 48% ownership in MeiraGTx by the Company, or a $24.0 million equity investment at the time of the initial transaction (Note 12).

In July and August 2015, a family member of the Chief Executive Officer and member provided the Company with interest-free loans totaling $2.0 million. The loans were repaid in full in August 2015.

In September 2015, the Company entered into an agreement with GoldenTree Asset Management LP and certain of its affiliated entities in connection with (i) a settlement of certain claims alleging breaches of a letter agreement between the Company and such entities relating to a prior investment by such entities in the Company's securities, which letter agreement was terminated as part of this settlement and (ii) participation by such entities in an aggregate amount of $15.0 million in the 2015 Credit Agreement, including the warrants issued in connection therewith, and the Senior Convertible Term Loan (the GoldenTree Agreement). Subject to certain terms and conditions contained therein, the GoldenTree Agreement provided GoldenTree Asset Management LP and certain of its affiliated entities with certain most favored nation rights, anti-dilution protections including the issuance of additional Class E redeemable convertible membership units with a conversion price equal to any down round price and a right to appoint a member of the Company's board of directors, among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016.

In June 2016, the Company entered into an agreement with 72 KDMN Investments, LLC whereby the Company agreed to extend certain rights to 72 KDMN Investments, LLC which shall survive closing of the IPO, including board of director designation rights and confidentiality rights, subject to standard exceptions. In addition, the Company agreed to provide 72 KDMN Investments, LLC with most favored nation rights which terminated upon the closing of the IPO on August 1, 2016. Andrew B. Cohen, a former member of our board of directors, is an affiliate of 72 KDMN. In January 2017, Mr. Cohen resigned from the Company's board of directors and the Company received notice that 72 KDMN forfeits, relinquishes and waives any and all rights it has to designate a director to the Company's board of directors.

In June 2016, Dr. Harlan W. Waksal, the Company's President and Chief Executive Officer, certain entities affiliated with GoldenTree Asset Management LP, Bart M. Schwartz, the chairman of the Company's board of directors, 72 KDMN and D. Dixon Boardman, a member of the Company's board of directors, subscribed for 86,957, 43,479, 21,740, 86,957 and 21,740 of the Company's Class E redeemable convertible units, respectively, at a value of $11.50 per unit.

In June 2016, the Company entered into certain agreements with Falcon Flight LLC and one of its affiliates in connection with a settlement of certain claims alleging breaches of a letter agreement between the Company and Falcon Flight LLC relating to a prior investment by Falcon Flight LLC and its affiliate in the Company's securities, which letter agreement was amended and restated as part of this settlement, which, together with a supplemental letter agreement, we refer to as the Falcon Flight Agreement. Subject to certain terms and conditions contained therein, the Falcon Flight Agreement provides Falcon Flight LLC and its affiliate with certain most favored nation rights, information rights, consent rights, anti-dilution protections including the issuance of 1,061,741 additional Class E redeemable convertible membership units with a conversion price equal to any down-round price, a right to designate a member of the Company's board of then managers or observer and notice requirements with respect to any waivers by the underwriters in connection with lock-up agreements,

among other things. The aforementioned rights terminated upon the closing of the IPO on August 1, 2016, except for indemnification of Falcon Flight LLC's board designee or observer, which survives termination. In addition, the Company agreed to pay $500,000 to Falcon Flight LLC within one business day following the consummation of the IPO, and $300,000 within sixty days following the consummation of the IPO. The Company recorded an estimate for this settlement of approximately $10.4 million in September 2015 and recorded an additional expense of $2.6 million in June 2016 based on the excess of the fair value of this settlement over the $10.4 million previously expensed in 2015.

Certain of the Company's existing institutional investors, including investors affiliated with certain of the Company's directors, purchased an aggregate of 2,708,332 shares of the Company's common stock in its IPO at the IPO price of $12.00 per share, for an aggregate purchase price of $32.5 million, and on the same terms as the shares that were sold to the public generally. Perceptive Advisors, LLC, Third Point Partners, LLC. and GoldenTree purchased 1,458,333 shares of the Company's common stock for $17.5 million, 1,041,666 shares of the Company's common stock for $12.5 million and 208,333 shares of the Company's common stock for $2.5 million, respectively.

20. Income Taxes

The Company files a consolidated tax return for Kadmon Holdings, Inc. and its domestic subsidiaries and the required information returns for its international subsidiaries, all of which are wholly owned. Where permitted, the Company files combined state returns, but in some instances separate company returns for certain subsidiaries on a stand-alone basis are required. For the year ended December 31, 2016, the Company recorded income tax expense of $0.3 million related to the $2.0 million milestone payment received from Jinghua. The Company recorded an immaterial amount of income tax benefit for the year ended December 31, 2015.

The income tax provision consists of the following components (in thousands):

	For the Year Ended December 31,		
	2016	2015	2014
Current tax expense (benefit)			
Foreign	$ 315	$ —	$ —
Federal	—	—	—
State	—	—	—
Total current tax expense	315	—	—
Deferred tax expense (benefit)			
Federal	(15)	1	16
State	42	(4)	(45)
Total deferred tax benefit	27	(3)	(29)
Total income tax expense (benefit)	**$ 342**	**$ (3)**	**$ (29)**

The income tax expense differs from the expense that would result from applying federal statutory rates to loss before income taxes as follows (in thousands):

	For the Year Ended December 31,					
	2016		2015		2014	
	Amount	Rate	Amount	Rate	Amount	Rate
Expected federal statutory income tax	$ (72,945)	-35.0%	$ (51,480)	-35.0%	$ (22,535)	-35.0%
State income taxes, net of federal benefits	(9,485)	-4.6%	(4,544)	-3.1%	(1,232)	-1.9%
Change in federal tax rate used for deferred purposes	200	0.1%	972	0.7%	—	0.0%
Other	—	0.0%	(6,492)	-4.4%	(4,213)	-6.9%
Valuation allowance	82,572	39.6%	61,541	41.8%	27,951	43.8%
Income tax expense (benefit)	**$ 342**	**0.1%**	**$ (3)**	**0.0%**	**$ (29)**	**0.0%**

Deferred income tax expense results primarily from the timing of temporary differences between the tax and financial statement carrying amounts of goodwill. The net deferred tax asset and liability in the accompanying consolidated balance sheets consists of the following components (in thousands):

	For the Year Ended December 31,	
	2016	2015
Deferred tax assets		
Net operating loss carryforward	$ 171,074	$ 116,757
Foreign tax credit carryforward (LT)	315	—
Capitalized research and development	78,147	69,965
Share-based compensation	22,233	6,167
Loss on equity investment	5,900	1,045
Organization costs	46	54
Depreciation	1,050	1,018
Intangibles	47,595	49,681
Inventory reserve and other	3,631	2,731
Total deferred tax assets	329,991	247,418
Deferred tax liability		
Goodwill	(1,376)	(1,349)
Total deferred tax liability	(1,376)	(1,349)
Total deferred tax assets, net	328,615	246,069
Valuation allowance	(329,991)	(247,418)
Deferred tax liability	$ (1,376)	$ (1,349)

At December 31, 2016, the Company has unused federal and state net operating loss carry-forwards of $432.8 million and $362.9 million, respectively, that may be applied against future taxable income. These carry-forwards expire at various dates through December 31, 2036. The Company experienced ownership changes under Internal Revenue Code Section 382 in 2010, 2011 and 2016, which limits the Company's ability to utilize net operating loss carry-forwards. The Company did not reduce the gross deferred tax assets related to the net operating loss carry-forwards, however, because the limitations do not hinder the Company's ability to potentially utilize all of the net operating loss carry-forwards.

In accordance with ASC 740, "Income Taxes," the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets at December 31, 2016 and 2015. The change in deferred tax liability has been recognized as income tax benefit in the consolidated statements of operations for the years ended December 31, 2016, 2015 and 2014 and as an income tax expense for the year ended December 31, 2015.

The federal income tax return for the period of September 16, 2010 through December 31, 2010 was audited by the Internal Revenue Service during 2012 and early 2013. As a result of the audit, the Company's operating loss carry-forwards were reduced by $1.4 million, which is reflected in the table above.

The Company follows guidance on accounting for uncertainty in income taxes which prescribes a minimum threshold a tax position is required to meet before being recognized in the financial statements. The Company does not have any liabilities as of December 31, 2016 and 2015 to account for potential income tax exposure. The Company is obligated to file income tax returns in the U.S. federal jurisdiction and several U.S. States. Since the Company had losses in the past, all prior years that generated net operating loss carry-forwards are open and subject to audit examination in relation to the net operating loss generated from those years.

21. Subsequent Events

Jinghua

The Company earned a $2.0 million milestone payment in January 2017, which was received in February 2017, and will be recorded as license and other revenue.

Camber Pharmaceuticals, Inc.

In February 2016, the Company entered into a supply and distribution agreement, as amended, with Camber for the purposes of marketing, selling and distributing tetrabenazine, valganciclovir, Abacavir, Entecavir, Lamivudine, Lamivudine (HBV) and Lamivudine and Zidovudine.. The initial term of the agreement was twelve months. In February 2017, the Company entered into a third amendment to the supply and distribution agreement with Camber extending the initial term of the agreement by an additional twelve months.

Princeton University

On December 8, 2010, the Company entered into a license agreement with Princeton whereby the Company obtained from Princeton a worldwide exclusive license and right to make, use and sell products identified by Princeton's Flux technology. In February 2017, the Company entered into a mutual termination agreement with Princeton. All rights and licenses granted under the agreement were immediately terminated and shall revert to the party granting such rights.

Private Placement

On March 13, 2017, the Company raised $22.7 million in gross proceeds, $21.3 million net of $1.4 million in placement agent fees, from the issuance of 6,767,855 shares of its common stock, at a price of $3.36 per share, and warrants to purchase 2,707,138 million shares of its common stock at an initial exercise price of $4.50 per share for a term of 13 months from the date of issuance. In connection with the offering, the Company has agreed to file a registration statement to register the shares of common stock underlying the common stock and warrants for resale. Under the agreement, the registration statement must be filed within 30 days of the closing of the financing and declared effective within the timeline provided in the agreement. If the applicable deadlines are not met, monthly liquidated damages of 2.0% of the subscription amount (with an 8.0% cap) will be due to the purchaser.

22. Quarterly Financial Data (unaudited)

The following table presents our unaudited quarterly financial data. Our quarterly results of operations for these periods are not necessarily indicative of our future results of operations.

(in thousands, except per share data)	Three Months Ended December 31,		Three Months Ended September 30,		Three Months Ended June 30,		Three Months Ended March 31,	
	2016	2015	2016	2015	2016	2015	2016	2015
Net sales	$ 3,010	$ 5,723	$ 4,345	$ 9,802	$ 4,967	$ 7,304	$ 6,192	$ 6,470
License and other revenue	1,267	2,215	1,350	1,482	1,453	1,475	3,471	1,248
Total revenue	4,277	7,938	5,695	11,284	6,420	8,779	9,663	7,718
Cost of sales	640	589	880	1,304	880	879	1,085	959
Write-down of inventory	119	205	129	1,143	2	821	135	105
Gross profit	3,518	7,144	4,686	8,837	5,538	7,079	8,443	6,654
Operating expenses:								
Research and development	8,706	10,214	9,550	8,439	8,544	7,065	9,040	7,840
Selling, general and administrative	15,299	22,321	48,311	39,408	18,869	21,815	23,401	21,196
Impairment of intangible asset	—	—	—	31,269	—	—	—	—
Gain on settlement of payable	—	—	(256)	—	—	—	(3,875)	—
Total operating expenses	24,005	32,535	57,605	79,116	27,413	28,880	28,566	29,036
Loss from operations	(20,487)	(25,391)	(52,919)	(70,279)	(21,875)	(21,801)	(20,123)	(22,382)
Total other expense	1,716	9,082	64,049	11,800	14,837	(19,276)	12,407	5,626
Income tax expense (benefit)	27	(3)	—	—	—	—	315	—
Net loss	(22,230)	(34,470)	(116,968)	(82,079)	(36,712)	(2,525)	(32,845)	(28,008)
Deemed dividend on convertible preferred stock and Class E redeemable convertible units	469	—	21,264	—	—	—	—	—
Net loss attributable to common stockholders	(22,699)	(34,470)	(138,232)(1)	(82,079)	(36,712)	(2,525)	(32,845)	(28,008)
Basic and diluted net loss per share of common stock	$ (0.50)	$ (4.15)	$ (4.23)	$ (9.94)	$ (4.42)	$ (0.31)	$ (3.96)	$ (3.58)
Weighted average basic and diluted shares of common stock outstanding	45,078,666	8,298,750	32,678,259 (2)	8,255,011	8,304,334	8,122,691	8,302,635	7,828,101

(1) Net loss attributable to common stockholders for the three months ended September 30, 2016 includes the beneficial conversion feature of the Company's debt upon conversion into shares of the Company's common stock on August 1, 2016 of $44.2 million, the beneficial conversion feature of certain outstanding warrants which became exercisable into shares of the Company's common stock on August 1, 2016 of $1.7 million, the deemed dividends on the Company's convertible preferred stock and Class E redeemable convertible units of $20.9 million and share-based compensation expense related to the Company's LTIP of $22.6 million.

(2) Weighted average basic and diluted shares of common stock outstanding for the three months ended September 30, 2016 includes shares issued as a result of the Corporate Conversion (Note 1).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Kadmon Holdings, Inc.

Date: March 22, 2017

By: /s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer
(Principal 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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Harlan W. Waksal Harlan W. Waksal	President and Chief Executive Officer (Principal Executive Officer)	March 22, 2017
/s/ Konstantin Poukalov Konstantin Poukalov	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	March 22, 2017
/s/ Charles Darder Charles Darder	Controller (Principal Accounting Officer)	March 22, 2017
/s/ Bart M. Schwartz Bart M. Schwartz	Director	March 22, 2017
/s/ Eugene Bauer Eugene Bauer	Director	March 22, 2017
/s/ D. Dixon Boardman D. Dixon Boardman	Director	March 22, 2017
/s/ Steven Meehan Steven Meehan	Director	March 22, 2017
/s/ Alexandria Forbes Alexandria Forbes	Director	March 22, 2017
/s/ Tasos Konidaris Tasos Konidaris	Director	March 22, 2017
/s/ Thomas E. Shenk Thomas E. Shenk	Director	March 22, 2017
/s/ Susan Wiviott Susan Wiviott	Director	March 22, 2017

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Certificate of Incorporation of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).
3.2	Certificate of Designations of Kadmon Holdings, Inc. creating the 5% Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).
3.3	Bylaws of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).
4.1	Form of Kadmon Holdings, Inc.'s Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-211949), filed with the SEC on July 14, 2016).
4.2	Form of Warrant to Purchase Common Stock issued to investors in Kadmon Holdings, Inc.'s March 8, 2017 financing (incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K Amendment No. 2 (File No. 001-37841), filed with the SEC on March 9, 2017).
10.1	Registration Rights Agreement by and between Kadmon Holdings, Inc. and the lenders under the Third Amended and Restated Convertible Credit Agreement (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016).
10.2	Second Waiver and Consent Agreement to Credit Agreement, dated as of June 8, 2016, by and among Kadmon Pharmaceuticals, the guarantors party thereto, the lenders from time to time party thereto and Perceptive Credit Opportunities Fund, L.P. (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.3	Third Waiver Agreement to Credit Agreement, dated September 29, 2016, by and among Kadmon Pharmaceuticals, LLC, the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings, L.P (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on November 9, 2016).
10.4	Amendment # 2 to Credit Agreement, dated November 4, 2016, by and among Kadmon Pharmaceuticals, LLC, the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings, L.P. (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on November 9, 2016).
10.5	Amendment No. 2 to Third A&R Credit Agreement dated June 8, 2016, between Kadmon Pharmaceuticals, LLC, the guarantors from time to time party thereto, the lenders from time to time party thereto and Macquarie US Trading LLC (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.6	Supply and Distribution Agreement, dated February 23, 2016, by and among Kadmon Pharmaceuticals, LLC and Camber Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.7	Amendment to Supply and Distribution Agreement, dated May 20, 2016, by and among Kadmon Pharmaceuticals, LLC and Camber Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.8*	Second Amendment to Supply and Distribution Agreement, dated August 23, 2016, by and among Kadmon Pharmaceuticals, LLC and Camber Pharmaceuticals, Inc.
10.9	Separation Agreement, dated February 3, 2016, by and between Kadmon Holdings, LLC and Samuel D. Waksal, Ph.D. (incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.10*	Kadmon Holdings, Inc. 2016 Equity Incentive Plan.
10.11*	Kadmon Holdings, Inc. 2016 Employee Stock Purchase Plan.
10.12	Exchange Agreement dated June 8, 2016 by and among Kadmon Holdings, LLC, Kadmon Pharmaceuticals, LLC and the lenders under the Third Amended and Restated Convertible Credit Agreement (incorporated herein by reference to Exhibit 10.49 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).

10.13	Registration Rights Agreement dated July 7, 2016 by and among Kadmon Holdings, LLC and Kadmon I, LLC on behalf of itself and each other member of Kadmon Holdings, LLC (incorporated herein by reference to Exhibit 10.51 to the Registrant's Registration Statement on S-1/A (File No. 333-211949), filed with the SEC on July 14, 2016).
10.14	Registration Rights Agreement dated June 8, 2016 by and among Kadmon Holdings, LLC and the lenders under the Third Amended and Restated Convertible Credit Agreement (incorporated herein by reference to Exhibit 10.52 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016).
10.15	Letter Agreement dated June 10, 2016 by and between Kadmon Holdings, LLC and 72 KDMN Investment, LLC (incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on S-1/A (File No. 333-211949), filed with the SEC on July 7, 2016).
10.16	Form of Indemnification to be entered into by Kadmon Holdings, Inc. and each of its directors, executive officers and certain key employees (incorporated herein by reference to Exhibit 10.55 to the Registrant's Registration Statement on S-1/A (File No. 333-211949), filed with the SEC on July 14, 2016).
10.17*	Third Amendment to Supply and Distribution Agreement, dated February 13, 2017, by and among Kadmon Pharmaceuticals, LLC and Camber Pharmaceuticals, Inc.
10.18	Securities Purchase Agreement, dated March 8, 2017, by and among Kadmon Holdings, Inc. and the investors referenced therein (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K Amendment No. 2 (File No. 001-37841), filed with the SEC on March 9, 2017).
10.19	Registration Rights Agreement, dated March 8, 2017, by and among Kadmon Holdings, Inc. and the investors referenced therein (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K Amendment No. 2 (File No. 001-37841), filed with the SEC on March 9, 2017).
10.20*	Fourth Waiver Agreement to Credit Agreement, dated March 22, 2017, by and among Kadmon Pharmaceuticals, LLC, the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings, L.P.
21.1*	List of subsidiaries.
23.1*	Consent of independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of The Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of The Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Kadmon Holdings, Inc. Form 10-K for the year ended December 31, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2016 and 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014, (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014, and (v) Notes to the Financial Statements.
*	Filed herewith.
**	Furnished herewith.

Exhibit 10.10

KADMON HOLDINGS, INC.

2016 EQUITY INCENTIVE PLAN

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KADMON HOLDINGS, INC.
2016 Equity Incentive Plan

1. ESTABLISHMENT, PURPOSE AND TERM OF PLAN.

1.1 **Establishment.** The Kadmon Holdings, Inc. 2016 Equity Incentive Plan (the *"**Plan**"*) is hereby established effective as of , 2016, the date of its approval by the stockholders of the Company (the *"**Effective Date**"*).

1.2 **Purpose.** The purpose of the Plan is to advance the interests of the Participating Company Group and its stockholders by providing an incentive to attract, retain and reward persons performing services for the Participating Company Group and by motivating such persons to contribute to the growth and profitability of the Participating Company Group. The Plan seeks to achieve this purpose by providing for Awards in the form of Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Performance Shares, Performance Units, Cash-Based Awards and Other Stock-Based Awards.

1.3 **Term of Plan.** The Plan shall continue in effect until its termination by the Committee; provided, however, that all Awards shall be granted, if at all, within ten (10) years from the Effective Date.

2. DEFINITIONS AND CONSTRUCTION.

2.1 **Definitions.** Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) *"**Affiliate**"* means (i) a parent entity, other than a Parent Corporation, that directly, or indirectly through one or more intermediary entities, controls the Company or (ii) a subsidiary entity, other than a Subsidiary Corporation, that is controlled by the Company directly or indirectly through one or more intermediary entities. For this purpose, the terms "parent," "subsidiary," "control" and "controlled by" shall have the meanings assigned such terms for the purposes of registration of securities on Form S-8 under the Securities Act.

(b) *"**Award**"* means any Option, Stock Appreciation Right, Restricted Stock Purchase Right, Restricted Stock Bonus, Restricted Stock Unit, Performance Share, Performance Unit, Cash-Based Award or Other Stock-Based Award granted under the Plan.

(c) *"**Award Agreement**"* means a written or electronic agreement between the Company and a Participant setting forth the terms, conditions and restrictions applicable to an Award.

