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

FORM 10-K

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

For the fiscal year ended December 31, 2016.

OR

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

For the transition period from _____ to _____.

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4087132**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Marina Park Drive, 12th Floor Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 466-3500

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

Common Stock, Par Value $0.001 Per Share	**Nasdaq Capital Market**
(Title of Class)	**(Name of Each Exchange on Which Registered)**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	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 ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was $524,807,000 as of June 30, 2016, based on the closing sale price of such stock as reported on the Nasdaq Capital Market.

There were 107,667,795 shares of the registrant's common stock outstanding as of February 22, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2017 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

KERYX BIOPHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2016

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "will," "project" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Auryxia® (ferric citrate), market share and product sales guidance;
- expectations regarding the commercialization of Auryxia;
- expectations regarding our ability to successfully develop and obtain U.S. Food and Drug Administration approval of Auryxia for the treatment of iron deficiency anemia in non-dialysis dependent chronic kidney disease patients;
- expectations regarding our ability to identify a commercial partner(s) to launch Fexeric® (ferric citrate coordination complex) in the European market;
- expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expected losses;
- expectations for future capital requirements;
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of ferric citrate or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and its subsidiary, Torii Pharmaceutical Co., Ltd.;
- expectations of the scope of patent protection with respect to Auryxia, Fexeric and Riona;
- expectations or ability to enter into marketing and other partnership agreements; and
- expectations or ability to enter into product acquisition and in-licensing transactions.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I

Unless the context requires otherwise, references in this report to "Keryx," "Company," "we," "us" and "our" and similar designations refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

ITEM 1. BUSINESS.

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, and approved in Europe as Fexeric. We are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent, CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that help patients with kidney disease. We use the brand name Auryxia only when we refer to the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines for the treatment of people with kidney disease to the market that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is a non-chewable, orally-administered phosphate binder for patients on dialysis. Auryxia is being marketed in the United States to renal care teams through our specialty salesforce and commercial infrastructure. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to continue to drive commercial adoption of Auryxia in the dialysis setting following the return of this medicine to patients in November 2016.

We also believe that we can maximize the potential of ferric citrate through potential label expansion for the treatment of IDA, NDD-CKD patients. We completed a pivotal Phase 3 clinical trial evaluating ferric citrate for this indication and presented results from this trial to the medical community at the American Society of Nephrology's Kidney Week 2016 Annual Meeting. The results from this trial were also published online in the *Journal of the American Society of Nephrology* in January 2017. We submitted a supplemental new drug application, or sNDA, to the U.S. Food and Drug Administration, or FDA, in January 2017 seeking to expand the label for Auryxia to include the treatment of IDA in NDD-CKD patients and expect that the sNDA will be accepted by the FDA for review. We anticipate a standard review cycle for this sNDA and, if approved, could potentially make the medicine available to these patients late in 2017. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist have IDA, NDD-CKD, including approximately 650,000 adults currently being treated by nephrologists for IDA. IDA is common in the NDD-CKD population and the prevalence and severity increases as CKD advances. IDA is symptomatic and can significantly impact quality of life. No oral iron medications are currently FDA-approved to treat IDA, NDD-CKD.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that help patients with kidney disease. Our business development activities include evaluating several clinical-drug candidates and commercial medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a work force of high-quality and talented people to support our potential growth.

CORPORATE INFORMATION

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. Our corporate offices are located at One Marina Park Drive, 12th Floor, Boston, Massachusetts 02210. Our telephone number is 617-466-3500, and our e-mail address is info@keryx.com.

We maintain a website with the address *http://www.keryx.com*. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to the Securities and Exchange Commission, or SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is *http://www.sec.gov*.

AURYXIA (FERRIC CITRATE)

Commercial Program

Auryxia is an oral, absorbable iron-based medicine approved in the United States for the control of serum phosphorus levels in patients with CKD on dialysis. It is also marketed in Japan under the brand name Riona by our Japanese partner, JT and Torii, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD. We receive royalties from JT and Torii based on their sales in Japan. Our efforts and associated expenses are focused on commercializing Auryxia in the United States.

Auryxia's mechanism of action works as an oral ferric iron tablet with the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes to reduce intestinal absorption and aid in the management of hyperphosphatemia in patients with CKD. The U.S. approval of Auryxia was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Auryxia effectively reduced serum phosphorus levels to within the Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Auryxia's pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation, or TSAT; whereas these parameters remained relatively constant in patients treated in the active control arm (Renvela® and/or Phoslo®) in our Phase 3 registration program. The most common adverse events for Auryxia-treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough.

Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. In addition, we have a small team of national account managers who are primarily responsible for working with insurance plans, health maintenance organizations and other payers to secure reimbursement and formulary access for Auryxia. In December 2014, we created the Keryx Patient Plus program to assist with patient accessibility to Auryxia. The Keryx Patient Plus program offers benefit verification, co-pay assistance for eligible commercial patients, a no-cost drug program for those who qualify, and a short-term prescription bridge program that may assist those already on Auryxia who are in danger of suffering a lapse in coverage.

In the third quarter of 2016, our collaborator, JT and Torii, commenced enrollment in a Phase 2 clinical trial of ferric citrate for the treatment of IDA.

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-

CKD. The EC also considered Fexeric as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union, or EU. We do not plan to launch Fexeric on our own in the EU.

Ferric Citrate Label Expansion Opportunity

Auryxia's mechanism of action has also shown to increase iron parameters, including TSAT and ferritins. In 2016, we completed the pivotal Phase 3 study of ferric citrate for the treatment of IDA, in adults with Stage 3-5 NDD-CKD. In March, we announced topline data from this trial, and in November we presented results from this study to the medical community at the American Society of Nephrology's Kidney Week 2016 Annual Meeting. The full data were subsequently published online in the peer-reviewed publication, *Journal of the American Society of Nephrology*, in January 2017. The study's primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period of the study. Secondary endpoints in the Phase 3 study included the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The results demonstrated statistically significant differences between ferric citrate- and placebo-treated patients for the primary endpoint and all pre-specified secondary endpoints. The majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period as comparted to 19 percent in the placebo group ($p<0.001$). Additionally, the safety profile of the investigational medicine was consistent with previously reported clinical studies of ferric citrate, with the majority of adverse events reported as mild to moderate. These results were included in the sNDA, submitted in January 2017 seeking to expand the label for ferric citrate to include the treatment of IDA in adults with NDD-CKD.

Foreign Operations

We have no foreign operations. Revenues from customers outside of the United States amounted to approximately 15% and 26% of our total revenues for 2016 and 2015, respectively. Sales of ferric citrate outside of the United States do not and are not expected to materially contribute to our revenues.

Market Opportunity

In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as ESRD). Managing ESRD is complex as many metabolic factors, such as iron and phosphorus, are out of balance. Phosphate retention and the resulting hyperphosphatemia in dialysis patients are typically associated with increased risk for heart and bone disease and death. The majority of ESRD patients require chronic treatment with phosphate-binding agents to lower and maintain serum phosphorus at acceptable levels. There are approximately 3.0 million prescriptions written in the United States for phosphate binders annually. Although the majority of dialysis patients are treated with phosphate binders, according to the Dialysis Outcomes and Practice Patterns Study, or DOPPS, program, 30-40 percent of these patients still have serum phosphorus levels above the KDOQI guidelines recommended range. DOPPS is one of the largest prospective studies of ESRD patients worldwide and includes samples from dialysis patients and units in multiple countries, including the United States to identify clinical practices that benefit patients. As we continue to increase utilization of Auryxia in the dialysis setting, our sales force is focused on asking renal care teams to try Auryxia on patients with serum phosphorus levels outside of the target range. At the American Society of Nephrology's 2016 Kidney Week in November, case study data from 92 patient charts for Auryxia were presented that showed treatment with this medicine lowered and maintained serum phosphorus levels in CKD patients on dialysis. Specifically, the majority of patients when started on Auryxia achieved target serum phosphorus levels within the KDOQI guideline target range at six months of treatment -- 48 percent and 65 percent of patients at one and six months, respectively.

In addition, it is estimated that more than 10 percent of the U.S. adult population is affected by CKD. As kidney function declines levels of serum phosphorus become more prevalent especially in non-dialysis stages 3-5 of CKD, which are the more progressive stages of CKD. Several studies have shown that higher serum phosphorus concentrations may be associated with increased mortality and morbidity in CKD; however, no phosphate binders are currently FDA approved for NDD-CKD.

IDA is extremely prevalent in the NDD-CKD population and is associated with fatigue, lethargy, decreased quality of life and is also believed to be associated with cardiovascular complications, hospitalizations, and increased mortality. Given our field force interacts primarily with nephrologists, we have conducted market research to assess how many patients under the care of a nephrologist have IDA and how many of those are treated. Our research shows that approximately 650,000 patients under the care of a nephrologist are treated for their IDA, and another 250,000 to 400,000 have IDA, but are not currently being treated. To treat this type of anemia, iron replacement therapy is essential to increase iron stores, which is reflected in ferritin and TSAT levels, and to raise hemoglobin levels. Market insights from proprietary research and Spherix Global Insights data show that a need exists for an effective, well-tolerated, convenient IDA treatment. Nephrologists report low satisfaction with

existing oral iron therapies due to tolerability. No oral iron medications are currently FDA-approved to treat IDA in NDD-CKD, and guidelines recommend treating first with oral iron. Erythropoiesis-stimulating agent, or ESAs, and intravenous, or IV, iron are viewed as effective treatment but are not frequently administered in NDD-CKD due to potential hypersensitivity reactions, including anaphylaxis and logistical complications associated with administering IV medicines in office settings.

CKD on Dialysis: Auryxia Approval and Phase 3 Registration Clinical Program

In September 2014, we received approval from the FDA to market Auryxia for the control of elevated serum phosphorus levels in patients with CKD on dialysis. In January 2014, our Japanese partner received approval from the Japanese Ministry of Health, Labour and Welfare to market Riona in Japan as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD. In September 2015, the EC approved Fexeric for the control of serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. These approvals to treat patients with CKD on dialysis in the United States were based on our Phase 3 clinical registration program in which we conducted a Phase 3 short-term trial (completed in November 2010), a Phase 3 long-term trial (completed in January 2013) and a long-term open label extension, or OLE, trial (completed in July 2014). The two Phase 3 trials showed that treatment with Auryxia resulted in changes in serum phosphorus levels during and at the end of treatment as compared to baseline that were statistically significant and increases in certain iron parameters, including ferritin, TSAT and hemoglobin levels, as compared to baseline.

The side-effect profile of Auryxia in these Phase 3 trials appeared similar to the profile of the control groups, which received Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate). No serious adverse events deemed to be drug-related were reported in the short-term Phase 3 trial. In the long-term Phase 3 trial, the most common adverse events were gastrointestinal-related, including: diarrhea, including soft stools (26% Auryxia vs. 14% control), nausea (15% Auryxia vs. 14% control), feces discoloration (17% Auryxia vs. 0% control), vomiting (9% Auryxia vs. 15% control) and constipation (8% Auryxia vs. 5% control). Adverse events were generally characterized as mild to moderate in nature in this trial. The overall serious adverse event rates in the long-term Phase 3 trial were 41.9% Auryxia vs. 49.7% control and there were no clinically meaningful or statistically significant differences between Auryxia and the control group in serum calcium levels, aluminum levels and liver enzymes, as measured by alanine transaminase, or ALT, and aspartate transaminase, or AST. The safety profile observed in the OLE trial was consistent with that seen in the long-term Phase 3 trial.

CKD on Dialysis: Auryxia Phase 3 Registration Clinical Program—Short-Term Trial

In November 2010, we completed a Phase 3 short-term, dose-ranging and efficacy trial of Auryxia for the treatment of hyperphosphatemia. This short-term trial was a multicenter, randomized, open-label trial with a two-week washout period, following which patients were randomized 1:1:1 to receive a fixed dose of Auryxia of either 1 gram, 6 grams or 8 grams per day for a treatment period of 28 days using a 1 gram oral tablet formulation. One hundred fifty-four hemodialysis patients were enrolled into the study. The intent-to-treat, or ITT, group included 146 patients, representing all patients who took at least one dose of Auryxia and provided a baseline (at the end of washout) and at least one post-baseline efficacy assessment. Efficacy assessments were taken weekly starting at baseline for four weeks.

The primary endpoint of the study was to determine whether there was a dose response in the change in serum phosphorus from baseline to Day 28 of treatment in the ITT group, using a regression analysis to evaluate this objective. The study met the primary endpoint, with the regression analysis indicating a highly statistically significant dose response ($p<0.0001$) where mean serum phosphorus levels changed from baseline to end of the trial by 0.1 mg/dL (n=50) with 1 g/day, -2.0 mg/dL (n=51) with 6 g/day and -2.2 mg/dL (n=45) with the 8 g/day dosing. Certain iron parameters, including serum ferritin and TSAT, were measured in the study. Over the 28-day treatment period, modest upward trends in ferritin and TSAT levels were observed in the 6 g/day and 8 g/day dose groups. No serious adverse events were deemed to be drug-related by the Data Safety Monitoring Committee in this clinical study.

CKD on Dialysis: Auryxia Phase 3 Registration Clinical Program—Long-Term Trial

In January 2013, we announced successful top-line results from the long-term Phase 3 study of Auryxia for the treatment of hyperphosphatemia in patients with CKD on dialysis. In this study, conducted pursuant to a special protocol assessment, or SPA, agreement with the FDA, Auryxia met the study's primary endpoint, described below, demonstrating a statistically significant change in serum phosphorus levels as compared to placebo over the four-week efficacy assessment period of the study. In addition, Auryxia met the key pre-defined secondary endpoints of increasing ferritin and TSAT and reducing the use of IV iron and ESAs as compared to the active control group (Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate)) over the 52-week safety assessment period of the study. This long-term study was the final component of our Phase 3 registration program.