(d) *"**Board**"* means the Board of Directors of the Company.

(e) *"**Cash-Based Award**"* means an Award denominated in cash and granted pursuant to Section 11.

(f) "***Cashless Exercise***" means a Cashless Exercise as defined in Section 6.3(b)(i).

(g) "***Cause***" means, unless such term or an equivalent term is otherwise defined by the applicable Award Agreement or other written agreement between a Participant and a Participating Company applicable to an Award, any of the following: (i) the Participant's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Participating Company documents or records; (ii) the Participant's material failure to abide by a Participating Company's code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct); (iii) the Participant's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of a Participating Company (including, without limitation, the Participant's improper use or disclosure of a Participating Company's confidential or proprietary information); (iv) any intentional act by the Participant which has a material detrimental effect on a Participating Company's reputation or business; (v) the Participant's repeated failure to perform any reasonable assigned duties after written notice from a Participating Company of, and a reasonable opportunity to cure, such failure; (vi) any material breach by the Participant of any employment, service, non-disclosure, non-competition, non-solicitation or other similar agreement between the Participant and a Participating Company, which breach is not cured pursuant to the terms of such agreement; or (vii) the Participant's conviction (including any plea of guilty or *nolo contendere*) of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which impairs the Participant's ability to perform his or her duties with a Participating Company.

(h) "***Change in Control***" means, unless such term or an equivalent term is otherwise defined by the applicable Award Agreement or other written agreement between the Participant and a Participating Company applicable to an Award, the occurrence of any one or a combination of the following:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as such term is defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total Fair Market Value or total combined voting power of the Company's then-outstanding securities entitled to vote generally in the election of Directors; provided, however, that a Change in Control shall not be deemed to have occurred if such degree of beneficial ownership results from any of the following: (A) an acquisition by any person who on the Effective Date is the beneficial owner of more than fifty percent (50%) of such voting power, (B) any acquisition directly from the Company, including, without limitation, pursuant to or in connection with a public offering of securities, (C) any acquisition by the Company, (D) any acquisition by a trustee or other fiduciary under an employee benefit plan of a Participating Company or (E) any acquisition by an entity owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the voting securities of the Company; or

(ii) an Ownership Change Event or series of related Ownership Change Events (collectively, a "***Transaction***") in which the stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction direct or

indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities entitled to vote generally in the election of Directors or, in the case of an Ownership Change Event described in Section 2.1(ee)(iii), the entity to which the assets of the Company were transferred (the "***Transferee***"), as the case may be; or

(iii) a date specified by the Committee following approval by the stockholders of a plan of complete liquidation or dissolution of the Company;

provided, however, that a Change in Control shall be deemed not to include a transaction described in subsections (i) or (ii) of this Section 2.1(h) in which a majority of the members of the board of directors of the continuing, surviving or successor entity, or parent thereof, immediately after such transaction is comprised of Incumbent Directors.

For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Committee shall determine whether multiple events described in subsections (i), (ii) and (iii) of this Section 2.1(h) are related and to be treated in the aggregate as a single Change in Control and its determination shall be final, binding and conclusive.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended, and any applicable regulations and administrative guidelines promulgated thereunder.

(j) "***Committee***" means the Compensation Committee and such other committee or subcommittee of the Board, if any, duly appointed to administer the Plan and having such powers in each instance as shall be specified by the Board. If, at any time, there is no committee of the Board then authorized or properly constituted to administer the Plan, the Board shall exercise all of the powers of the Committee granted herein, and, in any event, the Board may in its discretion exercise any or all of such powers.

(k) "***Company***" means Kadmon Holdings, Inc., a Delaware corporation, and any successor corporation thereto.

(l) "***Consultant***" means a person engaged to provide consulting or advisory services (other than as an Employee or a Director) to a Participating Company, provided that the identity of such person, the nature of such services or the entity to which such services are provided would not preclude the Company from offering or selling securities to such person pursuant to the Plan in reliance on registration on Form S-8 under the Securities Act.

(m) "***Covered Employee***" means, at any time the Plan is subject to Section 162(m), any Employee who is or may reasonably be expected to become a "covered employee" as defined in Section 162(m), or any successor statute, and who, with respect to a Performance Award, is designated, either as an individual Employee or a member of a class of Employees, by the Committee no later than the earlier of (i) the date that is ninety (90) days after the beginning of the Performance Period, or (ii) the date on which twenty-five percent (25%) of the Performance Period has elapsed, as a "Covered Employee" under this Plan for such applicable Performance Period.

(n) "***Director***" means a member of the Board.

(o) "***Disability***" means, unless such term or an equivalent term is otherwise defined by the applicable Award Agreement or other written agreement between the Participant and a Participating Company applicable to an Award, the permanent and total disability of the Participant, within the meaning of Section 22(e)(3) of the Code.

(p) "***Dividend Equivalent Right***" means the right of a Participant, granted at the discretion of the Committee or as otherwise provided by the Plan, to receive a credit for the account of such Participant in an amount equal to the cash dividends paid on one share of Stock for each share of Stock represented by an Award held by such Participant.

(q) "***Employee***" means any person treated as an employee (including an Officer or a Director who is also treated as an employee) in the records of a Participating Company and, with respect to any Incentive Stock Option granted to such person, who is an employee for purposes of Section 422 of the Code; provided, however, that neither service as a Director nor payment of a Director's fee shall be sufficient to constitute employment for purposes of the Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of an individual's rights, if any, under the terms of the Plan as of the time of the Company's determination of whether or not the individual is an Employee, all such determinations by the Company shall be final, binding and conclusive as to such rights, if any, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination as to such individual's status as an Employee.

(r) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(s) "***Fair Market Value***" means, as of any date, the value of a share of Stock or other property as determined by the Committee, in its discretion, or by the Company, in its discretion, if such determination is expressly allocated to the Company herein, subject to the following:

(i) Except as otherwise determined by the Committee, if, on such date, the Stock is listed or quoted on a national or regional securities exchange or quotation system, the Fair Market Value of a share of Stock shall be the closing price of a share of Stock as quoted on the national or regional securities exchange or quotation system constituting the primary market for the Stock, as reported in *The Wall Street Journal* or such other source as the Company deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or quotation system, the date on which the Fair Market Value shall be established shall be the last day on which the Stock was so traded or quoted prior to the relevant date, or such other appropriate day as shall be determined by the Committee, in its discretion.

(ii) Notwithstanding the foregoing, the Committee may, in its discretion, determine the Fair Market Value of a share of Stock on the basis of the opening,

closing, or average of the high and low sale prices of a share of Stock on such date or the preceding trading day, the actual sale price of a share of Stock received by a Participant, any other reasonable basis using actual transactions in the Stock as reported on a national or regional securities exchange or quotation system, or on any other basis consistent with the requirements of Section 409A. The Committee may also determine the Fair Market Value upon the average selling price of the Stock during a specified period that is within thirty (30) days before or thirty (30) days after such date, provided that, with respect to the grant of an Option or SAR, the commitment to grant such Award based on such valuation method must be irrevocable before the beginning of the specified period. The Committee may vary its method of determination of the Fair Market Value as provided in this Section for different purposes under the Plan to the extent consistent with the requirements of Section 409A.

(iii) If, on such date, the Stock is not listed or quoted on a national or regional securities exchange or quotation system, the Fair Market Value of a share of Stock shall be as determined by the Committee in good faith without regard to any restriction other than a restriction which, by its terms, will never lapse, and in a manner consistent with the requirements of Section 409A.

(t) "***Full Value Award***" means any Award settled in Stock, other than (i) an Option, (ii) a Stock Appreciation Right, or (iii) a Restricted Stock Purchase Right or an Other Stock-Based Award under which the Company will receive monetary consideration equal to the Fair Market Value (determined on the effective date of grant) of the shares subject to such Award.

(u) "***Incentive Stock Option***" means an Option intended to be (as set forth in the Award Agreement) and which qualifies as an incentive stock option within the meaning of Section 422(b) of the Code.

(v) "***Incumbent Director***" means a director who either (i) is a member of the Board as of the Effective Date or (ii) is elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but excluding a director who was elected or nominated in connection with an actual or threatened proxy contest relating to the election of directors of the Company).

(w) "***Insider***" means an Officer, a Director or other person whose transactions in Stock are subject to Section 16 of the Exchange Act.

(x) "***Net Exercise***" means a Net Exercise as defined in Section 6.3(b)(iii).

(y) "***Nonemployee Director***" means a Director who is not an Employee.

(z) "***Nonemployee Director Award***" means any Award granted to a Nonemployee Director.

(aa) "***Nonstatutory Stock Option***" means an Option not intended to be (as set forth in the Award Agreement) or which does not qualify as an incentive stock option within the meaning of Section 422(b) of the Code.

(bb) "***Officer***" means any person designated by the Board as an officer of the Company.

(cc) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option granted pursuant to the Plan.

(dd) "***Other Stock-Based Award***" means an Award denominated in shares of Stock and granted pursuant to Section 11.

(ee) "***Ownership Change Event***" means the occurrence of any of the following with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of securities of the Company representing more than fifty percent (50%) of the total combined voting power of the Company's then outstanding securities entitled to vote generally in the election of Directors; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company (other than a sale, exchange or transfer to one or more subsidiaries of the Company).

(ff) "***Parent Corporation***" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(gg) "***Participant***" means any eligible person who has been granted one or more Awards.

(hh) "***Participating Company***" means the Company or any Parent Corporation, Subsidiary Corporation or Affiliate.

(ii) "***Participating Company Group***" means, at any point in time, the Company and all other entities collectively which are then Participating Companies.

(jj) "***Performance Award***" means an Award of Performance Shares or Performance Units.

(kk) "***Performance Award Formula***" means, for any Performance Award, a formula or table established by the Committee pursuant to Section 10.3 which provides the basis for computing the value of a Performance Award at one or more levels of attainment of the applicable Performance Goal(s) measured as of the end of the applicable Performance Period.

(ll) "***Performance-Based Compensation***" means compensation under an Award that satisfies the requirements of Section 162(m) for certain performance-based compensation paid to Covered Employees.

(mm) "***Performance Goal***" means a performance goal established by the Committee pursuant to Section 10.3.

(nn) "***Performance Period***" means a period established by the Committee pursuant to Section 10.3 at the end of which one or more Performance Goals are to be measured.

(oo) "***Performance Share***" means a right granted to a Participant pursuant to Section 10 to receive a payment equal to the value of a Performance Share, as determined by the Committee, based upon attainment of applicable Performance Goal(s).

(pp) "***Performance Unit***" means a right granted to a Participant pursuant to Section 10 to receive a payment equal to the value of a Performance Unit, as determined by the Committee, based upon attainment of applicable Performance Goal(s).

(qq) "***Predecessor Plan***" means the Kadmon Holdings, LLC 2011 Equity Incentive Plan, and the Kadmon Holdings, LLC 2014 Long-Term Incentive Plan.

(rr) "***Restricted Stock Award***" means an Award of a Restricted Stock Bonus or a Restricted Stock Purchase Right.

(ss) "***Restricted Stock Bonus***" means Stock granted to a Participant pursuant to Section 8.

(tt) "***Restricted Stock Purchase Right***" means a right to purchase Stock granted to a Participant pursuant to Section 8.

(uu) "***Restricted Stock Unit***" means a right granted to a Participant pursuant to Section 9 to receive on a future date or occurrence of a future event a share of Stock or cash in lieu thereof, as determined by the Committee.

(vv) "***Rule 16b-3***" means Rule 16b-3 under the Exchange Act, as amended from time to time, or any successor rule or regulation.

(ww) "***SAR***" or "***Stock Appreciation Right***" means a right granted to a Participant pursuant to Section 7 to receive payment, for each share of Stock subject to such Award, of an amount equal to the excess, if any, of the Fair Market Value of a share of Stock on the date of exercise of the Award over the exercise price thereof.

(xx) "***Section 162(m)***" means Section 162(m) of the Code.

(yy) "***Section 409A***" means Section 409A of the Code.

(zz) "***Section 409A Deferred Compensation***" means compensation provided pursuant to an Award that constitutes nonqualified deferred compensation within the meaning of Section 409A.

(aaa) "***Securities Act***" means the Securities Act of 1933, as amended.

(bbb) "***Service***" means a Participant's employment or service with the Participating Company Group, whether as an Employee, a Director or a Consultant. Unless otherwise provided by the Committee, a Participant's Service shall not be deemed to have terminated merely because of a change in the capacity in which the Participant renders Service or a change in the Participating Company for which the Participant renders Service, provided that there is no interruption or termination of the Participant's Service. Furthermore, a Participant's

Service shall not be deemed to have been interrupted or terminated if the Participant takes any military leave, sick leave, or other bona fide leave of absence approved by the Company. However, unless otherwise provided by the Committee, if any such leave taken by a Participant exceeds ninety (90) days, then on the ninety-first (91st) day following the commencement of such leave the Participant's Service shall be deemed to have terminated, unless the Participant's right to return to Service is guaranteed by statute or contract. Notwithstanding the foregoing, unless otherwise designated by the Company or required by law, an unpaid leave of absence shall not be treated as Service for purposes of determining vesting under the Participant's Award Agreement. A Participant's Service shall be deemed to have terminated either upon an actual termination of Service or upon the business entity for which the Participant performs Service ceasing to be a Participating Company. Subject to the foregoing, the Company, in its discretion, shall determine whether the Participant's Service has terminated and the effective date of and reason for such termination.

(ccc) "***Stock***" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.5.

(ddd) "***Stock Tender Exercise***" means a Stock Tender Exercise as defined in Section 6.3(b)(ii).

(eee) "***Subsidiary Corporation***" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

(fff) "***Ten Percent Owner***" means a Participant who, at the time an Option is granted to the Participant, owns stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of a Participating Company (other than an Affiliate) within the meaning of Section 422(b)(6) of the Code.

(ggg) "***Trading Compliance Policy***" means the written policy of the Company pertaining to the purchase, sale, transfer or other disposition of the Company's equity securities by Directors, Officers, Employees or other service providers who may possess material, nonpublic information regarding the Company or its securities.

(hhh) "***Vesting Conditions***" mean those conditions established in accordance with the Plan prior to the satisfaction of which an Award or shares subject to an Award remain subject to forfeiture or a repurchase option in favor of the Company exercisable for the Participant's monetary purchase price, if any, for such shares upon the Participant's termination of Service or failure of a performance condition to be satisfied.

2.2 **Construction.** Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

3. ADMINISTRATION.

3.1 **Administration by the Committee.** The Plan shall be administered by the Committee. All questions of interpretation of the Plan, of any Award Agreement or of any other form of agreement or other document employed by the Company in the administration of the Plan or of any Award shall be determined by the Committee, and such determinations shall be final, binding and conclusive upon all persons having an interest in the Plan or such Award, unless fraudulent or made in bad faith. Any and all actions, decisions and determinations taken or made by the Committee in the exercise of its discretion pursuant to the Plan or Award Agreement or other agreement thereunder (other than determining questions of interpretation pursuant to the preceding sentence) shall be final, binding and conclusive upon all persons having an interest therein. All expenses incurred in connection with the administration of the Plan shall be paid by the Company.

3.2 **Authority of Officers.** Any Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election that is the responsibility of or that is allocated to the Company herein, provided that the Officer has apparent authority with respect to such matter, right, obligation, determination or election. To the extent permitted by applicable law, the Committee may, in its discretion, delegate to a committee comprised of one or more Officers the authority to grant one or more Awards, without further approval of the Committee, to any Employee, other than a person who, at the time of such grant, is an Insider or a Covered Employee, and to exercise such other powers under the Plan as the Committee may determine; provided, however, that (a) the Committee shall fix the maximum number of shares subject to Awards that may be granted by such Officers, (b) each such Award shall be subject to the terms and conditions of the appropriate standard form of Award Agreement approved by the Board or the Committee and shall conform to the provisions of the Plan, and (c) each such Award shall conform to such other limits and guidelines as may be established from time to time by the Committee.

3.3 **Administration with Respect to Insiders.** With respect to participation by Insiders in the Plan, at any time that any class of equity security of the Company is registered pursuant to Section 12 of the Exchange Act, the Plan shall be administered in compliance with the requirements, if any, of Rule 16b-3.

3.4 **Committee Complying with Section 162(m).** If the Company is a "publicly held corporation" within the meaning of Section 162(m), the Board may establish a Committee of "outside directors" within the meaning of Section 162(m) to approve the grant of any Award intended to result in the payment of Performance-Based Compensation.

3.5 **Powers of the Committee.** In addition to any other powers set forth in the Plan and subject to the provisions of the Plan, the Committee shall have the full and final power and authority, in its discretion:

(a) to determine the persons to whom, and the time or times at which, Awards shall be granted and the number of shares of Stock, units or monetary value to be subject to each Award;

(b) to determine the type of Award granted;

(c) to determine whether an Award granted to a Covered Employee shall be intended to result in Performance-Based Compensation;

(d) to determine the Fair Market Value of shares of Stock or other property;

(e) to determine the terms, conditions and restrictions applicable to each Award (which need not be identical) and any shares acquired pursuant thereto, including, without limitation, (i) the exercise or purchase price of shares pursuant to any Award, (ii) the method of payment for shares purchased pursuant to any Award, (iii) the method for satisfaction of any tax withholding obligation arising in connection with any Award, including by the withholding or delivery of shares of Stock, (iv) the timing, terms and conditions of the exercisability or vesting of any Award or any shares acquired pursuant thereto, (v) the Performance Measures, Performance Period, Performance Award Formula and Performance Goals applicable to any Award and the extent to which such Performance Goals have been attained, (vi) the time of expiration of any Award, (vii) the effect of any Participant's termination of Service on any of the foregoing, and (viii) all other terms, conditions and restrictions applicable to any Award or shares acquired pursuant thereto not inconsistent with the terms of the Plan;

(f) to determine whether an Award will be settled in shares of Stock, cash, other property or in any combination thereof;

(g) to approve one or more forms of Award Agreement;

(h) to amend, modify, extend, cancel or renew any Award or to waive any restrictions or conditions applicable to any Award or any shares acquired pursuant thereto;

(i) to accelerate, continue, extend or defer the exercisability or vesting of any Award or any shares acquired pursuant thereto, including with respect to the period following a Participant's termination of Service;

(j) to prescribe, amend or rescind rules, guidelines and policies relating to the Plan, or to adopt sub-plans or supplements to, or alternative versions of, the Plan, including, without limitation, as the Committee deems necessary or desirable to comply with the laws of, or to accommodate the tax policy, accounting principles or custom of, foreign jurisdictions whose residents may be granted Awards; and

(k) to correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award Agreement and to make all other determinations and take such other actions with respect to the Plan or any Award as the Committee may deem advisable to the extent not inconsistent with the provisions of the Plan or applicable law.

3.6 **Option or SAR Repricing.** Without the affirmative vote of holders of a majority of the shares of Stock cast in person or by proxy at a meeting of the stockholders of the Company at which a quorum representing a majority of all outstanding shares of Stock is present

or represented by proxy, the Committee shall not approve a program providing for either (a) the cancellation of outstanding Options or SARs having exercise prices per share greater than the then Fair Market Value of a share of Stock ("***Underwater Awards***") and the grant in substitution therefore of new Options or SARs having a lower exercise price, Full Value Awards or payments in cash, or (b) the amendment of outstanding Underwater Awards to reduce the exercise price thereof. This Section shall not be construed to apply to (i) "issuing or assuming a stock option in a transaction to which Section 424(a) applies," within the meaning of Section 424 of the Code, (ii) adjustments pursuant to the assumption of or substitution for an Option or SAR in a manner that would comply with Section 409A, or (iii) an adjustment pursuant to Section 4.5.

3.7 **Indemnification.** In addition to such other rights of indemnification as they may have as members of the Board or the Committee or as officers or employees of the Participating Company Group, to the extent permitted by applicable law, members of the Board or the Committee and any officers or employees of the Participating Company Group to whom authority to act for the Board, the Committee or the Company is delegated shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

4. SHARES SUBJECT TO PLAN.

4.1 **Maximum Number of Shares Issuable.** Subject to adjustment as provided in Sections 4.2, 4.3, 4.4 and 4.5, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be equal to **Six Million Seven Hundred Twenty Thousand (6,720,000)** shares and shall consist of authorized but unissued or reacquired shares of Stock or any combination thereof.

4.2 **Annual Increase in Maximum Number of Shares Issuable**. Subject to adjustment as provided in Section 4.5, the maximum aggregate number of shares of Stock that may be issued under the Plan as set forth in Section 4.1 shall be cumulatively increased on January 1, 2016 and on each subsequent January 1 through and including January 1, 2025, by a number of shares (the "***Annual Increase***") equal to the smaller of (a) 4% of the number of shares of Stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board.