This Phase 3 long-term study was a multicenter, randomized, open-label, safety and efficacy clinical trial in 441 CKD patients on hemodialysis or peritoneal dialysis. The study consisted of a 2-week washout period followed by a 52-week Safety Assessment Period in which patients were randomized 2:1 to receive either Auryxia or an active control (Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate)). The 52-week Safety Assessment Period was followed by a 4-week efficacy assessment period. During the efficacy assessment period, only those patients randomized to treatment with Auryxia during the safety assessment period and completed the safety assessment period were randomized in a 1:1 ratio to either continue treatment with Auryxia or switch to placebo for a 4-week treatment period. Patients were titrated during the study to achieve serum phosphorus levels that ranged between 3.5 to 5.5 mg/dL. Patients were included in the trial if ferritin was less than 1000 ng/mL and TSAT < 50%.

The primary objectives of this study were to determine the long-term safety of Auryxia in patients with CKD undergoing either hemodialysis or peritoneal dialysis, and the efficacy of Auryxia following 52 weeks of treatment in a four-week, randomized, open-label, placebo-controlled efficacy assessment period. Auryxia was administered using a 1 gram oral tablet formulation. Oral iron therapy was not permitted during the course of the study. IV iron therapy was at the physician's discretion, though was not permitted if a subject's serum ferritin level was greater than 1000 ng/mL or TSAT was greater than 30%. The use of ESAs was at the physician's discretion.

The primary efficacy endpoint of this trial was the mean change in serum phosphorus from baseline (Week 52) to end of the four-week efficacy assessment period (Week 56) versus placebo in the ITT group. The ITT group included 182 patients, representing all patients who took at least one dose of Auryxia or placebo in the efficacy assessment period and provided at least one post-baseline efficacy assessment. Auryxia met the primary efficacy endpoint with a highly statistically significant result ($p<0.0001$, in an analysis of covariance, or ANCOVA, model with treatment as the fixed effect and baseline as the covariate) where patients on placebo had a change in serum phosphorus form 5.4 mg/dL to 7.2 mg/dL and those on Auryxia changed from 5.1 mg/dL to 4.9 mg/dL demonstrating a 2.2 mg/dL least squares mean difference between groups.

During the 52-week safety assessment period, Auryxia maintained serum phosphorus in the normal range, with highly statistically significant changes in mean serum phosphorus concentration at Weeks 12, 24, 36, 48, and 52 as compared to baseline (Day 0, $p<0.0001$). In addition, as agreed to with the EC, the treatment difference between Auryxia and Renvela (sevelamer carbonate) at Week 12 of the safety assessment period in terms of change from baseline (Day 0) in serum phosphorus was analyzed. Auryxia successfully achieved the non-inferiority endpoint versus Renvela.

The objectives of the key iron-related secondary endpoints, which were all pre-specified in the statistical analysis plan in a sequential strategy to control overall Type I error rate, were to corroborate prior data which suggested that Auryxia may increase iron storage parameters and reduce the need for IV iron and/or ESAs as compared to the active control group. Auryxia met all the key pre-defined secondary efficacy endpoints related to iron storage parameters with statistically significant treatment differences as compared to the active control group (Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate)), as follows:

- Auryxia demonstrated a statistically significant treatment difference as compared to the active control group in mean change in serum ferritin from baseline (Day 0) to Week 52 from 593 ng/mL (n=253) at baseline to 895 ng/mL at the end of 52 weeks for Auryxia compared to those on active control where the serum ferritin level at baseline was 610 ng/mL (n=137) and at the end of the 52-week period was 632 ng/mL. Auryxia also demonstrated a statistically significant treatment difference as compared to the active control group in mean change in TSAT from baseline (Day 0) to Week 52 where the TSAT at baseline for Auryxia was 31% (n=252) and at the end of the 52-week period was 39% compared to the active control group where baseline TSAT was 31% (n=137) and at the end of the 52-week period was 30%.
- Each subject's average cumulative IV iron intake was calculated over the 52-week safety assessment period. The ITT group consisted of 271 patients and 138 patients for the Auryxia and active control groups, respectively. Auryxia demonstrated a 51% decrease in median IV iron intake as compared to the active control group (median 1.87 mg/day for Auryxia versus 3.83 mg/day for active control, $p<0.0001$). Each patient's average cumulative ESA intake was calculated over the 52-week safety assessment period. The ITT group consisted of 273 patients and 141 patients for the Auryxia and active control groups, respectively. Auryxia demonstrated a 24% decrease in median ESA intake as compared to the active control group (median 756 units/day for Auryxia versus 993 units/day for active control, $p<0.05$).
- Auryxia demonstrated a statistically significant treatment difference as compared to the active control group in mean change in hemoglobin from baseline (Day 0) to Week 52 ($p<0.05$) with a mean change

in hemoglobin in the Active control group of -0.6 g/dL and a mean change of -0.2 g/dL for those on Auryxia.

Safety and Tolerability Profile

For reference, patients previously intolerant to Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate) were ineligible to participate in this study. Based on an analysis of safety data, the side-effect profile of Auryxia and the active control group, or Active Control, appeared similar, with the most common adverse events gastrointestinal-related. The most common gastrointestinal adverse events were: diarrhea, including soft stools (26% Auryxia vs. 14% Active Control), nausea (15% Auryxia vs. 14% Active Control), feces discoloration (17% Auryxia vs. 0% Active Control), vomiting (9% Auryxia vs. 15% Active Control) and constipation (8% Auryxia vs. 5% Active Control). Adverse events were generally characterized as mild to moderate in nature.

The overall serious adverse event rates in the study were 41.9% Auryxia vs. 49.7% Active Control. Importantly, there were no clinically meaningful or statistically significant differences between Auryxia and the active control group in serum calcium levels, aluminum levels and liver enzymes, as measured by ALT and AST.

CKD on Dialysis: Auryxia Open-Label Safety Extension Study

In July 2014, we completed the long-term, OLE study for Auryxia in dialysis-dependent CKD patients. Patients who had participated in and successfully completed the long-term pivotal Phase 3 study were eligible for enrollment in the 48-week OLE study, providing for cumulative exposure to Auryxia of up to two years (n=17). Patients in the OLE study (n=168) were titrated to achieve and maintain serum phosphorus levels within a range of 3.5 to 5.5 mg/dL, with a maximum daily dose of 12 grams per day of Auryxia. The safety profile observed in the OLE study was consistent with that seen in the long-term pivotal Phase 3 study and there were no clinically meaningful changes in liver enzymes or aluminum levels over the course of the study.

NDD-CKD: Clinical Program Evaluating Ferric Citrate for the Treatment of Iron Deficiency Anemia

In addition to studying Auryxia to treat patients with CKD on dialysis, we have a clinical program to evaluate the use of ferric citrate for the treatment of IDA in the non-dialysis setting. As part of the program, we have completed a Phase 2 clinical trial and a Phase 3 clinical trial of ferric citrate to potentially gain FDA approval to use ferric citrate in patients with NDD-CKD.

Phase 3 Clinical Trial

In September 2014, we initiated a pivotal Phase 3 study of ferric citrate for the treatment of IDA in patients with Stage 3-5 NDD-CKD. This is a 24-week Phase 3, multi-center clinical trial, comprised of a 16-week, randomized, double-blind, placebo-controlled period, or the Randomized Period, followed by an 8-week open label safety extension period, where all patients received ferric citrate, or the Extension Period. Patients with CKD Stage 3-5 who were intolerant of or had an inadequate therapeutic response to oral iron supplements (with a limit of up to 20% of the target randomization in CKD Stage 5) and had a hemoglobin between 9.0 g/dL and £11.5 g/dL at screening for enrollment in the trial. In addition, patients with serum phosphorus <3.5 mg/dL were excluded from the trial. Unlike the Phase 2 NDD-CKD trial where dosing was based on serum phosphorus levels, in the Phase 3 study, ferric citrate was dosed, with meals, to obtain an increase in Hgb of >1.0 g/dL from baseline. Increase of study drug dose occurred only if the subject's serum phosphate is ≥3.0 mg/dL. The use of oral or IV iron, ESAs, receipt of blood transfusions and phosphate binders were not permitted at any time during the study.

The study's primary endpoint is a between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week Randomized Period. Secondary endpoints in this Phase 3 study include change from baseline to end of Randomized Period for hemoglobin, ferritin, TSAT and serum phosphorus.

In March 2016, we announced positive top-line results from the U.S.-based Phase 3 study of ferric citrate in treating IDA in patients with Stage 3-5 NDD-CKD. The study met its primary endpoint and all pre-specified secondary endpoints with statistical significance.

The pivotal Phase 3 study enrolled 234 patients who previously had not adequately responded to or tolerated oral iron therapies at 32 clinical sites in the United States. Patients were randomized 1:1 (ferric citrate versus placebo). Patients enrolled in this study were not allowed to receive any IV or oral iron, or ESAs during this study. The study had a 16-week, randomized, double-blind, placebo-controlled, efficacy period followed by an 8-week open-label safety extension period in which all patients remaining in the study, including the placebo group, received ferric citrate. During the 16-week efficacy period, ferric

citrate was administered at a starting dose of three tablets per day with food and could be titrated every four weeks by an additional three tablets for up to a maximum of 12 tablets per day; the mean dose received in ferric citrate treated patients was 5 tablets per day. The primary endpoint was the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week efficacy period. Baseline laboratory values were similar between the treatment arms.

Baseline laboratory values:	**Ferric Citrate (FC) (n=117)**	**Placebo (P) (n=115)**
Hemoglobin (g/dL)	10.4	10.4
TSAT (%)	20.2	19.6
Ferritin (ng/mL)	85.9	81.7
Serum phosphate (mg/dL)	4.2	4.1

Efficacy analyses were performed on an intent-to-treat population and included all enrolled patients who received at least one dose of ferric citrate or placebo and one post-treatment laboratory assessment. The analysis also used a sequential gatekeeping strategy for statistical testing of the secondary endpoints.

Primary and Secondary Endpoint Results

	Ferric Citrate (FC) (n=117)	**Placebo (P) (n=115)**	**P-Value**
Primary Endpoint:			
Proportion of patients achieving an increase in hemoglobin of > 1.0 g/dL at any time point during efficacy period* (%)	52.1	19.1	<0.001
Secondary Endpoints:			
Mean change in hemoglobin (g/dL)	0.75	(0.08)	<0.001
Mean change in TSAT (%)	17.8	(0.60)	<0.001
Mean change in ferritin (ng/mL)	162.5	(7.70)	<0.001
Proportion of patients with a durable response during the efficacy period (%)**	48.7	14.80	<0.001
Mean change in serum phosphate (mg/dL)	(0.43)	(0.22)	0.02

* Efficacy period defined as the 16-week randomized, double-blind, placebo controlled period.
** Sustained treatment effect on hemoglobin was defined as a mean change from baseline ≥0.75 g/dL over any 4-week time period during the efficacy period, provided that an increase of at least 1.0 g/dL had occurred during that 4-week period.

Safety and Tolerability Profile

The safety population in the study included all randomized patients who took at least one dose of study drug. The safety analysis demonstrated that ferric citrate was generally well tolerated in adults with Stage 3-5 NDD-CKD. Specifically, the results showed:

- During the efficacy period, the majority of adverse events reported were mild to moderate, with the most common being diarrhea (20.5% FC; 16.4% P), constipation (18.8% FC; 12.9% P), discolored feces (14.5% FC; 0% P), and nausea (11.1% FC; 2.6%P). During the efficacy period, hypophosphatemia was reported as an adverse event in four patients, one patient in the ferric citrate arm and three patients in the placebo arm.
- During the efficacy period, 26 percent (31/117) of ferric citrate-treated patients and 30 percent (35/116) of those receiving placebo discontinued treatment. Of the patients who discontinued, 12 patients treated with ferric citrate discontinued due to an adverse event, compared to 10 patients who received placebo.

- During the efficacy period, the rate of serious adverse events was balanced between the ferric citrate and placebo treatment groups, at 12% and 11%, respectively. None of the serious adverse events were deemed drug related.
- During the course of the study, there were two deaths reported, both in patients receiving ferric citrate; neither of which were related to study drug.

The company submitted an sNDA to the FDA in January 2017 seeking Auryxia label expansion to treat IDA in adults with NDD-CKD.

NDD-CKD: Phase 2 Clinical Trial

In November 2013, we announced successful top-line results from the U.S.-based Phase 2 study of ferric citrate in managing serum phosphorus and IDA in patients with Stage 3-5 NDD-CKD. In this study, ferric citrate met both co-primary endpoints, demonstrating statistically significant changes in both serum phosphorus and TSAT versus placebo over the 12-week treatment period. In addition, ferric citrate met the key secondary endpoints of increasing ferritin and hemoglobin, and decreasing fibroblast growth factor-23, or FGF-23, as compared to placebo.

This Phase 2 study was a multicenter, randomized, double-blind, placebo-controlled clinical trial in patients with Stage 3-5 NDD-CKD, with elevated serum phosphorus ≥4.0 mg/dL and IDA. The study consisted of a 2-week washout period (for subjects on a phosphate binder at screening) followed by a 12-week treatment period in which patients were randomized 1:1 to receive either ferric citrate or placebo. Dosing was based upon change serum phosphorus. One hundred forty-nine patients were randomized into the study from 20 sites in the United States. The use of IV or oral iron and ESAs were not permitted within 8 weeks and 4 weeks prior to the study, respectively, and not permitted during the course of the study.

Co-Primary and Key Secondary Endpoints

Ferric citrate demonstrated statistically significant improvements in both co-primary (serum phosphorus and TSAT) and all key secondary endpoints. The ITT group included 141 patients, representing all patients who took at least one dose of ferric citrate or placebo and provided at least one post-baseline efficacy assessment. In the group receiving ferric citrate, the mean serum phosphorus at baseline was 4.5 mg/dL (n=72) and at the end of the 12-week treatment period was 3.9 mg/dL. In the group receiving placebo, the mean serum phosphorus at baseline was 4.7 mg/dL (n=69) and at the end of the 12-week treatment period was 4.4 mg/dL. In the group receiving ferric citrate, the mean TSAT at baseline was 22% (n=72) and at the end of the 12-week treatment period was 32%. In the group receiving placebo, the mean TSAT at baseline was 21% (n=69) and at the end of the 12-week treatment period was 20%.