4.3 **Adjustment for Unissued or Forfeited Predecessor Plan Shares.** The maximum aggregate number of shares of Stock that may be issued under the Plan as set forth in Section 4.1 shall be cumulatively increased from time to time by:

(a) the aggregate number of shares of Stock that remain available for the future grant of awards under the Predecessor Plan immediately prior to its termination as of the Effective Date;

(b) the number of shares of Stock subject to that portion of any option or other award outstanding pursuant to the Predecessor Plan as of the Effective Date which, on or after the Effective Date, expires or is terminated or canceled for any reason without having been exercised or settled in full; and

(c) the number of shares of Stock acquired pursuant to the Predecessor Plan subject to forfeiture or repurchase by the Company for an amount not greater than the Participant's purchase price which, on or after the Effective Date, is so forfeited or repurchased;

provided, however, that the aggregate number of shares of Stock authorized for issuance under the Predecessor Plan that may become authorized for issuance under the Plan pursuant to this Section 4.3 shall not exceed 3,198,416 shares.

4.4 **Share Counting**. If an outstanding Award for any reason expires or is terminated or canceled without having been exercised or settled in full, or if shares of Stock acquired pursuant to an Award subject to forfeiture or repurchase are forfeited or repurchased by the Company for an amount not greater than the Participant's purchase price, the shares of Stock allocable to the terminated portion of such Award or such forfeited or repurchased shares of Stock shall again be available for issuance under the Plan. Shares of Stock shall not be deemed to have been issued pursuant to the Plan with respect to any portion of an Award that is settled in cash. Upon payment in shares of Stock pursuant to the exercise of an SAR, the number of shares available for issuance under the Plan shall be reduced by the gross number of shares for which the SAR is exercised. If the exercise price of an Option is paid by tender to the Company, or attestation to the ownership, of shares of Stock owned by the Participant, or by means of a Net Exercise, the number of shares available for issuance under the Plan shall be reduced by the gross number of shares for which the Option is exercised. Shares withheld or reacquired by the Company in satisfaction of tax withholding obligations pursuant to the exercise or settlement of Options or SARs pursuant to Section 16.2 shall not again be available for issuance under the Plan. Shares withheld or reacquired by the Company in satisfaction of tax withholding obligations pursuant to the vesting or settlement of Full Value Awards pursuant to Section 16.2 shall again become available for issuance under the Plan.

4.5 **Adjustments for Changes in Capital Structure.** Subject to any required action by the stockholders of the Company and the requirements of Sections 409A and 424 of the Code to the extent applicable, in the event of any change in the Stock effected without receipt of consideration by the Company, whether through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split, split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure of the Company, or in the event of payment of a dividend or distribution to the

stockholders of the Company in a form other than Stock (excepting regular, periodic cash dividends) that has a material effect on the Fair Market Value of shares of Stock, appropriate and proportionate adjustments shall be made in the number and kind of shares subject to the Plan and to any outstanding Awards, the Annual Increase, the Award limits set forth in Section 5.3, and in the exercise or purchase price per share under any outstanding Award in order to prevent dilution or enlargement of Participants' rights under the Plan. For purposes of the foregoing, conversion of any convertible securities of the Company shall not be treated as "effected without receipt of consideration by the Company." If a majority of the shares which are of the same class as the shares that are subject to outstanding Awards are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event) shares of another corporation (the "***New Shares***"), the Committee may unilaterally amend the outstanding Awards to provide that such Awards are for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise or purchase price per share of, the outstanding Awards shall be adjusted in a fair and equitable manner as determined by the Committee, in its discretion. Any fractional share resulting from an adjustment pursuant to this Section shall be rounded down to the nearest whole number and the exercise or purchase price per share shall be rounded up to the nearest whole cent. In no event may the exercise or purchase price, if any, under any Award be decreased to an amount less than the par value, if any, of the stock subject to such Award. The Committee in its discretion, may also make such adjustments in the terms of any Award to reflect, or related to, such changes in the capital structure of the Company or distributions as it deems appropriate, including modification of Performance Goals, Performance Award Formulas and Performance Periods. The adjustments determined by the Committee pursuant to this Section shall be final, binding and conclusive.

4.6 **Assumption or Substitution of Awards.** The Committee may, without affecting the number of shares of Stock reserved or available hereunder, authorize the issuance or assumption of benefits under this Plan in connection with any merger, consolidation, acquisition of property or stock, or reorganization upon such terms and conditions as it may deem appropriate, subject to compliance with Section 409A and any other applicable provisions of the Code.

5. ELIGIBILITY, PARTICIPATION AND AWARD LIMITATIONS.

5.1 **Persons Eligible for Awards.** Awards may be granted only to Employees, Consultants and Directors.

5.2 **Participation in the Plan.** Awards are granted solely at the discretion of the Committee. Eligible persons may be granted more than one Award. However, eligibility in accordance with this Section shall not entitle any person to be granted an Award, or, having been granted an Award, to be granted an additional Award.

5.3 **Incentive Stock Option Limitations**.

(a) ***Maximum Number of Shares Issuable Pursuant to Incentive Stock Options.*** Subject to adjustment as provided in Section 4.5, the maximum aggregate number of shares of Stock that may be issued under the Plan pursuant to the exercise of Incentive Stock Options shall not exceed **One Million Eight Thousand**

(1,008,000) shares, cumulatively increased on January 1, 2016 and on each subsequent January 1, through and including January 1, 2025, by a number of shares equal to the smaller of the Annual Increase determined under Section 4.2 or **Six Hundred Thousand (600,000)** shares. The maximum aggregate number of shares of Stock that may be issued under the Plan pursuant to all Awards other than Incentive Stock Options shall be the number of shares determined in accordance with Section 4.1, subject to adjustment as provided in Sections 4.2, 4.3, 4.4 and 4.5.

(b) ***Persons Eligible.*** An Incentive Stock Option may be granted only to a person who, on the effective date of grant, is an Employee of the Company, a Parent Corporation or a Subsidiary Corporation (each being an *"**ISO-Qualifying Corporation**"*). Any person who is not an Employee of an ISO-Qualifying Corporation on the effective date of the grant of an Option to such person may be granted only a Nonstatutory Stock Option.

(c) ***Fair Market Value Limitation.*** To the extent that options designated as Incentive Stock Options (granted under all stock plans of the Participating Company Group, including the Plan) become exercisable by a Participant for the first time during any calendar year for stock having a Fair Market Value greater than One Hundred Thousand Dollars ($100,000), the portion of such options which exceeds such amount shall be treated as Nonstatutory Stock Options. For purposes of this Section, options designated as Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of stock shall be determined as of the time the option with respect to such stock is granted. If the Code is amended to provide for a limitation different from that set forth in this Section, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Options as required or permitted by such amendment to the Code. If an Option is treated as an Incentive Stock Option in part and as a Nonstatutory Stock Option in part by reason of the limitation set forth in this Section, the Participant may designate which portion of such Option the Participant is exercising. In the absence of such designation, the Participant shall be deemed to have exercised the Incentive Stock Option portion of the Option first. Upon exercise of the Option, shares issued pursuant to each such portion shall be separately identified.

5.4 **Nonemployee Director Award Limit.** No Nonemployee Director shall be granted within any fiscal year of the Company one or more Nonemployee Director Awards pursuant to the Plan which in the aggregate are for more than a number of shares of Stock determined by dividing **three hundred thousand dollars U.S. ($300,000)** by the Fair Market Value of a share of Stock determined on the last trading day immediately preceding the date on which the applicable Nonemployee Director Award is granted.

6. STOCK OPTIONS.

Options shall be evidenced by Award Agreements specifying the number of shares of Stock covered thereby, in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

6.1 **Exercise Price.** The exercise price for each Option shall be established in the discretion of the Committee; provided, however, that (a) the exercise price per share shall be not less than the Fair Market Value of a share of Stock on the effective date of grant of the Option

and (b) no Incentive Stock Option granted to a Ten Percent Owner shall have an exercise price per share less than one hundred ten percent (110%) of the Fair Market Value of a share of Stock on the effective date of grant of the Option. Notwithstanding the foregoing, an Option (whether an Incentive Stock Option or a Nonstatutory Stock Option) may be granted with an exercise price less than the minimum exercise price set forth above if such Option is granted pursuant to an assumption or substitution for another option in a manner that would qualify under the provisions of Section 409A or Section 424(a) of the Code.

6.2 **Exercisability and Term of Options.** Options shall be exercisable at such time or times, or upon such event or events, and subject to such terms, conditions, performance criteria and restrictions as shall be determined by the Committee and set forth in the Award Agreement evidencing such Option; provided, however, that (a) no Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Option, (b) no Incentive Stock Option granted to a Ten Percent Owner shall be exercisable after the expiration of five (5) years after the effective date of grant of such Option and (c) no Option granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, shall be first exercisable until at least six (6) months following the date of grant of such Option (except in the event of such Employee's death, disability or retirement, upon a Change in Control, or as otherwise permitted by the Worker Economic Opportunity Act). Subject to the foregoing, unless otherwise specified by the Committee in the grant of an Option, each Option shall terminate ten (10) years after the effective date of grant of the Option, unless earlier terminated in accordance with its provisions.

6.3 **Payment of Exercise Price**.

(a) ***Forms of Consideration Authorized.*** Except as otherwise provided below, payment of the exercise price for the number of shares of Stock being purchased pursuant to any Option shall be made (i) in cash, by check or in cash equivalent; (ii) if permitted by the Committee and subject to the limitations contained in Section 6.3(b), by means of (1) a Cashless Exercise, (2) a Stock Tender Exercise or (3) a Net Exercise; (iii) by such other consideration as may be approved by the Committee from time to time to the extent permitted by applicable law, or (iv) by any combination thereof. The Committee may at any time or from time to time grant Options which do not permit all of the foregoing forms of consideration to be used in payment of the exercise price or which otherwise restrict one or more forms of consideration.

(b) ***Limitations on Forms of Consideration***.

(i) **Cashless Exercise.** A "***Cashless Exercise***" means the delivery of a properly executed notice of exercise together with irrevocable instructions to a broker providing for the assignment to the Company of the proceeds of a sale or loan with respect to some or all of the shares being acquired upon the exercise of the Option (including, without limitation, through an exercise complying with the provisions of Regulation T as promulgated from time to time by the Board of Governors of the Federal Reserve System). The Company reserves, at any and all times, the right, in the Company's sole and absolute discretion, to establish, decline to approve or terminate any program or procedures for the exercise of Options by means of a Cashless Exercise, including with respect to one or more Participants

specified by the Company notwithstanding that such program or procedures may be available to other Participants.

(ii) **Stock Tender Exercise.** A *"**Stock Tender Exercise**"* means the delivery of a properly executed exercise notice accompanied by a Participant's tender to the Company, or attestation to the ownership, in a form acceptable to the Company of whole shares of Stock owned by the Participant having a Fair Market Value that does not exceed the aggregate exercise price for the shares with respect to which the Option is exercised. A Stock Tender Exercise shall not be permitted if it would constitute a violation of the provisions of any law, regulation or agreement restricting the redemption of the Company's stock. If required by the Company, an Option may not be exercised by tender to the Company, or attestation to the ownership, of shares of Stock unless such shares either have been owned by the Participant for a period of time required by the Company (and not used for another option exercise by attestation during such period) or were not acquired, directly or indirectly, from the Company.

(iii) **Net Exercise.** A *"**Net Exercise**"* means the delivery of a properly executed exercise notice followed by a procedure pursuant to which (1) the Company will reduce the number of shares otherwise issuable to a Participant upon the exercise of an Option by the largest whole number of shares having a Fair Market Value that does not exceed the aggregate exercise price for the shares with respect to which the Option is exercised, and (2) the Participant shall pay to the Company in cash the remaining balance of such aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued.

6.4 **Effect of Termination of Service**.

(a) ***Option Exercisability.*** Subject to earlier termination of the Option as otherwise provided by this Plan and unless otherwise provided by the Committee, an Option shall terminate immediately upon the Participant's termination of Service to the extent that it is then unvested and shall be exercisable after the Participant's termination of Service to the extent it is then vested only during the applicable time period determined in accordance with this Section and thereafter shall terminate.

(i) **Disability.** If the Participant's Service terminates because of the Disability of the Participant, the Option, to the extent unexercised and exercisable for vested shares on the date on which the Participant's Service terminated, may be exercised by the Participant (or the Participant's guardian or legal representative) at any time prior to the expiration of twelve (12) months (or such longer or shorter period provided by the Award Agreement) after the date on which the Participant's Service terminated, but in any event no later than the date of expiration of the Option's term as set forth in the Award Agreement evidencing such Option (the *"**Option Expiration Date**"*).

(ii) **Death.** If the Participant's Service terminates because of the death of the Participant, the Option, to the extent unexercised and exercisable for vested shares on the date on which the Participant's Service terminated, may be exercised by the Participant's legal representative or other person who acquired the right to exercise the Option by reason of the Participant's death at any time prior to the expiration of twelve (12) months (or such longer or shorter period provided by the Award Agreement) after the date on which the

Participant's Service terminated, but in any event no later than the Option Expiration Date. The Participant's Service shall be deemed to have terminated on account of death if the Participant dies within three (3) months (or such longer or shorter period provided by the Award Agreement) after the Participant's termination of Service.

(iii) **Termination for Cause.** Notwithstanding any other provision of the Plan to the contrary, if the Participant's Service is terminated for Cause or if, following the Participant's termination of Service and during any period in which the Option otherwise would remain exercisable, the Participant engages in any act that would constitute Cause, the Option shall terminate in its entirety and cease to be exercisable immediately upon such termination of Service or act.

(iv) **Other Termination of Service.** If the Participant's Service terminates for any reason, except Disability, death or Cause, the Option, to the extent unexercised and exercisable for vested shares on the date on which the Participant's Service terminated, may be exercised by the Participant at any time prior to the expiration of three (3) months (or such longer or shorter period provided by the Award Agreement) after the date on which the Participant's Service terminated, but in any event no later than the Option Expiration Date.

(b) ***Extension if Exercise Prevented by Law.*** Notwithstanding the foregoing, other than termination of Service for Cause, if the exercise of an Option within the applicable time periods set forth in Section 6.4(a) is prevented by the provisions of Section 14 below, the Option shall remain exercisable until the later of (i) thirty (30) days after the date such exercise first would no longer be prevented by such provisions or (ii) the end of the applicable time period under Section 6.4(a), but in any event no later than the Option Expiration Date.

6.5 **Transferability of Options.** During the lifetime of the Participant, an Option shall be exercisable only by the Participant or the Participant's guardian or legal representative. An Option shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. Notwithstanding the foregoing, to the extent permitted by the Committee, in its discretion, and set forth in the Award Agreement evidencing such Option, an Option shall be assignable or transferable subject to the applicable limitations, if any, described in the General Instructions to Form S-8 under the Securities Act or, in the case of an Incentive Stock Option, only as permitted by applicable regulations under Section 421 of the Code in a manner that does not disqualify such Option as an Incentive Stock Option.

7. STOCK APPRECIATION RIGHTS.

Stock Appreciation Rights shall be evidenced by Award Agreements specifying the number of shares of Stock subject to the Award, in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

7.1 **Types of SARs Authorized.** SARs may be granted in tandem with all or any portion of a related Option (a "***Tandem SAR***") or may be granted independently of any Option (a "***Freestanding SAR***"). A Tandem SAR may only be granted concurrently with the grant of the related Option.

7.2 **Exercise Price.** The exercise price for each SAR shall be established in the discretion of the Committee; provided, however, that (a) the exercise price per share subject to a Tandem SAR shall be the exercise price per share under the related Option and (b) the exercise price per share subject to a Freestanding SAR shall be not less than the Fair Market Value of a share of Stock on the effective date of grant of the SAR. Notwithstanding the foregoing, an SAR may be granted with an exercise price lower than the minimum exercise price set forth above if such SAR is granted pursuant to an assumption or substitution for another stock appreciation right in a manner that would qualify under the provisions of Section 409A of the Code.

7.3 **Exercisability and Term of SARs**.

(a) ***Tandem SARs.*** Tandem SARs shall be exercisable only at the time and to the extent, and only to the extent, that the related Option is exercisable, subject to such provisions as the Committee may specify where the Tandem SAR is granted with respect to less than the full number of shares of Stock subject to the related Option. The Committee may, in its discretion, provide in any Award Agreement evidencing a Tandem SAR that such SAR may not be exercised without the advance approval of the Company and, if such approval is not given, then the Option shall nevertheless remain exercisable in accordance with its terms. A Tandem SAR shall terminate and cease to be exercisable no later than the date on which the related Option expires or is terminated or canceled. Upon the exercise of a Tandem SAR with respect to some or all of the shares subject to such SAR, the related Option shall be canceled automatically as to the number of shares with respect to which the Tandem SAR was exercised. Upon the exercise of an Option related to a Tandem SAR as to some or all of the shares subject to such Option, the related Tandem SAR shall be canceled automatically as to the number of shares with respect to which the related Option was exercised.

(b) ***Freestanding SARs.*** Freestanding SARs shall be exercisable at such time or times, or upon such event or events, and subject to such terms, conditions, performance criteria and restrictions as shall be determined by the Committee and set forth in the Award Agreement evidencing such SAR; provided, however, that (i) no Freestanding SAR shall be exercisable after the expiration of ten (10) years after the effective date of grant of such SAR and (ii) no Freestanding SAR granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, shall be first exercisable until at least six (6) months following the date of grant of such SAR (except in the event of such Employee's death, disability or retirement, upon a Change in Control, or as otherwise permitted by the Worker Economic Opportunity Act). Subject to the foregoing, unless otherwise specified by the Committee in the grant of a Freestanding SAR, each Freestanding SAR shall terminate ten (10) years after the effective date of grant of the SAR, unless earlier terminated in accordance with its provisions.

7.4 **Exercise of SARs.** Upon the exercise (or deemed exercise pursuant to Section 7.5) of an SAR, the Participant (or the Participant's legal representative or other person

who acquired the right to exercise the SAR by reason of the Participant's death) shall be entitled to receive payment of an amount for each share with respect to which the SAR is exercised equal to the excess, if any, of the Fair Market Value of a share of Stock on the date of exercise of the SAR over the exercise price. Payment of such amount shall be made (a) in the case of a Tandem SAR, solely in shares of Stock in a lump sum upon the date of exercise of the SAR and (b) in the case of a Freestanding SAR, in cash, shares of Stock, or any combination thereof as determined by the Committee, in a lump sum upon the date of exercise of the SAR. When payment is to be made in shares of Stock, the number of shares to be issued shall be determined on the basis of the Fair Market Value of a share of Stock on the date of exercise of the SAR. For purposes of Section 7, an SAR shall be deemed exercised on the date on which the Company receives notice of exercise from the Participant or as otherwise provided in Section 7.5.

7.5 **Deemed Exercise of SARs.** If, on the date on which an SAR would otherwise terminate or expire, the SAR by its terms remains exercisable immediately prior to such termination or expiration and, if so exercised, would result in a payment to the holder of such SAR, then any portion of such SAR which has not previously been exercised shall automatically be deemed to be exercised as of such date with respect to such portion.

7.6 **Effect of Termination of Service.** Subject to earlier termination of the SAR as otherwise provided herein and unless otherwise provided by the Committee, an SAR shall be exercisable after a Participant's termination of Service only to the extent and during the applicable time period determined in accordance with Section 6.4 (treating the SAR as if it were an Option) and thereafter shall terminate.

7.7 **Transferability of SARs.** During the lifetime of the Participant, an SAR shall be exercisable only by the Participant or the Participant's guardian or legal representative. An SAR shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. Notwithstanding the foregoing, to the extent permitted by the Committee, in its discretion, and set forth in the Award Agreement evidencing such Award, a Tandem SAR related to a Nonstatutory Stock Option or a Freestanding SAR shall be assignable or transferable subject to the applicable limitations, if any, described in the General Instructions to Form S-8 under the Securities Act.

8. RESTRICTED STOCK AWARDS.

Restricted Stock Awards shall be evidenced by Award Agreements specifying whether the Award is a Restricted Stock Bonus or a Restricted Stock Purchase Right and the number of shares of Stock subject to the Award, in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

8.1 **Types of Restricted Stock Awards Authorized.** Restricted Stock Awards may be granted in the form of either a Restricted Stock Bonus or a Restricted Stock Purchase Right. Restricted Stock Awards may be granted upon such conditions as the Committee shall determine, including, without limitation, upon the attainment of one or more Performance Goals

described in Section 10.4. If either the grant of or satisfaction of Vesting Conditions applicable to a Restricted Stock Award is to be contingent upon the attainment of one or more Performance Goals, the Committee shall follow procedures substantially equivalent to those set forth in Sections 10.3 through 10.5(a).

8.2 **Purchase Price.** The purchase price for shares of Stock issuable under each Restricted Stock Purchase Right shall be established by the Committee in its discretion. No monetary payment (other than applicable tax withholding) shall be required as a condition of receiving shares of Stock pursuant to a Restricted Stock Bonus, the consideration for which shall be services actually rendered to a Participating Company or for its benefit. Notwithstanding the foregoing, if required by applicable state corporate law, the Participant shall furnish consideration in the form of cash or past services rendered to a Participating Company or for its benefit having a value not less than the par value of the shares of Stock subject to a Restricted Stock Award.