The key secondary endpoints of the study measuring iron parameters were the mean changes in ferritin and hemoglobin from baseline to the end of the 12-week treatment period as compared to placebo in the ITT group. Ferric citrate significantly increased serum ferritin from 116 ng/mL at baseline to 189 ng/mL at the end of the treatment period, which was significantly higher than that of placebo (baseline 110 ng/mL; week 12 106 ng/mL). Mean hemoglobin change from baseline to the end of the 12-week treatment period was significantly higher in those that received ferric citrate than those that received placebo ($p<0.001$).

Mean Hemoglobin (g/dL)	Placebo (n=69)	Ferric Citrate (n=72)
Baseline	10.6	10.5
End of Treatment[1] (Week 12)	10.4	11.0
Treatment Difference p-value[2]		p<0.001

1 Last observation carried forward was used for missing data.
2 P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Patients were discontinued from the study if they had hemoglobin measurements <9.0 g/dL on two consecutive visits or serum phosphorus measurements ≥6.0 mg/dL on two consecutive visits following randomization. There were 12% treatment failures in the placebo group associated with low hemoglobin versus 1% on ferric citrate. In addition, there was a 3% serum phosphorus associated treatment failure in the placebo group compared to none on ferric citrate.

Safety and Tolerability Profile

The safety population in the study included all randomized patients who took at least one dose of study drug. Ferric citrate appeared to be safe and well-tolerated in this Phase 2 study, with discontinuation rates of 19% and 32% in the ferric citrate and placebo groups, respectively, including treatment failures. There were no study discontinuations due to hypophosphatemia in the study.

Serious adverse events occurred in six ferric citrate subjects (8%) versus ten placebo subjects (14%). Two deaths were recorded in the study, both from the placebo group. There were no clinically meaningful or statistically significant differences in serum calcium levels and liver enzymes as measured by ALT and AST.

COMMERCIAL ORGANIZATION

We have established a commercial organization to support the sales of Auryxia in the United States. Our sales force and managed markets organizations are responsible for promoting our products to health care professionals, providers, and payors.

Our U.S. sales force and managed markets organizations include approximately 125 employees. We market our products and educate physicians by calling on individual physicians and dietitians, advertising, public relation efforts, and other activities.

We also have established programs in the United States that provide our products to qualified uninsured or underinsured patients at no charge or at a reduced charge, based on specific eligibility criteria.

INTELLECTUAL PROPERTY AND PATENTS

General

Patents and other proprietary rights are very important to the development of our business. Our ability to protect our proprietary technologies from unauthorized use by third parties is limited by the extent to which our proprietary rights are covered by valid and enforceable patents supported by regulatory exclusivity, or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for Auryxia and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the United States and, when appropriate, internationally to cover methods of use, processes of manufacture, new chemical compounds, pharmaceutical compositions, dosing of the compounds and compositions, and improvements in each of these areas. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. We have a number of patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the Patent Term Extension program available under 35 U.S.C. § 156, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license (if a license is available on commercially reasonable terms) under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products

may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

Pursuant to our license with Panion & BF Biotech, Inc., or Panion, we have the exclusive rights under a series of patent and patent applications to commercialize Auryxia worldwide, excluding certain Asian-Pacific countries. These patents and patent applications include claims directed to compositions of matter, pharmaceutical compositions, methods of treatment, as well as methods for the manufacture of Auryxia.

Our patent rights include: (1) U.S. Patent No. 8,846,976, which expires in 2024 and includes claims covering a method of treating hyperphosphatemia using Auryxia and encompasses the dosing regimen approved by the FDA for Auryxia; (2) U.S. Patent Nos. 7,767,851, 8,299,298, 8,338,642, 8,609,896, 8,754,257, 8,754,258 and 9,050,316, which expire in 2024 and include either composition of matter claims, methods of use claims or both covering Auryxia; and (3) U.S. Patent No. 8,093,423, which expires in 2026 and includes methods of use claims covering Auryxia. The expiration dates referenced above are without regard to potential patent term extension. In addition, our patent portfolio includes a U.S. patent with claims directed to formulations of ferric citrate and U.S. patent applications directed to methods for the prophylaxis or treatment of hyperphosphatemia comprising administering a ferric citrate tablet , methods of improving at least one iron storage parameter (e.g., hemoglobin) in certain CKD patients comprising orally administering ferric citrate, and methods for treating IDA in certain CKD patients comprising orally administering a certain table formulation of ferric citrate.

The term of a patent will vary depending upon the legal term for a patent in the country in which the patent is obtained. Generally, the term for a patent is 20 years from the earliest filing date of a non-provisional patent application in the United States. In the United States, the term of a patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, the term of a U.S. patent that covers a drug, biological product or medical device approved by the FDA for commercial marketing may be eligible for patent term extension, provided statutory and regulatory requirements are met.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, such defense or protection could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Auryxia, increase the risk that a generic version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Auryxia. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent.

In addition, any limitations of our patent protection described above may adversely affect the value of our product candidate and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity or new formulation exclusivity, to provide market exclusivity for a drug candidate. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the United States, or, diseases that affect more than 200,000 individuals in the United States but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In the United States, the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that our drug candidate, Auryxia, or any drug candidates we may acquire or in-license, will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the United States, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the development, manufacture and commercialization of ferric citrate. Our current key strategic alliances are discussed below.

Panion & BF Biotech, Inc.

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc., or Panion. Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. To date, we have expensed an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of ferric citrate in the licensed territory, as well as a manufacturing fee for product manufactured for us in the licensed territory. For the years ended December 31, 2016 and 2015, we recorded approximately $1.6 million and $0.6 million, respectively, in cost of goods sold related to royalty payments due Panion relating to sales of Auryxia (ferric citrate) in the United States.

The license agreement terminates upon the expiration of our obligations to pay royalties thereunder. In addition, we may terminate the license agreement (i) in its entirety or (ii) with respect to one or more countries of the territory covered by the agreement, in either case upon 90 days' notice. We and Panion also have the right to terminate the license agreement upon the occurrence of a breach of a material provision of the license agreement and certain insolvency events.

Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or the Revised Agreement, with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the Sublicense Agreement.

In January 2013, JT and Torii filed its new drug application, or NDA, with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. Under the terms of the Revised Agreement, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of the NDA filing milestone.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, launched in May 2014 and being marketed in Japan by Torii under the brand name Riona, is indicated as an oral medicine for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, and may also receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii

occurred. We recorded $4.8 million and $3.5 million in license revenue related to royalties earned on net sales of Riona in Japan in 2016 and 2015, respectively. We record the associated mid-single digit percentage of net sales royalty expense due to Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. We recorded $2.9 million and $2.1 million in license expenses in 2016 and 2015, respectively, related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

The sublicense terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the sublicense agreement with or without cause upon at least six months prior written notice to us. Additionally, either party may terminate the sublicense agreement for cause upon 60 days' prior written notice after the breach of any material provision of the sublicense agreement, or after certain insolvency events.