8.3 **Purchase Period.** A Restricted Stock Purchase Right shall be exercisable within a period established by the Committee, which shall in no event exceed thirty (30) days from the effective date of the grant of the Restricted Stock Purchase Right.

8.4 **Payment of Purchase Price.** Except as otherwise provided below, payment of the purchase price for the number of shares of Stock being purchased pursuant to any Restricted Stock Purchase Right shall be made (a) in cash, by check or in cash equivalent, (b) by such other consideration as may be approved by the Committee from time to time to the extent permitted by applicable law, or (c) by any combination thereof.

8.5 **Vesting and Restrictions on Transfer.** Shares issued pursuant to any Restricted Stock Award may (but need not) be made subject to Vesting Conditions based upon the satisfaction of such Service requirements, conditions, restrictions or performance criteria, including, without limitation, Performance Goals as described in Section 10.4, as shall be established by the Committee and set forth in the Award Agreement evidencing such Award. During any period in which shares acquired pursuant to a Restricted Stock Award remain subject to Vesting Conditions, such shares may not be sold, exchanged, transferred, pledged, assigned or otherwise disposed of other than pursuant to an Ownership Change Event or as provided in Section 8.8. The Committee, in its discretion, may provide in any Award Agreement evidencing a Restricted Stock Award that, if the satisfaction of Vesting Conditions with respect to any shares subject to such Restricted Stock Award would otherwise occur on a day on which the sale of such shares would violate the provisions of the Trading Compliance Policy, then satisfaction of the Vesting Conditions automatically shall be determined on the next trading day on which the sale of such shares would not violate the Trading Compliance Policy. Upon request by the Company, each Participant shall execute any agreement evidencing such transfer restrictions prior to the receipt of shares of Stock hereunder and shall promptly present to the Company any and all certificates representing shares of Stock acquired hereunder for the placement on such certificates of appropriate legends evidencing any such transfer restrictions.

8.6 **Voting Rights; Dividends and Distributions.** Except as provided in this Section, Section 8.5 and any Award Agreement, during any period in which shares acquired pursuant to a Restricted Stock Award remain subject to Vesting Conditions, the Participant shall

have all of the rights of a stockholder of the Company holding shares of Stock, including the right to vote such shares and to receive all dividends and other distributions paid with respect to such shares; provided, however, that if so determined by the Committee and provided by the Award Agreement, such dividends and distributions shall be subject to the same Vesting Conditions as the shares subject to the Restricted Stock Award with respect to which such dividends or distributions were paid, and otherwise shall be paid no later than the end of the calendar year in which such dividends or distributions are paid to stockholders (or, if later, the 15th day of the third month following the date such dividends or distributions are paid to stockholders). In the event of a dividend or distribution paid in shares of Stock or other property or any other adjustment made upon a change in the capital structure of the Company as described in Section 4.5, any and all new, substituted or additional securities or other property (other than regular, periodic cash dividends) to which the Participant is entitled by reason of the Participant's Restricted Stock Award shall be immediately subject to the same Vesting Conditions as the shares subject to the Restricted Stock Award with respect to which such dividends or distributions were paid or adjustments were made.

8.7 **Effect of Termination of Service.** Unless otherwise provided by the Committee in the Award Agreement evidencing a Restricted Stock Award, if a Participant's Service terminates for any reason, whether voluntary or involuntary (including the Participant's death or disability), then (a) the Company shall have the option to repurchase for the purchase price paid by the Participant any shares acquired by the Participant pursuant to a Restricted Stock Purchase Right which remain subject to Vesting Conditions as of the date of the Participant's termination of Service and (b) the Participant shall forfeit to the Company any shares acquired by the Participant pursuant to a Restricted Stock Bonus which remain subject to Vesting Conditions as of the date of the Participant's termination of Service. The Company shall have the right to assign at any time any repurchase right it may have, whether or not such right is then exercisable, to one or more persons as may be selected by the Company.

8.8 **Nontransferability of Restricted Stock Award Rights.** Rights to acquire shares of Stock pursuant to a Restricted Stock Award shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or the laws of descent and distribution. All rights with respect to a Restricted Stock Award granted to a Participant hereunder shall be exercisable during his or her lifetime only by such Participant or the Participant's guardian or legal representative.

9. RESTRICTED STOCK UNITS.

Restricted Stock Unit Awards shall be evidenced by Award Agreements specifying the number of Restricted Stock Units subject to the Award, in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

9.1 **Grant of Restricted Stock Unit Awards.** Restricted Stock Unit Awards may be granted upon such conditions as the Committee shall determine, including, without limitation, upon the attainment of one or more Performance Goals described in Section 10.4. If either the

grant of a Restricted Stock Unit Award or the Vesting Conditions with respect to such Award is to be contingent upon the attainment of one or more Performance Goals, the Committee shall follow procedures substantially equivalent to those set forth in Sections 10.3 through 10.5(a).

9.2 **Purchase Price.** No monetary payment (other than applicable tax withholding, if any) shall be required as a condition of receiving a Restricted Stock Unit Award, the consideration for which shall be services actually rendered to a Participating Company or for its benefit. Notwithstanding the foregoing, if required by applicable state corporate law, the Participant shall furnish consideration in the form of cash or past services rendered to a Participating Company or for its benefit having a value not less than the par value of the shares of Stock issued upon settlement of the Restricted Stock Unit Award.

9.3 **Vesting.** Restricted Stock Unit Awards may (but need not) be made subject to Vesting Conditions based upon the satisfaction of such Service requirements, conditions, restrictions or performance criteria, including, without limitation, Performance Goals as described in Section 10.4, as shall be established by the Committee and set forth in the Award Agreement evidencing such Award. The Committee, in its discretion, may provide in any Award Agreement evidencing a Restricted Stock Unit Award that, if the satisfaction of Vesting Conditions with respect to any shares subject to the Award would otherwise occur on a day on which the sale of such shares would violate the provisions of the Trading Compliance Policy, then the satisfaction of the Vesting Conditions automatically shall be determined on the first to occur of (a) the next trading day on which the sale of such shares would not violate the Trading Compliance Policy or (b) the last day of the calendar year in which the original vesting date occurred.

9.4 **Voting Rights, Dividend Equivalent Rights and Distributions.** Participants shall have no voting rights with respect to shares of Stock represented by Restricted Stock Units until the date of the issuance of such shares (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). However, the Committee, in its discretion, may provide in the Award Agreement evidencing any Restricted Stock Unit Award that the Participant shall be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Stock during the period beginning on the date such Award is granted and ending, with respect to each share subject to the Award, on the earlier of the date the Award is settled or the date on which it is terminated. Dividend Equivalent Rights, if any, shall be paid by crediting the Participant with a cash amount or with additional whole Restricted Stock Units as of the date of payment of such cash dividends on Stock, as determined by the Committee. The number of additional Restricted Stock Units (rounded to the nearest whole number), if any, to be credited shall be determined by dividing (a) the amount of cash dividends paid on the dividend payment date with respect to the number of shares of Stock represented by the Restricted Stock Units previously credited to the Participant by (b) the Fair Market Value per share of Stock on such date. If so determined by the Committee and provided by the Award Agreement, such cash amount or additional Restricted Stock Units shall be subject to the same terms and conditions and shall be settled in the same manner and at the same time as the Restricted Stock Units originally subject to the Restricted Stock Unit Award. In the event of a dividend or distribution paid in shares of Stock or other property or any other adjustment made upon a change in the capital structure of the Company as described in Section 4.5, appropriate adjustments shall be made in the Participant's Restricted Stock Unit Award so that it represents

the right to receive upon settlement any and all new, substituted or additional securities or other property (other than regular, periodic cash dividends) to which the Participant would be entitled by reason of the shares of Stock issuable upon settlement of the Award, and all such new, substituted or additional securities or other property shall be immediately subject to the same Vesting Conditions as are applicable to the Award.

9.5 **Effect of Termination of Service.** Unless otherwise provided by the Committee and set forth in the Award Agreement evidencing a Restricted Stock Unit Award, if a Participant's Service terminates for any reason, whether voluntary or involuntary (including the Participant's death or disability), then the Participant shall forfeit to the Company any Restricted Stock Units pursuant to the Award which remain subject to Vesting Conditions as of the date of the Participant's termination of Service.

9.6 **Settlement of Restricted Stock Unit Awards.** The Company shall issue to a Participant on the date on which Restricted Stock Units subject to the Participant's Restricted Stock Unit Award vest or on such other date determined by the Committee in compliance with Section 409A, if applicable, and set forth in the Award Agreement one (1) share of Stock (and/or any other new, substituted or additional securities or other property pursuant to an adjustment described in Section 9.4) for each Restricted Stock Unit then becoming vested or otherwise to be settled on such date, subject to the withholding of applicable taxes, if any. If permitted by the Committee, the Participant may elect, consistent with the requirements of Section 409A, to defer receipt of all or any portion of the shares of Stock or other property otherwise issuable to the Participant pursuant to this Section, and such deferred issuance date(s) and amount(s) elected by the Participant shall be set forth in the Award Agreement. Notwithstanding the foregoing, the Committee, in its discretion, may provide for settlement of any Restricted Stock Unit Award by payment to the Participant in cash of an amount equal to the Fair Market Value on the payment date of the shares of Stock or other property otherwise issuable to the Participant pursuant to this Section.

9.7 **Nontransferability of Restricted Stock Unit Awards.** The right to receive shares pursuant to a Restricted Stock Unit Award shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. All rights with respect to a Restricted Stock Unit Award granted to a Participant hereunder shall be exercisable during his or her lifetime only by such Participant or the Participant's guardian or legal representative.

10. PERFORMANCE AWARDS.

Performance Awards shall be evidenced by Award Agreements in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

10.1 **Types of Performance Awards Authorized.** Performance Awards may be granted in the form of either Performance Shares or Performance Units. Each Award Agreement evidencing a Performance Award shall specify the number of Performance Shares or

Performance Units subject thereto, the Performance Award Formula, the Performance Goal(s) and Performance Period applicable to the Award, and the other terms, conditions and restrictions of the Award.

10.2 **Initial Value of Performance Shares and Performance Units.** Unless otherwise provided by the Committee in granting a Performance Award, each Performance Share shall have an initial monetary value equal to the Fair Market Value of one (1) share of Stock, subject to adjustment as provided in Section 4.5, on the effective date of grant of the Performance Share, and each Performance Unit shall have an initial monetary value established by the Committee at the time of grant. The final value payable to the Participant in settlement of a Performance Award determined on the basis of the applicable Performance Award Formula will depend on the extent to which Performance Goals established by the Committee are attained within the applicable Performance Period established by the Committee.

10.3 **Establishment of Performance Period, Performance Goals and Performance Award Formula.** In granting each Performance Award, the Committee shall establish in writing the applicable Performance Period, Performance Award Formula and one or more Performance Goals which, when measured at the end of the Performance Period, shall determine on the basis of the Performance Award Formula the final value of the Performance Award to be paid to the Participant. Unless otherwise permitted in compliance with the requirements under Section 162(m) with respect to each Performance Award intended to result in the payment of Performance-Based Compensation, the Committee shall establish the Performance Goal(s) and Performance Award Formula applicable to each Performance Award no later than the earlier of (a) the date ninety (90) days after the commencement of the applicable Performance Period or (b) the date on which 25% of the Performance Period has elapsed, and, in any event, at a time when the outcome of the Performance Goals remains substantially uncertain. Once established, the Performance Goals and Performance Award Formula applicable to a Performance Award intended to result in the payment of Performance-Based Compensation to a Covered Employee shall not be changed during the Performance Period. The Company shall notify each Participant granted a Performance Award of the terms of such Award, including the Performance Period, Performance Goal(s) and Performance Award Formula.

10.4 **Measurement of Performance Goals.** Performance Goals shall be established by the Committee on the basis of targets to be attained ("***Performance Targets***") with respect to one or more measures of business or financial performance (each, a "***Performance Measure***"), subject to the following:

(a) ***Performance Measures.*** Performance Measures shall be calculated in accordance with the Company's financial statements, or, if such measures are not reported in the Company's financial statements, they shall be calculated in accordance with generally accepted accounting principles, a method used generally in the Company's industry, or in accordance with a methodology established by the Committee prior to the grant of the Performance Award. As specified by the Committee, Performance Measures may be calculated with respect to the Company and each Subsidiary Corporation consolidated therewith for financial reporting purposes, one or more Subsidiary Corporations or such division or other business unit of any of them selected by the Committee. Unless otherwise determined by the Committee prior to the grant of the Performance Award, the Performance Measures applicable to the Performance

Award shall be calculated prior to the accrual of expense for any Performance Award for the same Performance Period and excluding the effect (whether positive or negative) on the Performance Measures of any change in accounting standards or any extraordinary, unusual or nonrecurring item, as determined by the Committee, occurring after the establishment of the Performance Goals applicable to the Performance Award. Each such adjustment, if any, shall be made solely for the purpose of providing a consistent basis from period to period for the calculation of Performance Measures in order to prevent the dilution or enlargement of the Participant's rights with respect to a Performance Award. Performance Measures may be based upon one or more of the following, as determined by the Committee:

(i) revenue;

(ii) sales;

(iii) expenses;

(iv) operating income;

(v) gross margin;

(vi) operating margin;

(vii) earnings before any one or more of: stock-based compensation expense, interest, taxes, depreciation and amortization;

(viii) pre-tax profit;

(ix) net operating income;

(x) net income;

(xi) economic value added;

(xii) free cash flow;

(xiii) operating cash flow;

(xiv) balance of cash, cash equivalents and marketable securities;

(xv) stock price;

(xvi) earnings per share;

(xvii) return on stockholder equity;

(xviii) return on capital;

(xix) return on assets;

(xx) return on investment;

(xxi) total stockholder return;

(xxii) market share;

(xxiii) product development;

(xxiv) research and development expenses;

(xxv) completion of an identified special project; and

(xxvi) completion of a joint venture or other corporate transaction.

(b) ***Performance Targets.*** Performance Targets may include a minimum, maximum, target level and intermediate levels of performance, with the final value of a Performance Award determined under the applicable Performance Award Formula by the Performance Target level attained during the applicable Performance Period. A Performance Target may be stated as an absolute value, an increase or decrease in a value, or as a value determined relative to an index, budget or other standard selected by the Committee.

10.5 **Settlement of Performance Awards**.

(a) ***Determination of Final Value.*** As soon as practicable following the completion of the Performance Period applicable to a Performance Award, the Committee shall certify in writing the extent to which the applicable Performance Goals have been attained and the resulting final value of the Award earned by the Participant and to be paid upon its settlement in accordance with the applicable Performance Award Formula.

(b) ***Discretionary Adjustment of Award Formula.*** In its discretion, the Committee may, either at the time it grants a Performance Award or at any time thereafter, provide for the positive or negative adjustment of the Performance Award Formula applicable to a Performance Award granted to any Participant who is not a Covered Employee to reflect such Participant's individual performance in his or her position with the Company or such other factors as the Committee may determine. If permitted under a Covered Employee's Award Agreement, the Committee shall have the discretion, on the basis of such criteria as may be established by the Committee, to reduce some or all of the value of the Performance Award that would otherwise be paid to the Covered Employee upon its settlement notwithstanding the attainment of any Performance Goal and the resulting value of the Performance Award determined in accordance with the Performance Award Formula. No such reduction may result in an increase in the amount payable upon settlement of another Participant's Performance Award that is intended to result in Performance-Based Compensation.

(c) ***Effect of Leaves of Absence.*** Unless otherwise required by law or a Participant's Award Agreement, payment of the final value, if any, of a Performance Award held by a Participant who has taken in excess of thirty (30) days in unpaid leaves of absence during a Performance Period shall be prorated on the basis of the number of days of the Participant's

Service during the Performance Period during which the Participant was not on an unpaid leave of absence.

(d) ***Notice to Participants.*** As soon as practicable following the Committee's determination and certification in accordance with Sections 10.5(a) and (b), the Company shall notify each Participant of the determination of the Committee.

(e) ***Payment in Settlement of Performance Awards.*** As soon as practicable following the Committee's determination and certification in accordance with Sections 10.5(a) and (b), but in any event within the Short-Term Deferral Period described in Section 15.1 (except as otherwise provided below or consistent with the requirements of Section 409A), payment shall be made to each eligible Participant (or such Participant's legal representative or other person who acquired the right to receive such payment by reason of the Participant's death) of the final value of the Participant's Performance Award. Payment of such amount shall be made in cash, shares of Stock, or a combination thereof as determined by the Committee. Unless otherwise provided in the Award Agreement evidencing a Performance Award, payment shall be made in a lump sum. If permitted by the Committee, the Participant may elect, consistent with the requirements of Section 409A, to defer receipt of all or any portion of the payment to be made to the Participant pursuant to this Section, and such deferred payment date(s) elected by the Participant shall be set forth in the Award Agreement. If any payment is to be made on a deferred basis, the Committee may, but shall not be obligated to, provide for the payment during the deferral period of Dividend Equivalent Rights or interest.

(f) ***Provisions Applicable to Payment in Shares.*** If payment is to be made in shares of Stock, the number of such shares shall be determined by dividing the final value of the Performance Award by the Fair Market Value of a share of Stock determined by the method specified in the Award Agreement. Shares of Stock issued in payment of any Performance Award may be fully vested and freely transferable shares or may be shares of Stock subject to Vesting Conditions as provided in Section 8.5. Any shares subject to Vesting Conditions shall be evidenced by an appropriate Award Agreement and shall be subject to the provisions of Sections 8.5 through 8.8 above.

10.6 **Voting Rights; Dividend Equivalent Rights and Distributions.** Participants shall have no voting rights with respect to shares of Stock represented by Performance Share Awards until the date of the issuance of such shares, if any (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). However, the Committee, in its discretion, may provide in the Award Agreement evidencing any Performance Share Award that the Participant shall be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Stock during the period beginning on the date the Award is granted and ending, with respect to each share subject to the Award, on the earlier of the date on which the Performance Shares are settled or the date on which they are forfeited. Such Dividend Equivalent Rights, if any, shall be credited to the Participant either in cash or in the form of additional whole Performance Shares as of the date of payment of such cash dividends on Stock, as determined by the Committee. The number of additional Performance Shares (rounded to the nearest whole number), if any, to be so credited shall be determined by dividing (a) the amount of cash dividends paid on the dividend payment date with respect to the number of shares of Stock represented by the Performance Shares

previously credited to the Participant by (b) the Fair Market Value per share of Stock on such date. Dividend Equivalent Rights, if any, shall be accumulated and paid to the extent that the related Performance Shares become nonforfeitable. Settlement of Dividend Equivalent Rights may be made in cash, shares of Stock, or a combination thereof as determined by the Committee, and may be paid on the same basis as settlement of the related Performance Share as provided in Section 10.5. Dividend Equivalent Rights shall not be paid with respect to Performance Units. In the event of a dividend or distribution paid in shares of Stock or other property or any other adjustment made upon a change in the capital structure of the Company as described in Section 4.5, appropriate adjustments shall be made in the Participant's Performance Share Award so that it represents the right to receive upon settlement any and all new, substituted or additional securities or other property (other than regular, periodic cash dividends) to which the Participant would be entitled by reason of the shares of Stock issuable upon settlement of the Performance Share Award, and all such new, substituted or additional securities or other property shall be immediately subject to the same Performance Goals as are applicable to the Award.

10.7 **Effect of Termination of Service.** Unless otherwise provided by the Committee and set forth in the Award Agreement evidencing a Performance Award, the effect of a Participant's termination of Service on the Performance Award shall be as follows:

(a) ***Death or Disability.*** If the Participant's Service terminates because of the death or Disability of the Participant before the completion of the Performance Period applicable to the Performance Award, the final value of the Participant's Performance Award shall be determined by the extent to which the applicable Performance Goals have been attained with respect to the entire Performance Period and shall be prorated based on the number of months of the Participant's Service during the Performance Period. Payment shall be made following the end of the Performance Period in any manner permitted by Section 10.5.

(b) ***Other Termination of Service.*** If the Participant's Service terminates for any reason except death or Disability before the completion of the Performance Period applicable to the Performance Award, such Award shall be forfeited in its entirety; provided, however, that in the event of an involuntary termination of the Participant's Service, the Committee, in its discretion, may waive the automatic forfeiture of all or any portion of any such Award and determine the final value of the Performance Award in the manner provided by Section 10.7(a). Payment of any amount pursuant to this Section shall be made following the end of the Performance Period in any manner permitted by Section 10.5.

10.8 **Nontransferability of Performance Awards.** Prior to settlement in accordance with the provisions of the Plan, no Performance Award shall be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. All rights with respect to a Performance Award granted to a Participant hereunder shall be exercisable during his or her lifetime only by such Participant or the Participant's guardian or legal representative.

11. CASH-BASED AWARDS AND OTHER STOCK-BASED AWARDS.

Cash-Based Awards and Other Stock-Based Awards shall be evidenced by Award Agreements in such form as the Committee shall establish. Such Award Agreements may incorporate all or any of the terms of the Plan by reference and shall comply with and be subject to the following terms and conditions:

11.1 **Grant of Cash-Based Awards**. Subject to the provisions of the Plan, the Committee, at any time and from time to time, may grant Cash-Based Awards to Participants in such amounts and upon such terms and conditions, including the achievement of performance criteria, as the Committee may determine.

11.2 **Grant of Other Stock-Based Awards**. The Committee may grant other types of equity-based or equity-related Awards not otherwise described by the terms of this Plan (including the grant or offer for sale of unrestricted securities, stock-equivalent units, stock appreciation units, securities or debentures convertible into common stock or other forms determined by the Committee) in such amounts and subject to such terms and conditions as the Committee shall determine. Other Stock-Based Awards may be made available as a form of payment in the settlement of other Awards or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may involve the transfer of actual shares of Stock to Participants, or payment in cash or otherwise of amounts based on the value of Stock and may include, without limitation, Awards designed to comply with or take advantage of the applicable local laws of jurisdictions other than the United States.

11.3 **Value of Cash-Based and Other Stock-Based Awards**. Each Cash-Based Award shall specify a monetary payment amount or payment range as determined by the Committee. Each Other Stock-Based Award shall be expressed in terms of shares of Stock or units based on such shares of Stock, as determined by the Committee. The Committee may require the satisfaction of such Service requirements, conditions, restrictions or performance criteria, including, without limitation, Performance Goals as described in Section 10.4, as shall be established by the Committee and set forth in the Award Agreement evidencing such Award. If the Committee exercises its discretion to establish performance criteria, the final value of Cash-Based Awards or Other Stock-Based Awards that will be paid to the Participant will depend on the extent to which the performance criteria are met. The establishment of performance criteria with respect to the grant or vesting of any Cash-Based Award or Other Stock-Based Award intended to result in Performance-Based Compensation shall follow procedures substantially equivalent to those applicable to Performance Awards set forth in Section 10.

11.4 **Payment or Settlement of Cash-Based Awards and Other Stock-Based Awards**. Payment or settlement, if any, with respect to a Cash-Based Award or an Other Stock-Based Award shall be made in accordance with the terms of the Award, in cash, shares of Stock or other securities or any combination thereof as the Committee determines. The determination and certification of the final value with respect to any Cash-Based Award or Other Stock-Based Award intended to result in Performance-Based Compensation shall comply with the requirements applicable to Performance Awards set forth in Section 10. To the extent

applicable, payment or settlement with respect to each Cash-Based Award and Other Stock-Based Award shall be made in compliance with the requirements of Section 409A.

11.5 **Voting Rights; Dividend Equivalent Rights and Distributions.** Participants shall have no voting rights with respect to shares of Stock represented by Other Stock-Based Awards until the date of the issuance of such shares of Stock (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), if any, in settlement of such Award. However, the Committee, in its discretion, may provide in the Award Agreement evidencing any Other Stock-Based Award that the Participant shall be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Stock during the period beginning on the date such Award is granted and ending, with respect to each share subject to the Award, on the earlier of the date the Award is settled or the date on which it is terminated. Such Dividend Equivalent Rights, if any, shall be paid in accordance with the provisions set forth in Section 9.4. Dividend Equivalent Rights shall not be granted with respect to Cash-Based Awards. In the event of a dividend or distribution paid in shares of Stock or other property or any other adjustment made upon a change in the capital structure of the Company as described in Section 4.5, appropriate adjustments shall be made in the Participant's Other Stock-Based Award so that it represents the right to receive upon settlement any and all new, substituted or additional securities or other property (other than regular, periodic cash dividends) to which the Participant would be entitled by reason of the shares of Stock issuable upon settlement of such Award, and all such new, substituted or additional securities or other property shall be immediately subject to the same Vesting Conditions and performance criteria, if any, as are applicable to the Award.

11.6 **Effect of Termination of Service**. Each Award Agreement evidencing a Cash-Based Award or Other Stock-Based Award shall set forth the extent to which the Participant shall have the right to retain such Award following termination of the Participant's Service. Such provisions shall be determined in the discretion of the Committee, need not be uniform among all Cash-Based Awards or Other Stock-Based Awards, and may reflect distinctions based on the reasons for termination, subject to the requirements of Section 409A, if applicable.

11.7 **Nontransferability of Cash-Based Awards and Other Stock-Based Awards.** Prior to the payment or settlement of a Cash-Based Award or Other Stock-Based Award, the Award shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Participant or the Participant's beneficiary, except transfer by will or by the laws of descent and distribution. The Committee may impose such additional restrictions on any shares of Stock issued in settlement of Cash-Based Awards and Other Stock-Based Awards as it may deem advisable, including, without limitation, minimum holding period requirements, restrictions under applicable federal securities laws, under the requirements of any stock exchange or market upon which such shares of Stock are then listed and/or traded, or under any state securities laws or foreign law applicable to such shares of Stock.

12.STANDARD FORMS OF AWARD AGREEMENT.

12.1**Award Agreements.** Each Award shall comply with and be subject to the terms and conditions set forth in the appropriate form of Award Agreement approved by the Committee and as amended from time to time. No Award or purported Award shall be a valid and binding obligation of the Company unless evidenced by a fully executed Award Agreement, which execution may be evidenced by electronic means.

12.2**Authority to Vary Terms.** The Committee shall have the authority from time to time to vary the terms of any standard form of Award Agreement either in connection with the grant or amendment of an individual Award or in connection with the authorization of a new standard form or forms; provided, however, that the terms and conditions of any such new, revised or amended standard form or forms of Award Agreement are not inconsistent with the terms of the Plan.

13.CHANGE IN CONTROL.

13.1**Effect of Change in Control on Awards.** Subject to the requirements and limitations of Section 409A, if applicable, the Committee may provide for any one or more of the following:

(a)***Accelerated Vesting.*** In its discretion, the Committee may provide in the grant of any Award or at any other time may take such action as it deems appropriate to provide for acceleration of the exercisability, vesting and/or settlement in connection with a Change in Control of each or any outstanding Award or portion thereof and shares acquired pursuant thereto upon such conditions, including termination of the Participant's Service prior to, upon, or following the Change in Control, and to such extent as the Committee determines.

(b)***Assumption, Continuation or Substitution.*** In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or other business entity or parent thereof, as the case may be (the "***Acquiror***"), may, without the consent of any Participant, assume or continue the Company's rights and obligations under each or any Award or portion thereof outstanding immediately prior to the Change in Control or substitute for each or any such outstanding Award or portion thereof a substantially equivalent award with respect to the Acquiror's stock, as applicable. For purposes of this Section, if so determined by the Committee in its discretion, an Award denominated in shares of Stock shall be deemed assumed if, following the Change in Control, the Award confers the right to receive, subject to the terms and conditions of the Plan and the applicable Award Agreement, for each share of Stock subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, other securities or property or a combination thereof) to which a holder of a share of Stock on the effective date of the Change in Control was entitled (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Stock); provided, however, that if such consideration is not solely common stock of the Acquiror, the Committee may, with the consent of the Acquiror, provide for the consideration to be received upon the exercise or settlement of the Award, for each share of Stock subject to the Award, to consist solely of common stock of the Acquiror equal in Fair Market Value to the per share consideration received by holders of Stock pursuant to the Change in Control. Any Award

or portion thereof which is neither assumed or continued by the Acquiror in connection with the Change in Control nor exercised or settled as of the time of consummation of the Change in Control shall terminate and cease to be outstanding effective as of the time of consummation of the Change in Control.

(c)***Cash-Out of Outstanding Stock-Based Awards.*** The Committee may, in its discretion and without the consent of any Participant, determine that, upon the occurrence of a Change in Control, each or any Award denominated in shares of Stock or portion thereof outstanding immediately prior to the Change in Control and not previously exercised or settled shall be canceled in exchange for a payment with respect to each vested share (and each unvested share, if so determined by the Committee) of Stock subject to such canceled Award in (i) cash, (ii) stock of the Company or of a corporation or other business entity a party to the Change in Control, or (iii) other property which, in any such case, shall be in an amount having a Fair Market Value equal to the Fair Market Value of the consideration to be paid per share of Stock in the Change in Control, reduced (but not below zero) by the exercise or purchase price per share, if any, under such Award. In the event such determination is made by the Committee, an Award having an exercise or purchase price per share equal to or greater than the Fair Market Value of the consideration to be paid per share of Stock in the Change in Control may be canceled without payment of consideration to the holder thereof. Payment pursuant to this Section (reduced by applicable withholding taxes, if any) shall be made to Participants in respect of the vested portions of their canceled Awards as soon as practicable following the date of the Change in Control and in respect of the unvested portions of their canceled Awards in accordance with the vesting schedules applicable to such Awards.

13.2**Effect of Change in Control on Nonemployee Director Awards.** Subject to the requirements and limitations of Section 409A, if applicable, including as provided by Section 15.4(f), in the event of a Change in Control, each outstanding Nonemployee Director Award shall become immediately exercisable and vested in full and, except to the extent assumed, continued or substituted for pursuant to Section 13.1(b), shall be settled effective immediately prior to the time of consummation of the Change in Control.

13.3**Federal Excise Tax Under Section 4999 of the Code**.

(a)***Excess Parachute Payment.*** If any acceleration of vesting pursuant to an Award and any other payment or benefit received or to be received by a Participant would subject the Participant to any excise tax pursuant to Section 4999 of the Code due to the characterization of such acceleration of vesting, payment or benefit as an "excess parachute payment" under Section 280G of the Code, then, provided such election would not subject the Participant to taxation under Section 409A, the Participant may elect to reduce the amount of any acceleration of vesting called for under the Award in order to avoid such characterization.

(b)***Determination by Tax Firm.*** To aid the Participant in making any election called for under Section 13.3(a), no later than the date of the occurrence of any event that might reasonably be anticipated to result in an "excess parachute payment" to the Participant as described in Section 13.3(a), the Company shall request a determination in writing by the professional firm engaged by the Company for general tax purposes, or, if the tax firm so engaged by the Company is serving as accountant or auditor for the Acquiror, the Company will

appoint a nationally recognized tax firm to make the determinations required by this Section (the "***Tax Firm***"). As soon as practicable thereafter, the Tax Firm shall determine and report to the Company and the Participant the amount of such acceleration of vesting, payments and benefits which would produce the greatest after-tax benefit to the Participant. For the purposes of such determination, the Tax Firm may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Participant shall furnish to the Tax Firm such information and documents as the Tax Firm may reasonably request in order to make its required determination. The Company shall bear all fees and expenses the Tax Firm charges in connection with its services contemplated by this Section.

14.COMPLIANCE WITH SECURITIES LAW.

The grant of Awards and the issuance of shares of Stock pursuant to any Award shall be subject to compliance with all applicable requirements of federal, state and foreign law with respect to such securities and the requirements of any stock exchange or market system upon which the Stock may then be listed. In addition, no Award may be exercised or shares issued pursuant to an Award unless (a) a registration statement under the Securities Act shall at the time of such exercise or issuance be in effect with respect to the shares issuable pursuant to the Award, or (b) in the opinion of legal counsel to the Company, the shares issuable pursuant to the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares under the Plan shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained. As a condition to issuance of any Stock, the Company may require the Participant to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company.

15.COMPLIANCE WITH SECTION 409A.

15.1**Awards Subject to Section 409A.** The Company intends that Awards granted pursuant to the Plan shall either be exempt from or comply with Section 409A, and the Plan shall be so construed. The provisions of this Section 15 shall apply to any Award or portion thereof that constitutes or provides for payment of Section 409A Deferred Compensation. Such Awards may include, without limitation:

(a)A Nonstatutory Stock Option or SAR that includes any feature for the deferral of compensation other than the deferral of recognition of income until the later of (i) the exercise or disposition of the Award or (ii) the time the stock acquired pursuant to the exercise of the Award first becomes substantially vested.

(b)Any Restricted Stock Unit Award, Performance Award, Cash-Based Award or Other Stock-Based Award that either (i) provides by its terms for settlement of all or any portion of the Award at a time or upon an event that will or may occur later than the end of the Short-Term Deferral Period (as defined below) or (ii) permits the Participant granted the

Award to elect one or more dates or events upon which the Award will be settled after the end of the Short-Term Deferral Period.

Subject to the provisions of Section 409A, the term "***Short-Term Deferral Period***" means the 2½ month period ending on the later of (i) the 15th day of the third month following the end of the Participant's taxable year in which the right to payment under the applicable portion of the Award is no longer subject to a substantial risk of forfeiture or (ii) the 15th day of the third month following the end of the Company's taxable year in which the right to payment under the applicable portion of the Award is no longer subject to a substantial risk of forfeiture. For this purpose, the term "substantial risk of forfeiture" shall have the meaning provided by Section 409A.

15.2**Deferral and/or Distribution Elections.** Except as otherwise permitted or required by Section 409A, the following rules shall apply to any compensation deferral and/or payment elections (each, an "***Election***") that may be permitted or required by the Committee pursuant to an Award providing Section 409A Deferred Compensation:

(a)Elections must be in writing and specify the amount of the payment in settlement of an Award being deferred, as well as the time and form of payment as permitted by this Plan.

(b)Elections shall be made by the end of the Participant's taxable year prior to the year in which services commence for which an Award may be granted to the Participant.

(c)Elections shall continue in effect until a written revocation or change in Election is received by the Company, except that a written revocation or change in Election must be received by the Company prior to the last day for making the Election determined in accordance with paragraph (b) above or as permitted by Section 15.3.

15.3**Subsequent Elections.** Except as otherwise permitted or required by Section 409A, any Award providing Section 409A Deferred Compensation which permits a subsequent Election to delay the payment or change the form of payment in settlement of such Award shall comply with the following requirements:

(a)No subsequent Election may take effect until at least twelve (12) months after the date on which the subsequent Election is made.

(b)Each subsequent Election related to a payment in settlement of an Award not described in Section 15.4(a)(ii), 15.4(a)(iii) or 15.4(a)(vi) must result in a delay of the payment for a period of not less than five (5) years from the date on which such payment would otherwise have been made.

(c)No subsequent Election related to a payment pursuant to Section 15.4(a)(iv) shall be made less than twelve (12) months before the date on which such payment would otherwise have been made.

(d)Subsequent Elections shall continue in effect until a written revocation or change in the subsequent Election is received by the Company, except that a written revocation or change in a subsequent Election must be received by the Company prior to the last day for making the subsequent Election determined in accordance the preceding paragraphs of this Section 15.3.

15.4**Payment of Section 409A Deferred Compensation**.

(a)***Permissible Payments.*** Except as otherwise permitted or required by Section 409A, an Award providing Section 409A Deferred Compensation must provide for payment in settlement of the Award only upon one or more of the following:

(i)The Participant's "separation from service" (as defined by Section 409A);

(ii)The Participant's becoming "disabled" (as defined by Section 409A);

(iii)The Participant's death;

(iv)A time or fixed schedule that is either (i) specified by the Committee upon the grant of an Award and set forth in the Award Agreement evidencing such Award or (ii) specified by the Participant in an Election complying with the requirements of Section 15.2 or 15.3, as applicable;

(v)A change in the ownership or effective control or the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 409A; or

(vi)The occurrence of an "unforeseeable emergency" (as defined by Section 409A).

(b)***Installment Payments***. It is the intent of this Plan that any right of a Participant to receive installment payments (within the meaning of Section 409A) shall, for all purposes of Section 409A, be treated as a right to a series of separate payments.

(c)***Required Delay in Payment to Specified Employee Pursuant to Separation from Service.*** Notwithstanding any provision of the Plan or an Award Agreement to the contrary, except as otherwise permitted by Section 409A, no payment pursuant to Section 15.4(a)(i) in settlement of an Award providing for Section 409A Deferred Compensation may be made to a Participant who is a "specified employee" (as defined by Section 409A) as of the date of the Participant's separation from service before the date (the "***Delayed Payment Date***") that is six (6) months after the date of such Participant's separation from service, or, if earlier, the date of the Participant's death. All such amounts that would, but for this paragraph, become payable prior to the Delayed Payment Date shall be accumulated and paid on the Delayed Payment Date.

(d)***Payment Upon Disability.*** All distributions of Section 409A Deferred Compensation payable pursuant to Section 15.4(a)(ii) by reason of a Participant becoming disabled shall be paid in a lump sum or in periodic installments as established by the Participant's Election. If the Participant has made no Election with respect to distributions of Section 409A Deferred Compensation upon becoming disabled, all such distributions shall be paid in a lump sum upon the determination that the Participant has become disabled.

(e)***Payment Upon Death.*** If a Participant dies before complete distribution of amounts payable upon settlement of an Award subject to Section 409A, such undistributed amounts shall be distributed to his or her beneficiary under the distribution method for death established by the Participant's Election upon receipt by the Committee of satisfactory notice and confirmation of the Participant's death. If the Participant has made no Election with respect to distributions of Section 409A Deferred Compensation upon death, all such distributions shall be paid in a lump sum upon receipt by the Committee of satisfactory notice and confirmation of the Participant's death.

(f)***Payment Upon Change in Control.*** Notwithstanding any provision of the Plan or an Award Agreement to the contrary, to the extent that any amount constituting Section 409A Deferred Compensation would become payable under this Plan by reason of a Change in Control, such amount shall become payable only if the event constituting a Change in Control would also constitute a change in ownership or effective control of the Company or a change in the ownership of a substantial portion of the assets of the Company within the meaning of Section 409A. Any Award which constitutes Section 409A Deferred Compensation and which would vest and otherwise become payable upon a Change in Control as a result of the failure of the Acquiror to assume, continue or substitute for such Award in accordance with Section 13.1(b) shall vest to the extent provided by such Award but shall be converted automatically at the effective time of such Change in Control into a right to receive, in cash on the date or dates such award would have been settled in accordance with its then existing settlement schedule (or as required by Section 15.4(c)), an amount or amounts equal in the aggregate to the intrinsic value of the Award at the time of the Change in Control.

(g)***Payment Upon Unforeseeable Emergency.*** The Committee shall have the authority to provide in the Award Agreement evidencing any Award providing for Section 409A Deferred Compensation for payment pursuant to Section 15.4(a)(vi) in settlement of all or a portion of such Award in the event that a Participant establishes, to the satisfaction of the Committee, the occurrence of an unforeseeable emergency. In such event, the amount(s) distributed with respect to such unforeseeable emergency cannot exceed the amounts reasonably necessary to satisfy the emergency need plus amounts necessary to pay taxes reasonably anticipated as a result of such distribution(s), after taking into account the extent to which such emergency need is or may be relieved through reimbursement or compensation by insurance or otherwise, by liquidation of the Participant's assets (to the extent the liquidation of such assets would not itself cause severe financial hardship) or by cessation of deferrals under the Award. All distributions with respect to an unforeseeable emergency shall be made in a lump sum upon the Committee's determination that an unforeseeable emergency has occurred. The Committee's decision with respect to whether an unforeseeable emergency has occurred and the manner in which, if at all, the payment in settlement of an Award shall be altered or modified, shall be final, conclusive, and not subject to approval or appeal.

(h)***Prohibition of Acceleration of Payments.*** Notwithstanding any provision of the Plan or an Award Agreement to the contrary, this Plan does not permit the acceleration of the time or schedule of any payment under an Award providing Section 409A Deferred Compensation, except as permitted by Section 409A.

(i)***No Representation Regarding Section 409A Compliance***. Notwithstanding any other provision of the Plan, the Company makes no representation that Awards shall be exempt from or comply with Section 409A. No Participating Company shall be liable for any tax, penalty or interest imposed on a Participant by Section 409A.

16.TAX WITHHOLDING.

16.1**Tax Withholding in General.** The Company shall have the right to deduct from any and all payments made under the Plan, or to require the Participant, through payroll withholding, cash payment or otherwise, to make adequate provision for, the federal, state, local and foreign taxes (including social insurance), if any, required by law to be withheld by any Participating Company with respect to an Award or the shares acquired pursuant thereto. The Company shall have no obligation to deliver shares of Stock, to release shares of Stock from an escrow established pursuant to an Award Agreement, or to make any payment in cash under the Plan until the Participating Company Group's tax withholding obligations have been satisfied by the Participant.

16.2**Withholding in or Directed Sale of Shares.** The Company shall have the right, but not the obligation, to deduct from the shares of Stock issuable to a Participant upon the exercise or settlement of an Award, or to accept from the Participant the tender of, a number of whole shares of Stock having a Fair Market Value, as determined by the Company, equal to all or any part of the tax withholding obligations of any Participating Company. The Fair Market Value of any shares of Stock withheld or tendered to satisfy any such tax withholding obligations shall not exceed the amount determined by the applicable minimum statutory withholding rates. The Company may require a Participant to direct a broker, upon the vesting, exercise or settlement of an Award, to sell a portion of the shares subject to the Award determined by the Company in its discretion to be sufficient to cover the tax withholding obligations of any Participating Company and to remit an amount equal to such tax withholding obligations to such Participating Company in cash.