COMPETITION

The pharmaceutical and biotechnology industries are highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Auryxia is competing in the United States with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi), or Genzyme, PhosLo (calcium acetate), marketed by Fresenius Medical Care, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Auryxia is differentiated in the marketplace versus these FDA-approved phosphate binders

Aluminum-type phosphate binders were widely used in the past. However, the systemic absorption of aluminum from these agents and the potential toxicity associated with their use no longer make this type of binder a viable long-term treatment option.

Calcium-type phosphate binders are commonly used to bind dietary phosphate; however, they promote positive net calcium balance and an increased risk of metastatic calcification in many patients, especially in those patients taking vitamin D analogs and those with adynamic bone disease. Calcification of the cardiovascular system is believed to represent a significant risk factor for morbidity and mortality in patients with CKD.

Non-calcium-based, non-absorbed phosphate binders, including sevelamer hydrochloride and sevelamer carbonate are among the most prescribed phosphate binders in the United States. Compared to the calcium-type binders, fewer coronary and aortic calcifications have been documented, however, there is a risk of metabolic acidosis with sevelamer hydrochloride, as well as the potential for gastrointestinal problems, and sevelamer can affect concomitant vitamin K and vitamin D treatment.

Lanthanum-type phosphate binders are another alternative. Lanthanum is a rare earth element and is minimally absorbed in the gastrointestinal tract. Lower level tissue deposition, particularly in bone and liver, has been observed in animals. However, the long-term, potentially harmful, effects due to the accumulation of lanthanum in these tissues have not been clearly determined.

The need for alternative phosphate-binding agents has long been recognized, especially given the increasing prevalence of ESRD and shortcomings with current therapies available to such patients.

Auryxia, currently our only drug product, which we launched in December 2014, is competing with existing therapies. In addition, other companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting with Auryxia, including the treatment of hyperphosphatemia and IDA. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Some of these potential competing drugs are further advanced in development than Auryxia and other potential drug candidates we may acquire or in-license, and may be commercialized earlier. Additional information can be found in this report in Item 1A under the heading "Risk Factors—Other Risks Related to Our Business."

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug, Auryxia, for use in clinical trials and for sales.

We believe that we have established contract manufacturing relationships for the supply of Auryxia to ensure that we will have sufficient material for clinical trials and ongoing commercial sales. In addition, we are establishing the basis for long-term commercial production capabilities to supply the potential expanded demand for Auryxia in future years. As with any supply program, obtaining raw materials of the required quality and quantity cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

As we continue to build inventory for the expanded commercialization of Auryxia, we intend to engage additional suppliers to produce Auryxia under current Good Manufacturing Practice, or cGMP, requirements. Our third-party manufacturers have a limited number of facilities in which Auryxia can be produced and will have limited experience in manufacturing Auryxia in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state and foreign government agencies to ensure strict compliance with cGMP and other state and federal requirements and corresponding foreign standards. Any of our contractors in Europe face similar challenges from the numerous European Union and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations and periodic auditing. If they are deemed out of compliance with cGMPs, approvals could be delayed, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with applicable requirements and standards and may require significant lead times and delay, and disruption of supply. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATION

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development in the United States typically involves the performance of nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate, well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical and other nonclinical tests must comply with certain federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about

product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, and (iii) under protocols detailing the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, at each site where a clinical trial will be performed for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or it may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in instances where the clinical trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome, and confirmation of the result in a second clinical trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA is also subject to annual product and establishment user fees which typically increase annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months, while most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing

practice requirements, or cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe and effective use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, clinical trial sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these clinical trials after completion. Disclosure of the results of these clinical trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to make certain certifications to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain or carve out any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from

approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes such changes.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents or their agents may apply for up to a five-year patent extension for delays caused by FDA regulatory review. The allowable patent term extension is calculated as half of the drug's testing phase—the time between IND submission and NDA submission—and all of the review phase—the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

We have filed applications under the patent term extension provisions of 35 U.S.C. § 156 for U.S. Patent Nos. 8,299,298, 8,093,423, 7,767,851, 5,753,706, and 8,338,642 for delays caused by FDA regulatory review. If granted, we can utilize the patent term extension on one of these patents, however, we cannot assure you that we can obtain any extension of the term of these patents. Upon expiration of these patents, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition and/or method of use as our product, so long as the competitors do not infringe any other patents that we may own or license.

For patents that might expire before a determination regarding patent term extension, the patent owner or its agent may request an interim patent term extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely.

We have filed for an interim patent term extension in accordance with 35 U.S.C. § 156(e)(2) for U.S. Patent No. 5,753,706.

In addition, certain other non-jurisdictions, including Japan, have provisions that provide for patent term extension. In October 2014, following the regulatory approval of Riona in Japan, the Japan Patent office granted the patent term extensions filed by our sublicensee, JT, for Japanese Patents Nos. 4964585 and 4173553. As a result of the extension of patent term, Japanese Patents Nos. 4964585 and 4173553 will expire in November 2025 and November 2022, respectively.

Advertising and Promotion

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data 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 drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication where orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Special Protocol Assessment

A company may reach an agreement with FDA under the Special Protocol Assessment, or SPA, process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the clinical trial begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the clinical trial sponsor fails to follow the protocol that was agreed upon with the FDA.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre NDA meeting. The FDA will respond within 60 calendar days of receipt of the request. Priority review, which is requested at the time of NDA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post marketing clinical trials to confirm the appropriateness of the surrogate marker clinical trial.

In the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. The FDA published a final guidance on May 30, 2014, entitled "Expedited Programs for Serious Conditions—Drugs and Biologics." One of the expedited programs added by FDASIA is that for Breakthrough Therapy. A Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). A sponsor may request Breakthrough Therapy designation at the time that the IND is submitted, or no later than at the end of Phase 2 meeting. The FDA will respond to a Breakthrough Therapy designation request within sixty days of receipt of the request. A drug that receives Breakthrough Therapy designation is eligible for all fast track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase 1 and commitment from the FDA involving senior managers.

Foreign Approval

Should we wish to market our products outside the United States, we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies may apply for foreign marketing authorizations at a national level. However, within the EU, registration procedures are available to companies wishing to market a product in more than one EU member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Pharmaceutical Coverage, Pricing and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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 coverage and reimbursement for any product that might be approved, 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 health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for brand named prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

As noted above, even if we are able to secure regulatory approval, sales of any of our products may suffer if the government and third party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased, and we expect this sentiment will continue to increase the pressure on drug pricing. 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

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

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

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;
- The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- The provision under the ACA commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; and
- State law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state to state thereby complicating compliance efforts.

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

As noted above, the federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment from federal programs, including Medicare and Medicaid.

Although we would 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. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third party reimbursement for our products, and the sale and marketing of our products are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off label promotion of drugs. Penalties for such violations could include three times the actual damages sustained by the government, mandatory civil penalties between $5,500 and $11,000 for each separate false claim, exclusion from participation in federal healthcare programs, and the potential implication of various federal criminal statutes. Private individuals also have the ability to bring actions under the federal False Claims Act, or qui tam actions, and certain states have enacted laws based on the federal False Claims Act.