17.AMENDMENT, SUSPENSION OR TERMINATION OF PLAN.

The Committee may amend, suspend or terminate the Plan at any time. However, without the approval of the Company's stockholders, there shall be (a) no increase in the maximum aggregate number of shares of Stock that may be issued under the Plan (except by operation of the provisions of Sections 4.2, 4.3, 4.4 and 4.5), (b) no change in the class of persons eligible to receive Incentive Stock Options, and (c) no other amendment of the Plan that would require approval of the Company's stockholders under any applicable law, regulation or rule, including the rules of any stock exchange or quotation system upon which the Stock may then be listed or quoted. No amendment, suspension or termination of the Plan shall affect any then outstanding Award unless expressly provided by the Committee. Except as provided by the next sentence, no amendment, suspension or termination of the Plan may have a materially

adverse effect on any then outstanding Award without the consent of the Participant. Notwithstanding any other provision of the Plan or any Award Agreement to the contrary, the Committee may, in its sole and absolute discretion and without the consent of any Participant, amend the Plan or any Award Agreement, to take effect retroactively or otherwise, as it deems necessary or advisable for the purpose of conforming the Plan or such Award Agreement to any present or future law, regulation or rule applicable to the Plan, including, but not limited to, Section 409A.

18.MISCELLANEOUS PROVISIONS.

18.1**Repurchase Rights.** Shares issued under the Plan may be subject to one or more repurchase options, or other conditions and restrictions as determined by the Committee in its discretion at the time the Award is granted. The Company shall have the right to assign at any time any repurchase right it may have, whether or not such right is then exercisable, to one or more persons as may be selected by the Company. Upon request by the Company, each Participant shall execute any agreement evidencing such transfer restrictions prior to the receipt of shares of Stock hereunder and shall promptly present to the Company any and all certificates representing shares of Stock acquired hereunder for the placement on such certificates of appropriate legends evidencing any such transfer restrictions.

18.2**Forfeiture Events**.

(a)The Committee may specify in an Award Agreement that the Participant's rights, payments, and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of specified events, in addition to any otherwise applicable vesting or performance conditions of an Award. Such events may include, but shall not be limited to, termination of Service for Cause or any act by a Participant, whether before or after termination of Service, that would constitute Cause for termination of Service, or any accounting restatement due to material noncompliance of the Company with any financial reporting requirements of securities laws as a result of which, and to the extent that, such reduction, cancellation, forfeiture, or recoupment is required by applicable securities laws.

(b)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, any Participant who knowingly or through gross negligence engaged in the misconduct, or who knowingly or through gross negligence failed to prevent the misconduct, and any Participant 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 (i) the amount of any payment in settlement of an Award received by such Participant during the twelve- (12-) month period following the first public issuance or filing with the United States Securities and Exchange Commission (whichever first occurred) of the financial document embodying such financial reporting requirement, and (ii) any profits realized by such Participant from the sale of securities of the Company during such twelve- (12-) month period.

18.3**Provision of Information.** Each Participant shall be given access to information concerning the Company equivalent to that information generally made available to the Company's common stockholders.

18.4**Rights as Employee, Consultant or Director.** No person, even though eligible pursuant to Section 5, shall have a right to be selected as a Participant, or, having been so selected, to be selected again as a Participant. Nothing in the Plan or any Award granted under the Plan shall confer on any Participant a right to remain an Employee, Consultant or Director or interfere with or limit in any way any right of a Participating Company to terminate the Participant's Service at any time. To the extent that an Employee of a Participating Company other than the Company receives an Award under the Plan, that Award shall in no event be understood or interpreted to mean that the Company is the Employee's employer or that the Employee has an employment relationship with the Company.

18.5**Rights as a Stockholder.** A Participant shall have no rights as a stockholder with respect to any shares covered by an Award until the date of the issuance of such shares (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for dividends, distributions or other rights for which the record date is prior to the date such shares are issued, except as provided in Section 4.5 or another provision of the Plan.

18.6**Delivery of Title to Shares.** Subject to any governing rules or regulations, the Company shall issue or cause to be issued the shares of Stock acquired pursuant to an Award and shall deliver such shares to or for the benefit of the Participant by means of one or more of the following: (a) by delivering to the Participant evidence of book entry shares of Stock credited to the account of the Participant, (b) by depositing such shares of Stock for the benefit of the Participant with any broker with which the Participant has an account relationship, or (c) by delivering such shares of Stock to the Participant in certificate form.

18.7**Fractional Shares.** The Company shall not be required to issue fractional shares upon the exercise or settlement of any Award.

18.8**Retirement and Welfare Plans**. Neither Awards made under this Plan nor shares of Stock or cash paid pursuant to such Awards may be included as "compensation" for purposes of computing the benefits payable to any Participant under any Participating Company's retirement plans (both qualified and non-qualified) or welfare benefit plans unless such other plan expressly provides that such compensation shall be taken into account in computing a Participant's benefit.

18.9**Beneficiary Designation.** Subject to local laws and procedures, each Participant may file with the Company a written designation of a beneficiary who is to receive any benefit under the Plan to which the Participant is entitled in the event of such Participant's death before he or she receives any or all of such benefit. Each designation will revoke all prior designations by the same Participant, shall be in a form prescribed by the Company, and will be effective only when filed by the Participant in writing with the Company during the Participant's lifetime. If a married Participant designates a beneficiary other than the Participant's spouse, the effectiveness of such designation may be subject to the consent of the Participant's spouse. If a

Participant dies without an effective designation of a beneficiary who is living at the time of the Participant's death, the Company will pay any remaining unpaid benefits to the Participant's legal representative.

18.10**Severability**. If any one or more of the provisions (or any part thereof) of this Plan shall be held invalid, illegal or unenforceable in any respect, such provision shall be modified so as to make it valid, legal and enforceable, and the validity, legality and enforceability of the remaining provisions (or any part thereof) of the Plan shall not in any way be affected or impaired thereby.

18.11**No Constraint on Corporate Action.** Nothing in this Plan shall be construed to: (a) limit, impair, or otherwise affect the Company's or another Participating Company's right or power to make adjustments, reclassifications, reorganizations, or changes of its capital or business structure, or to merge or consolidate, or dissolve, liquidate, sell, or transfer all or any part of its business or assets; or (b) limit the right or power of the Company or another Participating Company to take any action which such entity deems to be necessary or appropriate.

18.12**Unfunded Obligation.** Participants shall have the status of general unsecured creditors of the Company. Any amounts payable to Participants pursuant to the Plan shall be considered unfunded and unsecured obligations for all purposes, including, without limitation, Title I of the Employee Retirement Income Security Act of 1974. No Participating Company shall be required to segregate any monies from its general funds, or to create any trusts, or establish any special accounts with respect to such obligations. The Company shall retain at all times beneficial ownership of any investments, including trust investments, which the Company may make to fulfill its payment obligations hereunder. Any investments or the creation or maintenance of any trust or any Participant account shall not create or constitute a trust or fiduciary relationship between the Committee or any Participating Company and a Participant, or otherwise create any vested or beneficial interest in any Participant or the Participant's creditors in any assets of any Participating Company. The Participants shall have no claim against any Participating Company for any changes in the value of any assets which may be invested or reinvested by the Company with respect to the Plan.

18.13**Choice of Law.** Except to the extent governed by applicable federal law, the validity, interpretation, construction and performance of the Plan and each Award Agreement shall be governed by the laws of the State of Delaware without regard to its conflict of law rules.

IN WITNESS WHEREOF, the undersigned Secretary of the Company certifies that the foregoing sets forth the Kadmon Holdings, Inc. 2016 Equity Incentive Plan as duly adopted by the Board on , 2016.

_____

, Secretary

Exhibit 10.11

KADMON HOLDINGS, INC.

2016 EMPLOYEE STOCK PURCHASE PLAN

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Kadmon Holdings, Inc.
2016 Employee Stock Purchase Plan

1. **ESTABLISHMENT, PURPOSE AND TERM OF PLAN.**

1.1 **Establishment.** The Kadmon Holdings, Inc. 2016 Employee Stock Purchase Plan (the *"**Plan**"*) is hereby established effective as of the effective date of the initial registration by the Company of its Stock under Section 12 of the Securities Exchange Act of 1934, as amended (the *"**Effective Date**"*).

1.2 **Purpose.** The purpose of the Plan is to advance the interests of the Company and its stockholders by providing an incentive to attract, retain and reward Eligible Employees of the Participating Company

Group and by motivating such persons to contribute to the growth and profitability of the Participating Company Group. The Plan provides such Eligible Employees with an opportunity to acquire a proprietary interest in the Company through the purchase of Stock. The Company intends that the Plan qualify as an "employee stock purchase plan" under Section 423 of the Code (including any amendments or replacements of such section), and the Plan shall be so construed.

1.3 **Term of Plan.** The Plan shall continue in effect until its termination by the Committee.

2. **DEFINITIONS AND CONSTRUCTION.**

2.1 **Definitions.** Any term not expressly defined in the Plan but defined for purposes of Section 423 of the Code shall have the same definition herein. Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) "***Board***" means the Board of Directors of the Company.

(b) "***Change in Control***" means the occurrence of any one or a combination of the following:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as such term is defined in Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total Fair Market Value or total combined voting power of the Company's then-outstanding securities entitled to vote generally in the election of Directors; provided, however, that a Change in Control shall not be deemed to have occurred if such degree of beneficial ownership results from any of the following: (A) an acquisition by any person who on the Effective Date is the beneficial owner of more than fifty percent (50%) of such voting power, (B) any acquisition directly from the Company, including, without limitation, pursuant to or in connection with a public offering of securities, (C) any acquisition by the Company, (D) any acquisition by a trustee or other fiduciary under an employee benefit plan of a Participating Company or (E) any acquisition by an entity owned

directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the voting securities of the Company; or

(ii) an Ownership Change Event or series of related Ownership Change Events (collectively, a "***Transaction***") in which the stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities entitled to vote generally in the election of Directors or, in the case of an Ownership Change Event described in Section 2.1(p)(iii), the entity to which the assets of the Company were transferred (the "***Transferee***"), as the case may be; or

(iii) a date specified by the Committee following approval by the stockholders of a plan of complete liquidation or dissolution of the Company;

provided, however, that a Change in Control shall be deemed not to include a transaction described in subsections (i) or (ii) of this Section 2.1(b) in which a majority of the members of the board of directors of the continuing, surviving or successor entity, or parent thereof, immediately after such transaction is comprised of Incumbent Directors.

For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Committee shall determine whether multiple events described in subsections (i), (ii) and (iii) of this Section 2.1(b) are related and to be treated in the aggregate as a single Change in Control, and its determination shall be final, binding and conclusive.

(c) "***Code***" means the Internal Revenue Code of 1986, as amended, and any applicable regulations promulgated thereunder.

(d) "***Committee***" means the Compensation Committee and such other committee or subcommittee of the Board, if any, duly appointed to administer the Plan and having such powers in each instance as shall be specified by the Board. If, at any time, there is no committee of the Board then authorized or properly constituted to administer the Plan, the Board shall exercise all of the powers of the Committee granted herein, and, in any event, the Board may in its discretion exercise any or all of such powers.

(e) "***Company***" means Kadmon Holdings, Inc., a Delaware corporation, or any successor corporation thereto.

(f) "***Compensation***" means, with respect to any Offering Period, regular base wages or salary, overtime payments, shift premiums and payments for paid time off, calculated before deduction of (i) any income or employment tax withholdings or (ii) any amounts deferred pursuant to Section 401(k) or Section 125 of the Code. Compensation shall be limited to such amounts actually payable in cash or deferred during the Offering Period. Compensation shall not include (i) sign-on bonuses, annual or other incentive bonuses, commissions, profit-sharing distributions or other incentive-type payments, (ii) any contributions made by a Participating Company on the Participant's behalf to any employee benefit or welfare

plan now or hereafter established (other than amounts deferred pursuant to Section 401(k) or Section 125 of the Code), (iii) payments in lieu of notice, payments pursuant to a severance agreement, termination pay, moving allowances, relocation payments, or (iv) any amounts directly or indirectly paid pursuant to the Plan or any other stock purchase, stock option or other stock-based compensation plan, or any other compensation not expressly included by this Section.

(g) "***Eligible Employee***" means an Employee who meets the requirements set forth in Section 5 for eligibility to participate in the Plan.

(h) "***Employee***" means a person treated as an employee of a Participating Company for purposes of Section 423 of the Code. A Participant shall be deemed to have ceased to be an Employee either upon an actual termination of employment or upon the corporation employing the Participant ceasing to be a Participating Company. For purposes of the Plan, an individual shall not be deemed to have ceased to be an Employee while on any military leave, sick leave, or other bona fide leave of absence approved by the Company of ninety (90) days or less. If an individual's leave of absence exceeds ninety (90) days, the individual shall be deemed to have ceased to be an Employee on the ninety-first (91st) day of such leave unless the individual's right to reemployment with the Participating Company Group is guaranteed either by statute or by contract.

(i) "***Fair Market Value***" means, as of any date:

(i) If, on such date, the Stock is listed or quoted on a national or regional securities exchange or quotation system, the closing price of a share of Stock as quoted on the national or regional securities exchange or quotation system constituting the primary market for the Stock, as reported in *The Wall Street Journal* or such other source as the Company deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or quotation system, the date on which the Fair Market Value is established shall be the last day on which the Stock was so traded or quoted prior to the relevant date, or such other appropriate day as determined by the Committee, in its discretion.

(ii) If, on the relevant date, the Stock is not then listed on a national or regional securities exchange or quotation system, the Fair Market Value of a share of Stock shall be as determined in good faith by the Committee.

(j) "***Incumbent Director***" means a director who either (i) is a member of the Board as of the Effective Date or (ii) is elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but excluding a director who was elected or nominated in connection with an actual or threatened proxy contest relating to the election of directors of the Company).

(k) "***Non-United States Offering***" means a separate Offering covering Eligible Employees of one or more Participating Companies whose Eligible Employees are subject to a prohibition under applicable law on payroll deductions, as described in Section 11.1(b).

(l) "***Offering***" means an offering of Stock pursuant to the Plan, as provided in Section 6.

(m) "***Offering Date***" means, for any Offering Period, the first day of such Offering Period.

(n) "***Offering Period***" means a period, established by the Committee in accordance with Section 6, during which an Offering is outstanding.

(o) "***Officer***" means any person designated by the Board as an officer of the Company.

(p) "***Ownership Change Event***" means the occurrence of any of the following with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of securities of the Company representing more than fifty percent (50%) of the total combined voting power of the Company's then outstanding securities entitled to vote generally in the election of Directors; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company (other than a sale, exchange or transfer to one or more subsidiaries of the Company).

(q) "***Parent Corporation***" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(r) "***Participant***" means an Eligible Employee who has become a participant in an Offering Period in accordance with Section 7 and remains a participant in accordance with the Plan.

(s) "***Participating Company***" means the Company and any Parent Corporation or Subsidiary Corporation designated by the Committee as a corporation the Employees of which may, if Eligible Employees, participate in the Plan. The Committee shall have the discretion to determine from time to time which Parent Corporations or Subsidiary Corporations shall be Participating Companies. The Committee shall designate from time to time and set forth in Appendix A to this Plan those Participating Companies whose Eligible Employees may participate in the Plan.

(t) "***Participating Company Group***" means, at any point in time, the Company and all other corporations collectively which are then Participating Companies.

(u) "***Purchase Date***" means, for any Offering Period, the last day of such Offering Period, or, if so determined by the Committee, the last day of each Purchase Period occurring within such Offering Period.

(v) "***Purchase Period***" means a period, established by the Committee in accordance with Section 6, included within an Offering Period and on the final date of which outstanding Purchase Rights are exercised.

(w) "***Purchase Price***" means the price at which a share of Stock may be purchased under the Plan, as determined in accordance with Section 9.

(x) "***Purchase Right***" means an option granted to a Participant pursuant to the Plan to purchase such shares of Stock as provided in Section 8, which the Participant may or may not exercise during the Offering Period in which such option is outstanding. Such option arises from the right of a Participant to withdraw any payroll deductions or other funds accumulated on behalf of the Participant and not previously applied to the purchase of Stock under the Plan, and to terminate participation in the Plan at any time during an Offering Period.

(y) "***Registration Date***" means the effective date of the registration on Form S-8 of shares of Stock issuable pursuant to the Plan.

(z) "***Securities Act***" means the Securities Act of 1933, as amended.

(aa) "***Stock***" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.3.

(bb) "***Subscription Agreement***" means a written or electronic agreement, in such form as is specified by the Company, stating an Employee's election to participate in the Plan and authorizing payroll deductions under the Plan from the Employee's Compensation or other method of payment authorized by the Committee pursuant to Section 11.1(b).

(cc) "***Subscription Date***" means the last business day prior to the Offering Date of an Offering Period or such earlier date as the Company shall establish.

(dd) "***Subsidiary Corporation***" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

2.2 **Construction.** Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

3. **ADMINISTRATION.**

3.1 **Administration by the Committee.** The Plan shall be administered by the Committee. All questions of interpretation of the Plan, of any form of agreement or other document employed by the Company in the administration of the Plan, or of any Purchase Right shall be determined by the Committee, and such determinations shall be final, binding and conclusive upon all persons having an interest in the Plan or the Purchase Right, unless fraudulent or made in bad faith. Subject to the provisions of the Plan, the Committee shall determine all of the relevant terms and conditions of Purchase Rights; provided, however, that all Participants granted Purchase Rights pursuant to an Offering shall have the same rights and privileges within the meaning of Section 423(b)(5) of the Code. Any and all actions, decisions

and determinations taken or made by the Committee in the exercise of its discretion pursuant to the Plan or any agreement thereunder (other than determining questions of interpretation pursuant to the second sentence of this Section 3.1) shall be final, binding and conclusive upon all persons having an interest therein. All expenses incurred in connection with the administration of the Plan shall be paid by the Company.

3.2 **Authority of Officers.** Any Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election that is the responsibility of or that is allocated to the Company herein, provided that the Officer has apparent authority with respect to such matter, right, obligation, determination or election.

3.3 **Power to Adopt Sub-Plans or Varying Terms with Respect to Non-U.S. Employees.** The Committee shall have the power, in its discretion, to adopt one or more sub-plans of the Plan as the Committee deems necessary or desirable to comply with the laws or regulations, tax policy, accounting principles or custom of foreign jurisdictions applicable to employees of a subsidiary business entity of the Company, provided that any such sub-plan shall not be within the scope of an "employee stock purchase plan" within the meaning of Section 423 of the Code. Any of the provisions of any such sub-plan may supersede the provisions of this Plan, other than Section 4. Except as superseded by the provisions of a sub-plan, the provisions of this Plan shall govern such sub-plan. Alternatively and in order to comply with the laws of a foreign jurisdiction, the Committee shall have the power, in its discretion, to grant Purchase Rights in an Offering to citizens or residents of a non-U.S. jurisdiction (without regard to whether they are also citizens of the United States or resident aliens) that provide terms which are less favorable than the terms of Purchase Rights granted under the same Offering to Employees resident in the United States.

3.4 **Power to Establish Separate Offerings with Varying Terms.** The Committee shall have the power, in its discretion, to establish separate, simultaneous or overlapping Offerings having different terms and conditions and to designate the Participating Company or Companies that may participate in a particular Offering, provided that each Offering shall individually comply with the terms of the Plan and the requirements of Section 423(b)(5) of the Code that all Participants granted Purchase Rights pursuant to such Offering shall have the same rights and privileges within the meaning of such section.

3.5 **Policies and Procedures Established by the Company.** Without regard to whether any Participant's Purchase Right may be considered adversely affected, the Company may, from time to time, consistent with the Plan and the requirements of Section 423 of the Code, establish, change or terminate such rules, guidelines, policies, procedures, limitations, or adjustments as deemed advisable by the Company, in its discretion, for the proper administration of the Plan, including, without limitation, (a) a minimum payroll deduction amount required for participation in an Offering, (b) a limitation on the frequency or number of changes permitted in the rate of payroll deduction during an Offering, (c) an exchange ratio applicable to amounts withheld or paid in a currency other than United States dollars, (d) a payroll deduction greater than or less than the amount designated by a Participant in order to adjust for the Company's delay or mistake in processing a Subscription Agreement or in otherwise effecting a Participant's election under the Plan or as advisable to comply with the requirements of Section 423 of the Code, and (e) determination of the date and manner by which the Fair Market Value of a share of

Stock is determined for purposes of administration of the Plan. All such actions by the Company shall be taken consistent with the requirements under Section 423(b)(5) of the Code that all Participants granted Purchase Rights pursuant to an Offering shall have the same rights and privileges within the meaning of such section, except as otherwise permitted by Section 3.3 and the regulations under Section 423 of the Code.

3.6 **Indemnification.** In addition to such other rights of indemnification as they may have as members of the Board or the Committee or as officers or employees of the Participating Company Group, to the extent permitted by applicable law, members of the Board or the Committee and any officers or employees of the Participating Company Group to whom authority to act for the Board, the Committee or the Company is delegated shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

4. **SHARES SUBJECT TO PLAN.**

4.1 **Maximum Number of Shares Issuable.** Subject to adjustment as provided in Sections 4.2 and 4.3, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be **One Million One Hundred Twenty Five Thousand (1,125,000)** and shall consist of authorized but unissued or reacquired shares of Stock, or any combination thereof. If an outstanding Purchase Right for any reason expires or is terminated or canceled, the shares of Stock allocable to the unexercised portion of that Purchase Right shall again be available for issuance under the Plan.

4.2 **Annual Increase in Maximum Number of Shares Issuable.** Subject to adjustment as provided in Section 4.3, the maximum aggregate number of shares of Stock that may be issued under the Plan as set forth in Section 4.1 shall be cumulatively increased automatically on January 1, 2017 and on each subsequent January 1, through and including January 1, 2025 by a number of shares (the *"**Annual Increase**"*) equal to the smallest of (a**) one and one half percent** (**1.5%**) of the number of shares of Stock issued and outstanding on the immediately preceding December 31, (b) **Seven Hundred Fifty Thousand (750,000)** shares, or (c) an amount determined by the Board.

4.3 **Adjustments for Changes in Capital Structure.** Subject to any required action by the stockholders of the Company and the requirements of Section 424 of the Code to the extent applicable, in the event of any change in the Stock effected without receipt of consideration by the Company, whether through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split,

split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure of the Company, or in the event of payment of a dividend or distribution to the stockholders of the Company in a form other than Stock (excepting regular, periodic cash dividends) that has a material effect on the Fair Market Value of shares of Stock, appropriate and proportionate adjustments shall be made in the number and kind of shares subject to the Plan, the Annual Increase, the limit on the shares which may be purchased by any Participant during an Offering (as described in Sections 8.1 and 8.2) and each Purchase Right, and in the Purchase Price in order to prevent dilution or enlargement of Participants' rights under the Plan. For purposes of the foregoing, conversion of any convertible securities of the Company shall not be treated as "effected without receipt of consideration by the Company." If a majority of the shares which are of the same class as the shares that are subject to outstanding Purchase Rights are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event) shares of another corporation (the *"**New Shares**"*), the Committee may unilaterally amend the outstanding Purchase Rights to provide that such Purchase Rights are for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise price per share of, the outstanding Purchase Rights shall be adjusted in a fair and equitable manner as determined by the Committee, in its discretion. Any fractional share resulting from an adjustment pursuant to this Section shall be rounded down to the nearest whole number, and in no event may the Purchase Price be decreased to an amount less than the par value, if any, of the stock subject to the Purchase Right. The adjustments determined by the Committee pursuant to this Section 4.3 shall be final, binding and conclusive.

5. **ELIGIBILITY**.

5.1 **Employees Eligible to Participate.** Each Employee of a Participating Company is eligible to participate in the Plan and shall be deemed an Eligible Employee, except the following:

(a) Any Employee who is customarily employed by the Participating Company Group for twenty (20) hours or less per week; or

(b) Any Employee who is customarily employed by the Participating Company Group for not more than five (5) months in any calendar year.

5.2 **Exclusion of Certain Stockholders.** Notwithstanding any provision of the Plan to the contrary, no Employee shall be treated as an Eligible Employee and granted a Purchase Right under the Plan if, immediately after such grant, the Employee would own, or hold options to purchase, stock of the Company or of any Parent Corporation or Subsidiary Corporation possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of such corporation, as determined in accordance with Section 423(b)(3) of the Code. For purposes of this Section 5.2, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of such Employee.

5.3 **Determination by Company.** The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee or an Eligible Employee and the effective date of such individual's attainment or termination of such status, as the case may be. For purposes of an individual's participation in or

other rights, if any, under the Plan as of the time of the Company's determination of whether or not the individual is an Employee, all such determinations by the Company shall be final, binding and conclusive as to such rights, if any, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination as to such individual's status as an Employee.

6. **OFFERINGS.**

The Plan shall be implemented by sequential Offerings of approximately six (6) months' duration or such other duration as the Committee shall determine. Offering Periods shall commence on or about the first trading days of April and October of each year and end on or about the last trading days of the next September and March, respectively, occurring thereafter. No Pre-Registration Offering Period shall be permitted. Notwithstanding the foregoing, the Committee may establish additional or alternative concurrent, sequential or overlapping Offering Periods, a different duration for one or more Offering Periods or different commencing or ending dates for such Offering Periods; provided, however, that no Offering Period may have a duration exceeding twenty-seven (27) months. If the Committee shall so determine in its discretion, each Offering Period may consist of two (2) or more consecutive Purchase Periods having such duration as the Committee shall specify, and the last day of each such Purchase Period shall be a Purchase Date. If the first or last day of an Offering Period or a Purchase Period is not a day on which the principal stock exchange or quotation system on which the Stock is then listed is open for trading, the Company shall specify the trading day that will be deemed the first or last day, as the case may be, of the Offering Period or Purchase Period.

7. **PARTICIPATION IN THE PLAN.**

7.1 **Initial Participation.**

(a) **Generally.** An Eligible Employee may become a Participant in an Offering Period by delivering a properly completed written or electronic Subscription Agreement to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) not later than the close of business on the Subscription Date established by the Company for that Offering Period. An Eligible Employee who does not deliver a properly completed Subscription Agreement in the manner permitted or required on or before the Subscription Date for an Offering Period shall not participate in the Plan for that Offering Period or for any subsequent Offering Period unless the Eligible Employee subsequently delivers a properly completed Subscription Agreement to the appropriate Company office or representative on or before the Subscription Date for such subsequent Offering Period. An Employee who becomes an Eligible Employee after the Offering Date of an Offering Period shall not be eligible to participate in that Offering Period but may participate in any subsequent Offering Period provided the Employee is still an Eligible Employee as of the Offering Date of such subsequent Offering Period.

7.2 **Continued Participation.**

(a) **Generally.** A Participant shall automatically participate in the next Offering Period commencing immediately after the final Purchase Date of each Offering

Period in which the Participant participates provided that the Participant remains an Eligible Employee on the Offering Date of the new Offering Period and has not either (a) withdrawn from the Plan pursuant to Section 12.1, or (b) terminated employment or otherwise ceased to be an Eligible Employee as provided in Section 13. A Participant who may automatically participate in a subsequent Offering Period, as provided in this Section, is not required to deliver any additional Subscription Agreement for the subsequent Offering Period in order to continue participation in the Plan. However, a Participant may deliver a new Subscription Agreement for a subsequent Offering Period in accordance with the procedures set forth in Section 7.1(a) if the Participant desires to change any of the elections contained in the Participant's then effective Subscription Agreement.

8. **RIGHT TO PURCHASE SHARES.**

8.1 **Grant of Purchase Right.** Except as otherwise provided below, on the Offering Date of each Offering Period, each Participant in such Offering Period shall be granted automatically a Purchase Right consisting of an option to purchase the lesser of (a) that number of whole shares of Stock determined by dividing the Dollar Limit (determined as provided below) by the Fair Market Value of a share of Stock on such Offering Date or (b) the Share Limit (determined as provided below). The Committee may, in its discretion and prior to the Offering Date of any Offering Period, (i) change the method of, or any of the foregoing factors in, determining the number of shares of Stock subject to Purchase Rights to be granted on such Offering Date, or (ii) specify a maximum aggregate number of shares that may be purchased by all Participants in an Offering or on any Purchase Date within an Offering Period. No Purchase Right shall be granted on an Offering Date to any person who is not, on such Offering Date, an Eligible Employee. For the purposes of this Section, the *"**Dollar Limit**"* shall be determined by multiplying $2,083.33 by the number of months (rounded to the nearest whole month) in the Offering Period and rounding to the nearest whole dollar, and the *"**Share Limit**"* shall be determined by multiplying two hundred (200) shares by the number of months (rounded to the nearest whole month) in the Offering Period and rounding to the nearest whole share.

8.2 **Calendar Year Purchase Limitation.** Notwithstanding any provision of the Plan to the contrary, no Participant shall be granted a Purchase Right which permits his or her right to purchase shares of Stock under the Plan to accrue at a rate which, when aggregated with such Participant's rights to purchase shares under all other employee stock purchase plans of a Participating Company intended to meet the requirements of Section 423 of the Code, exceeds Twenty-Five Thousand Dollars ($25,000) in Fair Market Value (or such other limit, if any, as may be imposed by the Code) for each calendar year in which such Purchase Right is outstanding at any time. For purposes of the preceding sentence, the Fair Market Value of shares purchased during a given Offering Period shall be determined as of the Offering Date for such Offering Period. The limitation described in this Section shall be applied in conformance with Section 423(b)(8) of the Code and the regulations thereunder.

9. **PURCHASE PRICE.**

The Purchase Price at which each share of Stock may be acquired in an Offering Period upon the exercise of all or any portion of a Purchase Right shall be established by the Committee; provided, however, that the Purchase Price on each Purchase Date shall not be less

than eighty-five percent (85%) of the lesser of (a) the Fair Market Value of a share of Stock on the Offering Date of the Offering Period or (b) the Fair Market Value of a share of Stock on the Purchase Date. Subject to adjustment as provided by the Plan and unless otherwise provided by the Committee, the Purchase Price for each Offering Period shall be eighty-five percent (85%) of the lesser of (a) the Fair Market Value of a share of Stock on the Offering Date of the Offering Period or (b) the Fair Market Value of a share of Stock on the Purchase Date.

10. **ACCUMULATION OF PURCHASE PRICE THROUGH PAYROLL DEDUCTION.**

Except as provided in Section 11.1(b) with respect to a Non-United States Offering, shares of Stock acquired pursuant to the exercise of all or any portion of a Purchase Right may be paid for only by means of payroll deductions from the Participant's Compensation accumulated during the Offering Period for which such Purchase Right was granted, subject to the following:

10.1 **Amount of Payroll Deductions.** Except as otherwise provided herein, the amount to be deducted under the Plan from a Participant's Compensation on each pay day during an Offering Period shall be determined by the Participant's Subscription Agreement. The Subscription Agreement shall set forth the percentage of the Participant's Compensation to be deducted on each pay day during an Offering Period in whole percentages of not less than one percent (1%) (except as a result of an election pursuant to Section 10.3 to stop payroll deductions effective following the first pay day during an Offering) or more than ten percent (10%). The Committee may change the foregoing limits on payroll deductions effective as of any Offering Date.

10.2 **Commencement of Payroll Deductions.** Payroll deductions shall commence on the first pay day following the Offering Date and shall continue to the end of the Offering Period unless sooner altered or terminated as provided herein.

10.3 **Election to Decrease or Stop Payroll Deductions.** During an Offering Period, a Participant may elect to decrease the rate of or to stop deductions from his or her Compensation by delivering to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) an amended Subscription Agreement authorizing such change on or before the "Change Notice Date." The *"**Change Notice Date**"* shall be a date prior to the beginning of the first pay period for which such election is to be effective as established by the Company from time to time and announced to the Participants. A Participant who elects, effective following the first pay day of an Offering Period, to decrease the rate of his or her payroll deductions to zero percent (0%) shall nevertheless remain a Participant in such Offering Period unless the Participant withdraws from the Plan as provided in Section 12.1.

10.4 **Administrative Suspension of Payroll Deductions.** The Company may, in its discretion, suspend a Participant's payroll deductions under the Plan as the Company deems advisable to avoid accumulating payroll deductions in excess of the amount that could reasonably be anticipated to purchase the maximum number of shares of Stock permitted (a) under the Participant's Purchase Right, or (b) during a calendar year under the limit set forth in Section 8.2. Unless the Participant has either withdrawn from the Plan as provided in

Section 12.1 or has ceased to be an Eligible Employee, suspended payroll deductions shall be resumed at the rate specified in the Participant's then effective Subscription Agreement either (i) at the beginning of the next Offering Period if the reason for suspension was clause (a) in the preceding sentence, or (ii) at the beginning of the next Offering Period having a first Purchase Date that falls within the subsequent calendar year if the reason for suspension was clause (b) in the preceding sentence.

10.5 **Participant Accounts.** Individual bookkeeping accounts shall be maintained for each Participant. All payroll deductions from a Participant's Compensation (and other amounts received from a non-United States Participant pursuant to Section 11.1(b)) shall be credited to such Participant's Plan account and shall be deposited with the general funds of the Company. All such amounts received or held by the Company may be used by the Company for any corporate purpose.

10.6 **No Interest Paid.** Interest shall not be paid on sums deducted from a Participant's Compensation pursuant to the Plan or otherwise credited to the Participant's Plan account.

11. **PURCHASE OF SHARES.**

11.1 **Exercise of Purchase Right.**

(a) **Generally.** Except as provided in Section 11.1(b), on each Purchase Date of an Offering Period, each Participant who has not withdrawn from the Plan and whose participation in the Offering has not otherwise terminated before such Purchase Date shall automatically acquire pursuant to the exercise of the Participant's Purchase Right the number of whole shares of Stock determined by dividing (a) the total amount of the Participant's payroll deductions accumulated in the Participant's Plan account during the Offering Period and not previously applied toward the purchase of Stock by (b) the Purchase Price. However, in no event shall the number of shares purchased by the Participant during an Offering Period exceed the number of shares subject to the Participant's Purchase Right. No shares of Stock shall be purchased on a Purchase Date on behalf of a Participant whose participation in the Offering or the Plan has terminated before such Purchase Date.

(b) **Purchase by Non-United States Participants for Whom Payroll Deductions Are Prohibited by Applicable Law.** Notwithstanding Section 11.1(a), where payroll deductions on behalf of Participants who are citizens or residents of countries other than the United States (without regard to whether they are also citizens of the United States or resident aliens) are prohibited by applicable law, the Committee may establish a separate Offering (a "***Non-United States Offering***") covering all Eligible Employees of one or more Participating Companies subject to such prohibition on payroll deductions. The Non-United States Offering shall provide another method for payment of the Purchase Price with such terms and conditions as shall be administratively convenient and comply with applicable law. On each Purchase Date of the Offering Period applicable to a Non-United States Offering, each Participant who has not withdrawn from the Plan and whose participation in such Offering Period has not otherwise terminated before such Purchase Date shall automatically acquire pursuant to the exercise of the Participant's Purchase Right a number of whole shares of Stock

determined in accordance with Section 11.1(a) to the extent of the total amount of the Participant's Plan account balance accumulated during the Offering Period in accordance with the method established by the Committee and not previously applied toward the purchase of Stock. However, in no event shall the number of shares purchased by a Participant during such Offering Period exceed the number of shares subject to the Participant's Purchase Right. The Company shall refund to a Participant in a Non-United States Offering in accordance with Section 11.4 any excess Purchase Price payment received from such Participant.

11.2 **Pro Rata Allocation of Shares.** If the number of shares of Stock which might be purchased by all Participants on a Purchase Date exceeds the number of shares of Stock remaining available for issuance under the Plan or the maximum aggregate number of shares of Stock that may be purchased on such Purchase Date pursuant to a limit established by the Committee pursuant to Section 8.1, the Company shall make a pro rata allocation of the shares available in as uniform a manner as practicable and as the Company determines to be equitable. Any fractional share resulting from such pro rata allocation to any Participant shall be disregarded.

11.3 **Delivery of Title to Shares.** Subject to any governing rules or regulations, as soon as practicable after each Purchase Date, the Company shall issue or cause to be issued to or for the benefit of each Participant the shares of Stock acquired by the Participant on such Purchase Date by means of one or more of the following: (a) by delivering to the Participant evidence of book entry shares of Stock credited to the account of the Participant, (b) by depositing such shares of Stock for the benefit of the Participant with any broker with which the Participant has an account relationship, or (c) by delivering such shares of Stock to the Participant in certificate form.

11.4 **Return of Plan Account Balance.** Any cash balance remaining in a Participant's Plan account following any Purchase Date shall be refunded to the Participant as soon as practicable after such Purchase Date. However, if the cash balance to be returned to a Participant pursuant to the preceding sentence is less than the amount that would have been necessary to purchase an additional whole share of Stock on such Purchase Date, the Company may retain the cash balance in the Participant's Plan account to be applied toward the purchase of shares of Stock in the subsequent Purchase Period or Offering Period.

11.5 **Tax Withholding.** At the time a Participant's Purchase Right is exercised, in whole or in part, or at the time a Participant disposes of some or all of the shares of Stock he or she acquires under the Plan, the Participant shall make adequate provision for the federal, state, local and foreign taxes (including social insurance), if any, required to be withheld by any Participating Company upon exercise of the Purchase Right or upon such disposition of shares, respectively. A Participating Company may, but shall not be obligated to, withhold from the Participant's compensation the amount necessary to meet such withholding obligations.

11.6 **Expiration of Purchase Right.** Any portion of a Participant's Purchase Right remaining unexercised after the end of the Offering Period to which the Purchase Right relates shall expire immediately upon the end of the Offering Period.

11.7 **Provision of Reports and Stockholder Information to Participants.** Each Participant who has exercised all or part of his or her Purchase Right shall receive, as soon as practicable after the Purchase Date, a report of such Participant's Plan account setting forth the total amount credited to his or her Plan account prior to such exercise, the number of shares of Stock purchased, the Purchase Price for such shares, the date of purchase and the cash balance, if any, remaining immediately after such purchase that is to be refunded or retained in the Participant's Plan account pursuant to Section 11.4. The report required by this Section may be delivered in such form and by such means, including by electronic transmission, as the Company may determine. In addition, each Participant shall be provided information concerning the Company equivalent to that information provided generally to the Company's common stockholders.

12. **WITHDRAWAL FROM PLAN.**

12.1 **Voluntary Withdrawal from the Plan.** A Participant may withdraw from the Plan by signing and delivering to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) a written or electronic notice of withdrawal on a form provided by the Company for this purpose. Such withdrawal may be elected at any time prior to the end of an Offering Period; provided, however, that if a Participant withdraws from the Plan after a Purchase Date, the withdrawal shall not affect shares of Stock acquired by the Participant on such Purchase Date. A Participant who voluntarily withdraws from the Plan is prohibited from resuming participation in the Plan in the same Offering from which he or she withdrew, but may participate in any subsequent Offering by again satisfying the requirements of Sections 5 and 7.1. The Company may impose, from time to time, a requirement that the notice of withdrawal from the Plan be on file with the Company office or representative designated by the Company for a reasonable period prior to the effectiveness of the Participant's withdrawal.

12.2 **Return of Plan Account Balance.** Upon a Participant's voluntary withdrawal from the Plan pursuant to Section 12.1, the Participant's accumulated Plan account balance which has not been applied toward the purchase of shares of Stock shall be refunded to the Participant as soon as practicable after the withdrawal, without the payment of any interest, and the Participant's interest in the Plan and the Offering shall terminate. Such amounts to be refunded in accordance with this Section may not be applied to any other Offering under the Plan.

13. **TERMINATION OF EMPLOYMENT OR ELIGIBILITY.**

Upon a Participant's ceasing, prior to a Purchase Date, to be an Employee of the Participating Company Group for any reason, including retirement, disability or death, or upon the failure of a Participant to remain an Eligible Employee, the Participant's participation in the Plan shall terminate immediately. In such event, the Participant's Plan account balance which has not been applied toward the purchase of shares of Stock shall, as soon as practicable, be returned to the Participant or, in the case of the Participant's death, to the Participant's beneficiary designated in accordance with Section 20, if any, or legal representative, and all of the Participant's rights under the Plan shall terminate. Interest shall not be paid on sums returned

pursuant to this Section 13. A Participant whose participation has been so terminated may again become eligible to participate in the Plan by satisfying the requirements of Sections 5 and 7.1.

14. **EFFECT OF CHANGE IN CONTROL ON PURCHASE RIGHTS.**

In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or parent thereof, as the case may be (the *"**Acquiring Corporation**"*), may, without the consent of any Participant, assume or continue the Company's rights and obligations under outstanding Purchase Rights or substitute substantially equivalent purchase rights for the Acquiring Corporation's stock. If the Acquiring Corporation elects not to assume, continue or substitute for the outstanding Purchase Rights, the Purchase Date of the then current Offering Period shall be accelerated to a date before the date of the Change in Control specified by the Committee, but the number of shares of Stock subject to outstanding Purchase Rights shall not be adjusted. All Purchase Rights which are neither assumed or continued by the Acquiring Corporation in connection with the Change in Control nor exercised as of the date of the Change in Control shall terminate and cease to be outstanding effective as of the date of the Change in Control.

15. **NONTRANSFERABILITY OF PURCHASE RIGHTS.**

Neither payroll deductions or other amounts credited to a Participant's Plan account nor a Participant's Purchase Right may be assigned, transferred, pledged or otherwise disposed of in any manner other than as provided by the Plan or by will or the laws of descent and distribution. (A beneficiary designation pursuant to Section 20 shall not be treated as a disposition for this purpose.) Any such attempted assignment, transfer, pledge or other disposition shall be without effect, except that the Company may treat such act as an election to withdraw from the Plan as provided in Section 12.1. A Purchase Right shall be exercisable during the lifetime of the Participant only by the Participant.