RESEARCH AND DEVELOPMENT

Company sponsored research and development expenses totaled $29.5 million in 2016, $36.7 million in 2015 and $51.5 million in 2014. Research and development expenses consist primarily of salaries and related personnel costs (including stock-based compensation expense), fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-FDA approval inventory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview."

SEGMENT REPORTING

We conduct our operations in one business segment as further described in Note 14 - Business Segments to our consolidated financial statements.

EMPLOYEES

As of February 12, 2017, we had 193 full and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition and/or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks related to our business and industry

We have a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2016, we had an accumulated deficit of $835.1 million. As we continue our research and development and initial commercial efforts, we will incur increasing losses. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug, Auryxia. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug.

We are highly dependent on the commercial success of Auryxia in the United States for the foreseeable future and as a result we may be unable to attain profitability and positive cash flow from operations.

In September 2014, the FDA approved Auryxia for the control of serum phosphorus levels in patients with CKD on dialysis. The commercial success of Auryxia will depend on a number of factors, including:

- the effectiveness of Auryxia as a treatment for adult patients with CKD on dialysis;

- the adoption of Auryxia by physicians, which depends on whether physicians view it as a safe and effective treatment to lower serum phosphorus levels in patients with CKD on dialysis;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the recent interruption in its supply;
- the size of the treatable patient population;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, Auryxia by providing third party payers with a strong value proposition based on the existing burden of illness associated with CKD patients on dialysis and the benefits of Auryxia;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with Auryxia;
- our ability to obtain and maintain strong intellectual property protection for Auryxia;
- the development or commercialization of competing products or therapies for the control of serum phosphorus levels in patients with CKD on dialysis; and
- our ability to identify reliable suppliers and successfully manufacture Auryxia.

In addition to these factors, the commercial success of Auryxia is also dependent on gaining approval from the FDA to market Auryxia in the United States for additional indications, including for the treatment of IDA, in patients with Stage 3-5 NDD-CKD, which is the indication being studied in our recently completed Phase 3 clinical trial.

Our revenues from the commercialization of Auryxia are subject to these and other factors, and therefore may be unpredictable from quarter-to-quarter. Ultimately, we may never generate sufficient revenues from Auryxia to reach or maintain profitability or sustain our anticipated levels of operations.

We have limited experience as a company in sales and marketing, and with respect to pricing and obtaining adequate third-party reimbursement and as a result we may be unable to effectively market our product and retain market access.

We currently have limited experience as a company in sales and marketing and with respect to pricing and obtaining adequate third-party reimbursement for drugs. In order to market Auryxia, if it is approved in the United States for the treatment of IDA in patients with Stage 3-5 NDD-CKD, we intend to expand our marketing organization and hire additional sales representatives, which will require substantial effort and significant management and financial resources. We will need to devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is intense and may be particularly difficult for us as no drug has previously been marketed for the treatment of IDA in patients with Stage 3-5 NDD-CKD. Additionally, our investment in this infrastructure might be lost if Auryxia is not approved for the treatment of IDA in patients with Stage 3-5 NDD-CKD.

Approval of Fexeric (ferric citrate coordination complex) in the European Union does not ensure successful commercialization and reimbursement.

On September 23, 2015, the EC approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union, or EU.

We are not currently marketing Fexeric in the EU, however we are seeking potential partners to commercialize Fexeric in the EU. We cannot assure you that we will be able to find a commercialization partner in the EU or that we will be able to agree to acceptable terms with any partner to launch and commercialize Fexeric in the EU.

The commercial success of Fexeric is subject to the same risks we face with commercializing Auryxia in the United States. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement for Fexeric is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner's ability to successfully commercialize Fexeric in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling Fexeric on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of Fexeric in that country.

Our potential revenues from the commercialization of Fexeric in the EU are subject to these and other factors, and therefore we may never reach or maintain profitability in the EU.

Auryxia may cause undesirable side effects or have other properties that could limit its commercial potential.

The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia in the United States were diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing Auryxia (14%) in clinical trials. If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, if we or others detect unexpected safety signals for Auryxia or any products perceived to be similar to Auryxia, or if any of the foregoing are perceived to have occurred, then:

- sales of Auryxia may be impaired;
- regulatory approvals for Auryxia may be restricted or withdrawn;
- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals, or we may decide to conduct a product recall;
- reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of Auryxia within its indicated populations, as well as be precluded from studying Auryxia in additional indications and populations or in new formulations; and
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Auryxia, likely increase our expenses and impair our ability to successfully commercialize Auryxia.

Furthermore, as we explore development opportunities to enhance the clinical profile of Auryxia, any clinical trials conducted, if successful, may expand the patient populations treated with Auryxia within or outside of its current indications or patient populations, which could result in the identification of previously unknown side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. In addition, now that Auryxia is commercially available, it will be used in a wider population and in less rigorously controlled environments than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of Auryxia is associated with serious adverse effects, undermining our commercialization efforts.

We rely on third parties to manufacture and analytically test our drug. If these third parties do not successfully manufacture and test our drug, our business will be harmed.

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug for commercial distribution and use in clinical trials. We may not be able to enter into future contract agreements with these third-parties on terms acceptable to us, if at all.

Our ability to conduct clinical trials, manufacture and commercialize our drug will depend on the ability of such third parties to manufacture our drug on a large scale at a competitive cost and in accordance with cGMPs and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Significant scale-up of manufacturing may result in unanticipated technical challenges and will require validation studies that are subject to FDA inspection. Scale-up and technology transfer activities can be complex, and insufficient process knowledge can result in a poorly scaled up process with inadequate process control. A lack of process control can lead to increased deviations during the manufacturing process, out of specification test results, batch rejection and the possible distribution of drug products that do not conform to predetermined specifications. In addition, a variety of factors can affect a contract manufacturer's qualifications to produce acceptable product, including deficiencies in the contractor's quality unit, lack of training, a shortage of qualified personnel, capacity constraints and changes in the contractor's commercial or quality related priorities. Any of these difficulties, if they occur, and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to an interruption in the supply of our drug to the market, particularly given that some of the third parties we intend to employ in the manufacturing process are single source providers. As a result of the large quantity of materials required for Auryxia production and the large quantities of Auryxia that is required for our commercial success, the commercial viability of Auryxia will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to continually produce the API and finished drug product on a commercial scale. Failure to achieve and maintain these levels of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our scale-up and technology transfer of Auryxia and continued commercial scale manufacture of Auryxia may lead to significant delays in our development and commercial timelines and negatively impact our financial performance. For example, a production-related issue resulted in an interruption in the supply of Auryxia in the third and fourth quarters of 2016. This supply interruption negatively impacted our revenues in

2016. Although we have resolved this supply interruption and taken steps designed to prevent future interruptions in the supply of Auryxia, any additional supply interruptions would negatively and materially impact our reputation and financial condition.