16. **COMPLIANCE WITH SECURITIES LAW.**

The issuance of shares under the Plan shall be subject to compliance with all applicable requirements of federal, state and foreign law with respect to such securities. A Purchase Right may not be exercised if the issuance of shares upon such exercise would constitute a violation of any applicable federal, state or foreign securities laws or other law or regulations or the requirements of any securities exchange or market system upon which the Stock may then be listed. In addition, no Purchase Right may be exercised unless (a) a registration statement under the Securities Act shall at the time of exercise of the Purchase Right be in effect with respect to the shares issuable upon exercise of the Purchase Right, or (b) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Purchase Right may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares under the Plan shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained. As a condition to the exercise of a Purchase Right, the Company may require the Participant to satisfy any qualifications that may be necessary or

appropriate, to evidence compliance with any applicable law or regulation, and to make any representation or warranty with respect thereto as may be requested by the Company.

17. **RIGHTS AS A STOCKHOLDER AND EMPLOYEE.**

A Participant shall have no rights as a stockholder by virtue of the Participant's participation in the Plan until the date of the issuance of the shares of Stock purchased pursuant to the exercise of the Participant's Purchase Right (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for dividends, distributions or other rights for which the record date is prior to the date such shares are issued, except as provided in Section 4.3. Nothing herein shall confer upon a Participant any right to continue in the employ of the Participating Company Group or interfere in any way with any right of the Participating Company Group to terminate the Participant's employment at any time.

18. **NOTIFICATION OF DISPOSITION OF SHARES.**

The Company may require the Participant to give the Company prompt notice of any disposition of shares of Stock acquired by exercise of a Purchase Right. The Company may require that until such time as a Participant disposes of shares of Stock acquired upon exercise of a Purchase Right, the Participant shall hold all such shares in the Participant's name until the later of two years after the date of grant of such Purchase Right or one year after the date of exercise of such Purchase Right. The Company may direct that the certificates evidencing shares of Stock acquired by exercise of a Purchase Right refer to such requirement to give prompt notice of disposition.

19. **LEGENDS.**

The Company may at any time place legends or other identifying symbols referencing any applicable federal, state or foreign securities law restrictions or any provision convenient in the administration of the Plan on some or all of the certificates representing shares of Stock issued under the Plan. The Participant shall, at the request of the Company, promptly present to the Company any and all certificates representing shares acquired pursuant to a Purchase Right in the possession of the Participant in order to carry out the provisions of this Section. Unless otherwise specified by the Company, legends placed on such certificates may include but shall not be limited to the following:

"THE SHARES EVIDENCED BY THIS CERTIFICATE WERE ISSUED BY THE CORPORATION TO THE REGISTERED HOLDER UPON THE PURCHASE OF SHARES UNDER AN EMPLOYEE STOCK PURCHASE PLAN AS DEFINED IN SECTION 423 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED. THE TRANSFER AGENT FOR THE SHARES EVIDENCED HEREBY SHALL NOTIFY THE CORPORATION IMMEDIATELY OF ANY TRANSFER OF THE SHARES BY THE REGISTERED HOLDER HEREOF. THE REGISTERED HOLDER SHALL HOLD ALL SHARES PURCHASED UNDER THE PLAN IN THE REGISTERED HOLDER'S NAME (AND NOT IN THE NAME OF ANY NOMINEE)."

20. **DESIGNATION OF BENEFICIARY.**

20.1 **Designation Procedure.** Subject to local laws and procedures, a Participant may file a written designation of a beneficiary who is to receive (a) shares and cash, if any, from the Participant's Plan account if the Participant dies subsequent to a Purchase Date but prior to delivery to the Participant of such shares and cash, or (b) cash, if any, from the Participant's Plan account if the Participant dies prior to the exercise of the Participant's Purchase Right. If a married Participant designates a beneficiary other than the Participant's spouse, the effectiveness of such designation may be subject to the consent of the Participant's spouse. A Participant may change his or her beneficiary designation at any time by written notice to the Company.

20.2 **Absence of Beneficiary Designation.** If a Participant dies without an effective designation pursuant to Section 20.1 of a beneficiary who is living at the time of the Participant's death, the Company shall deliver any shares or cash credited to the Participant's Plan account to the Participant's legal representative or as otherwise required by applicable law.

21. **NOTICES.**

All notices or other communications by a Participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

22. **AMENDMENT OR TERMINATION OF THE PLAN.**

The Committee may at any time amend, suspend or terminate the Plan, except that (a) no such amendment, suspension or termination shall affect Purchase Rights previously granted under the Plan unless expressly provided by the Committee, and (b) no such amendment, suspension or termination may adversely affect a Purchase Right previously granted under the Plan without the consent of the Participant, except to the extent permitted by the Plan or as may be necessary to qualify the Plan as an employee stock purchase plan pursuant to Section 423 of the Code or to comply with any applicable law, regulation or rule. In addition, an amendment to the Plan must be approved by the stockholders of the Company within twelve (12) months of the adoption of such amendment if such amendment would authorize the sale of more shares than are then authorized for issuance under the Plan or would change the definition of the corporations that may be designated by the Committee as Participating Companies. Notwithstanding the foregoing, in the event that the Committee determines that continuation of the Plan or an Offering would result in unfavorable financial accounting consequences to the Company, the Committee may, in its discretion and without the consent of any Participant, including with respect to an Offering Period then in progress: (i) terminate the Plan or any Offering Period, (ii) accelerate the Purchase Date of any Offering Period, (iii) reduce the discount or the method of determining the Purchase Price in any Offering Period (e.g., by determining the Purchase Price solely on the basis of the Fair Market Value on the Purchase Date), (iv) reduce the maximum number of shares of Stock that may be purchased in any Offering Period, or (v) take any combination of the foregoing actions.

IN WITNESS WHEREOF, the undersigned Secretary of the Company certifies that the foregoing sets forth the Kadmon Holdings, Inc. 2016 Employee Stock Purchase Plan as duly adopted by the Board on , 2016.

, Secretary

APPENDIX A

Participating Companies

Kadmon Holdings, Inc.
Kadmon Corporation, LLC
Kadmon Pharmaceuticals, LLC

Exhibit 10.17

THIRD AMENDMENT TO
SUPPLY AND DISTRIBUTION AGREEMENT

This Third Amendment modifies the Supply and Distribution Agreement by and between Kadmon Pharmaceuticals, LLC, a Pennsylvania Limited Liability Company ("**KADMON**"), with its principal place of business at 119 Commonwealth Drive, Warrendale, PA 15086 and Camber Pharmaceuticals, Inc., a Delaware company ("**CAMBER**"), with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854, effective as of February 23, 2016 and amended on May 20, 2016 and August 23, 2016 (collectively, the "**Agreement**"). Capitalized terms not otherwise defined herein have the meanings ascribed to them in the Agreement.

RECITALS

WHEREAS, KADMON and CAMBER previously entered into the Agreement for the purposes of marketing, selling and distributing the Products in the Territory and now wish to extend the term of the Agreement.

NOW, THEREFORE, in consideration of the representations, warranties and covenants set forth herein, the Parties agree to amend the Agreement as follows:

1. This Amendment shall become effective on the date it is fully executed by both parties.

2. Section 9.1 is hereby amended to extend the Initial Term of the Agreement by an additional twelve (12) months from the date of the end of the Initial Term, unless earlier terminated in accordance with Section 9.2 of the Agreement or otherwise mutually agreed in writing by the Parties.

3. To the extent not otherwise changed or affected by this Amendment, both Parties agree that all terms, conditions, provisions and/or covenants included in the original Agreement will continue to have the same force and effect intended.

IN WITNESS WHEREOF, the parties hereto have each caused this Amendment to be executed by their duly authorized officers.

KADMON PHARMACEUTICALS, LLC	**CAMBER PHARMACEUTICALS, INC.**
By:_____	By:_____
Name: Haya Taitel	Name:
Date: February 9, 2017	Date:

Exhibit 10.20

FOURTH WAIVER AGREEMENT TO CREDIT AGREEMENT

This FOURTH WAIVER AGREEMENT TO CREDIT AGREEMENT, dated as of March 22, 2017 (this "Agreement"), is entered into by and among Kadmon Pharmaceuticals, LLC, a Pennsylvania limited liability company (the "Borrower"), the guarantors party hereto and each of the lenders listed on the signature pages hereof under the heading "LENDERS". Unless otherwise defined herein or the context otherwise requires, terms used in this Agreement, including its preamble and recitals, have the meanings provided in the Credit Agreement (defined below).

W I T N E S S E T H:

WHEREAS, the Borrower, the Guarantors from time to time party thereto, the Lenders from time to time party thereto and Perceptive Credit Holdings, LP, as Collateral Representative, have entered into that certain Credit Agreement, dated as of August 28, 2015 (as subsequently amended or otherwise modified from time to time, the "Credit Agreement");

WHEREAS, the Borrower has requested that the Majority Lenders waive Section 8.01(c) of the Credit Agreement but only to the extent necessary to permit the required report and opinion of BDO USA LLP for fiscal year 2016 (the "2016 Annual Report") to contain a "going concern" or like qualification, exception or explanation (the "Specified Qualification"); and

WHEREAS, upon the request of the Borrower and subject to the terms and conditions set forth herein, the Majority Lenders have agreed to waive the requirement set forth in Section 8.01(c) and permit the Specified Qualification only to the extent applicable to fiscal year 2016.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows.

Article I
DEFINITIONS

SECTION 1.1. Certain Terms. The following terms (whether or not underscored) when used in this Agreement, including its preamble and recitals, shall have the following meanings (such definitions to be equally applicable to the singular and plural forms thereof):

"2016 Annual Report" is defined in the second recital.

"Agreement" is defined in the preamble.

"Borrower" is defined in the preamble.

"Credit Agreement" is defined in the first recital.

"Effective Date" is defined in Section 2.1 of this Agreement.

Article II
CERTAIN AMENDMENTS AND MODIFICATION TO the CREDIT AGREEMENT

SECTION 2.1. Partial Waiver of Commitments Under Section 8.01(c). Effective as of the date hereof (the "Effective Date"), the Lenders hereby agree to waive the requirements of Section 8.01(c) of the Credit Agreement to the extent, and only to the extent, necessary to permit the 2016 Annual Report to contain the Specified Qualification.

SECTION 2.2. Limited Waiver. Except as expressly so waived or consented to, as applicable, the parties hereto expressly acknowledge and agree that (i) all other terms and provisions of the Credit Agreement and each other Loan Document shall continue in full force and effect in accordance with its terms and (ii) any waivers, consents or other modifications set forth in this Agreement are limited as expressly set forth herein, and shall not be deemed to constitute a waiver of any Default or Event of Default or any future breach of the Credit Agreement or any of the other Loan Documents.

Article III
conditions TO EFFECTIVENESS

SECTION 3.1. Conditions to Effectiveness. This Agreement shall become effective as of the Effective Date upon satisfaction of the following:

(a) the Lenders shall have received counterparts of this Agreement duly executed by each of the Obligors and the Lenders party hereto; and

(b) the Lenders shall have received a certificate, dated as of the date hereof and duly executed and delivered by a Responsible Officer of the Borrower certifying as to the matters set forth in Articles IV and V hereof.

Article IV
Representations and Warranties

To induce the Lenders to enter into this Agreement, each Obligor represents and warrants to the Collateral Representative and the Lenders as set forth below.

SECTION 4.1. Validity, etc. This Agreement, the Credit Agreement and the other Loan Documents (both before and after giving effect to this Agreement) constitute the legal, valid and binding obligation of such Obligor, enforceable in accordance with its respective terms, subject to the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally, general equitable principles (whether considered in a proceeding in equity or at law) and an implied covenant of good faith and fair dealing.

SECTION 4.2. Representations and Warranties, etc. Immediately prior to, on the Effective Date and immediately after giving effect to, this Agreement, the following statements shall be true and correct:

(a) the representations and warranties set forth in each Loan Document shall, in each case, be true and correct in all material respects with the same effect as if then made (unless stated to relate solely to an earlier date, in which case such representations and warranties shall be true and correct in all material respects as of such earlier date); and

(b) no Default or Event of Default shall have then occurred and be continuing.

Article V
Confirmation

SECTION 5.1. Guarantees, Security Interest, Continued Effectiveness. Each Obligor hereby consents to the modifications made to the Loan Documents pursuant to this Agreement and hereby agrees that, after giving effect to this Agreement, each Loan Document to which it is a party is and shall continue to be in full force and effect and the same are hereby ratified in all respects, except that upon the occurrence of the Waiver Effective Date, all references in such Loan Documents to the "Credit Agreement", "Loan Documents", "thereunder", "thereof", or words of similar import shall mean the Credit Agreement and the other Loan Documents, as amended or otherwise modified by this Agreement.

Article VI
Miscellaneous

SECTION 6.1. Cross-References. References in this Agreement to any Article or Section are, unless otherwise specified, to such Article or Section of this Agreement.

SECTION 6.2. Loan Document Pursuant to Credit Agreement. This Agreement is a Loan Document executed pursuant to the Credit Agreement and shall (unless otherwise expressly indicated therein) be construed, administered and applied in accordance with all of the terms and provisions of the Credit Agreement, as amended hereby, including Section 13 thereof.

SECTION 6.3. Successors and Assigns. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective permitted successors and assigns.

SECTION 6.4. Counterparts. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart.

SECTION 6.5. Governing Law. **THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK, WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAWS THAT WOULD RESULT IN THE APPLICATION OF THE LAWS OF ANY OTHER JURISDICTION; PROVIDED THAT SECTION 5-1401 OF THE NEW YORK GENERAL OBLIGATIONS LAW SHALL APPLY.**

SECTION 6.6. Full Force and Effect; Limited Waiver and Consent. Except as expressly amended hereby, the Obligors each jointly and severally agree that all of the

representations, warranties, terms, covenants, conditions and other provisions of the Credit Agreement and the other Loan Documents shall remain unchanged and shall continue to be, and shall remain, in full force and effect in accordance with their respective terms. The amendments, consents and other waivers and modifications set forth in this Agreement shall be limited precisely as provided for herein to the provisions expressly amended herein or otherwise modified or waived hereby and shall not be deemed to be an amendment to, waiver of, consent to or modification of any other term or provision of the Credit Agreement or any other Loan Document or of any transaction or further or future action on the part of any Obligor which would require the consent of the Lenders under the Credit Agreement, the Credit Agreement or any of the Loan Documents.

SECTION 6.7. No Waiver. Except as otherwise specified herein, this Agreement is not, and shall not be deemed to be, a waiver or consent to any Default or Event of Default, or other non-compliance now existing or hereafter arising under the Credit Agreement and the other Loan Documents.

[Signature pages to follow]

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be duly executed and delivered by a Responsible Officer as of the date first above written.

borrower:

Kadmon PHARMACEUTICALS, LLC

By:

Name:

Title:

Guarantors:

Kadmon Corporation, LLC

By:

Name:

Title:

Kadmon Holdings, INC

By:

Name:

Title:

Kadmon Research Institute, LLC

By:

Name:

Title:

Three rivers research institute i, LLC

By:

Name:

Title:

three rivers biologicS, LLC

By:

Name:

Title:

three rivers global pharma, LLC

By:

Name:

Title:

COLLATERAL REPRESENTATIVE:

PERceptive credit holdings, Lp
By: Perceptive Credit Opportunities GP, LLC, its general partner

By
Name:
Title:

By
Name:
Title:

MAJORITY LENDERS:

PERceptive credit holdings, Lp
By: Perceptive Credit Opportunities GP, LLC, its general partner

By
Name:
Title:

By
Name:
Title:

Exhibit 10.8

SECOND AMENDMENT TO
SUPPLY AND DISTRIBUTION AGREEMENT

This Second Amendment modifies the Supply and Distribution Agreement by and between Kadmon Pharmaceuticals, LLC, a Pennsylvania Limited Liability Company ("**KADMON**"), with its principal place of business at 119 Commonwealth Drive, Warrendale, PA 15086 and Camber Pharmaceuticals, Inc., a Delaware company ("**CAMBER**"), with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854, effective as of February 23, 2016 and amended on May 20, 2016 (collectively, the "**Agreement**"). Capitalized terms not otherwise defined herein have the meanings ascribed to them in the Agreement.

RECITALS

WHEREAS, KADMON and CAMBER previously entered into the Agreement for the purposes of marketing, selling and distributing the Products in the Territory;

WHEREAS, CAMBER has Regulatory Approval to manufacture, sell, and distribute the Products identified in the revised Product Appendix attached hereto, and has, either directly or through its Affiliates, the capability to manufacture the Products;

WHEREAS, KADMON wishes to obtain commercial supplies of the Products identified in the revised Product Appendix attached hereto from CAMBER for distribution by KADMON in the Territory; and

WHEREAS, CAMBER desires to appoint KADMON, and KADMON desires to accept such appointment by CAMBER, as a Distributor for the purposes of marketing, selling and distributing the Products identified in the revised Product Appendix attached hereto in the Territory, subject to the terms and conditions of the Agreement.

NOW, THEREFORE, in consideration of the representations, warranties and covenants set forth herein, the Parties agree to amend the Agreement as follows:

1. This Amendment shall become effective the date it is fully executed by both parties (the "**Effective Date**").

2. Exhibit A of the Agreement shall be replaced with the revised Exhibit A attached hereto.

3. Exhibit D of the Agreement shall be replaced with the revised Exhibit D attached hereto.

4. To the extent not otherwise changed or affected by this Amendment, both Parties agree that all terms, conditions, provisions and/or covenants included in the original Agreement will continue to have the same force and effect intended.

[*signature page to follow*]

IN WITNESS WHEREOF, the parties hereto have each caused this Amendment to be executed by their duly authorized officers.

KADMON PHARMACEUTICALS, LLC

By:_____
Name & Title: Eva Heyman, Chief Commercial Officer
Date: March 22, 2017

CAMBER PHARMACEUTICALS, INC.

By:_____
Name & Title:
Date:

EXHIBIT A: PRODUCT APPENDIX

Product	Dosage	Unit	NDC
TETRABENAZINE	12.5MG	112 CT	31722-821-11
TETRABENAZINE	25MG	112 CT	31722-822-11
VALGANCICLOVIR	450MG	60 CT	31722-832-60
ABACAVIR	300MG	60 CT	31722-557-60
ENTECAVIR	0.5MG	30 CT	31722-833-30
ENTECAVIR	0.5MG	90 CT	31722-833-90
ENTECAVIR	1MG	30 CT	31722-834-30
LAMIVUDINE	100MG	60 CT	31722-752-60
LAMIVUDINE	150MG	60 CT	31722-753-60
LAMIVUDINE	300MG	30 CT	31722-754-30
LAMIVUDINE/ ZIDOVUDINE	150MG/300MG	60 CT	31722-506-60

EXHIBIT D: PRICING

Product	Dosage	Unit	NDC	Price
TETRABENAZINE	12.5MG	112 CT	31722-821-11	$500.00 per unit
TETRABENAZINE	25MG	112 CT	31722-822-11	$950.00 per unit
VALGANCICLOVIR	450MG	60 CT	31722-832-60	$726.00 per unit
ABACAVIR	300MG	60 CT	31722-557-60	$94.00 per unit
ENTECAVIR	0.5MG	30 CT	31722-833-30	$126.86 per unit
ENTECAVIR	0.5MG	90 CT	31722-833-90	$400.59 per unit
ENTECAVIR	1MG	30 CT	31722-834-30	$126.86 per unit
LAMIVUDINE	100MG	60 CT	31722-752-60	$122.29 per unit
LAMIVUDINE	150MG	60 CT	31722-753-60	$35.09 per unit
LAMIVUDINE	300MG	30 CT	31722-754-30	$35.09 per unit
LAMIVUDINE/ ZIDOVUDINE	150MG/300MG	60 CT	31722-506-60	$46.78 per unit

EXHIBIT 21.1

List of Subsidiaries of the Registrant

Name of Subsidiary	Jurisdiction of Organization
Kadmon Corporation, LLC	Delaware
Kadmon Pharmaceuticals, LLC	Pennsylvania

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Kadmon Holdings, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No.333-213748) of Kadmon Holdings, Inc. of our report dated March 22, 2017, relating to the consolidated financial statements which appear in the December 31, 2016 annual report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
New York, New York

March 22, 2017

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Harlan W. Waksal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kadmon Holdings, 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)):

   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) 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

   c) 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.

Dated: March 22, 2017

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULES 13a-14 AND 15d-14, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Konstantin Poukalov, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kadmon Holdings, 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)):

   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) 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

   c) 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.

Dated: March 22, 2017

/s/ Konstantin Poukalov
Konstantin Poukalov
Executive Vice President, Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Kadmon Holdings, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Harlan W. Waksal, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 22, 2017

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Annual Report on Form 10-K of Kadmon Holdings, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Konstantin Poukalov, Executive Vice President, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 22, 2017

/s/ Konstantin Poukalov
Konstantin Poukalov
Executive Vice President, Chief Financial Officer