Our third-party manufacturers may not perform as required under the terms of our supply agreement or quality agreement, or may not remain in the contract manufacturing business for the time required by us to successfully manufacture and distribute our drug. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with cGMPs, as well as other governmental regulations and corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, and are ultimately held responsible for their regulatory compliance, we cannot assure you that unforeseen changes at these contractors will not occur that could change their regulatory standing. The same issues apply to contract analytical services which we use for quality, impurity and release testing of our drug. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract, supplier qualification and periodic audits, but unforeseen circumstances could affect our third-party manufacturers' compliance with applicable regulations and standards. As we continue to scale up production, we continue to develop analytical tools for Auryxia drug substance and drug product testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to obtain and maintain FDA approval. Moreover, even with effective analytical methods available, there is no assurance that we will be able to analyze all the raw materials and qualify all impurities to the satisfaction of the FDA, possibly requiring additional analytical studies, analytical method development, or preclinical studies, which could significantly delay our ability to receive regulatory approvals for our drug. Additionally, changes in the analytical specifications required by the FDA or other regulatory authority, such as United States Pharmacopeial Convention standards, from time to time, could delay our ability to receive regulatory approvals for our drug or our commercial efforts. Switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult and time consuming because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance or drug product must meet established specifications at each manufacturing facility. It may be difficult and time consuming for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Auryxia, the loss of any of our drug substance or drug product manufacturers would result in significant additional costs and delays in our development program and as demonstrated by our recent interruption in the supply of Auryxia, negatively impact our sales of Auryxia.

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

We do not possess all of the capabilities to fully commercialize our product on our own. From time to time, we may need to contract with additional third parties, or renew or revise contracts with existing third parties, to:

- manufacture our drug;
- assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and
- market and distribute our drug.

We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our product independently, which could result in significant delays. Furthermore, such failure could result in the termination of license rights to our product. If these manufacturing, development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our product. We cannot predict the form or scope that any such collaboration might take, and we may pursue other strategic alternatives if terms or proposed collaborations are not attractive. To the extent that we rely on third parties to research, develop or commercialize our product, we are unable to control whether such product will be scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face decreased sales and/or delays in achieving the business or regulatory milestones required for additional commercialization of our current drug and any future drug candidate.

We will incur significant liability if it is determined that we are promoting any "off-label" use of Auryxia.

Physicians are permitted to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Such "off-label" uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and

other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses or promote drugs using marketing claims that are not otherwise consistent with the FDA-approved labeling, including comparative or superiority claims that are not consistent with the FDA-approved labeling or supported by substantial evidence. Accordingly, we may not promote Auryxia in the United States for use in any indications other than for the control of serum phosphorus levels in patients with CKD on dialysis and all promotional claims must be consistent with the FDA-approved labeling for Auryxia. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained as well as the false advertising or misleading promotion of drugs. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion of drugs will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products in certain circumstances. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program designed to ensure that all such activities are performed in a legal and compliant manner, Auryxia is our first commercial product, so our implementation of our compliance program in connection with commercialization activities is still relatively new.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

- government and health administration authorities;
- private health insurers;
- managed care programs; and
- other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products, as well as the timing of coverage and reimbursement decisions by third-party payors. Third-party payors, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which for the first time established prescription drug coverage for Medicare beneficiaries, under Medicare Part D. Under this program, beneficiaries purchase insurance coverage from private insurance companies to cover the cost of their prescription drugs. Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as the Patient Protection Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act of 2010, could result in lower prices or rejection of coverage and reimbursement for our drug. In addition, third-party insurance coverage may not be available to patients for our product. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our product, its market acceptance may be significantly reduced.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not (and do not expect in the future to) control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. These regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding

and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, or FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;
- the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and
- the federal Physician Payments Sunshine Act, which was passed as part of the Patient Protection and Affordable Care Act of 2010, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report certain payments and transfers of value made to physicians and teaching hospitals.

If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

In preparation for the commercial launch of Auryxia, we assembled an experienced compliance team who compiled a program based on industry best practices designed to ensure our commercialization of Auryxia complies with all applicable laws, regulations and industry standards. We also hire, manage and incentivize our employees around a culture of compliance, trust, respect and ownership. Because our program is relatively new and the requirements in this area are constantly evolving, we cannot be certain that our program will eliminate all areas of potential exposure. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

If our competitors develop and market products that are less expensive, have a reduced pill burden, more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug product obsolete or noncompetitive. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Auryxia is competing in the United States with other FDA-approved phosphate binders such as Renagel (sevelamer hydrochloride) and Renvela (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi), or Genzyme, PhosLo (calcium acetate), marketed by Fresenius Medical Care, Fosrenol (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS and metal-based options such as aluminum and magnesium. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Auryxia is differentiated in the marketplace versus these FDA-approved phosphate binders. In addition, we may have to compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. There are several parties pursuing approval of pending Abbreviated New Drug Applications, or

ANDAs, for generic Renvela with the FDA. In addition, a generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the United States in October 2008. In addition, upon the expiration of its core patents, generic formulations of Fosrenol may be launched. These generic formulations could have a further material effect on the pricing of phosphate binders.

Furthermore, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug product. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

If we lose our key personnel or are unable to attract and retain additional personnel, our operations could be disrupted and our business could be harmed.

As of February 12, 2017 we had 193 full and part-time employees. To successfully develop and commercialize our drug and any drug candidates we may in-license or acquire, we must be able to attract and retain highly skilled personnel. Our limited resources may hinder our efforts to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel our ability to continue to execute on our business plan could be materially impaired.

Greg Madison assumed the Chief Executive Officer role following the resignation of Mr. Bentsur on April 30, 2015. Previously, Mr. Madison was appointed to our Board of Directors in March 2015. Mr. Madison joined Keryx in February 2014 as Executive Vice President and Chief Operating Officer to transition Keryx from a development stage organization into a fully integrated commercial entity, and bring to Keryx a wealth of relevant expertise in both the phosphate binder and IDA markets.

Brian Adams joined Keryx in April 2014 as General Counsel and was additionally appointed as our Corporate Secretary in March 2015.

In April 2015, we appointed John F. Neylan, M.D., as our Senior Vice President and Chief Medical Officer.

In July 2015, we appointed Scott Holmes as our Senior Vice President and Chief Financial Officer. James F. Oliviero left the Company after serving in various finance capacities for twelve years, including as our Chief Financial Officer since 2009.

In January 2017, we appointed Christine Carberry as our Chief Operating Officer.

Although we have employment agreements with Greg Madison, Brian Adams, John F. Neylan, M.D., Scott Holmes and Christine Carberry, these agreements do not prevent them from terminating their employment with us.

Risks associated with our product development efforts

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete our clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same disease that we are studying. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner or at all. In addition, conducting multi-national studies adds another level of complexity and risk. As a result, we may be subject to events affecting countries outside the United States.

Negative or inconclusive results from the clinical trials we conduct, such as the recently completed Phase 3 study of Auryxia for the treatment of IDA in patients with NDD-CKD, or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials. For example, in May 2012, we abandoned our development efforts and terminated our license for KRX-0401 (perifosine) following negative results from the Phase 3 trial for KRX-0401. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our Phase 3 study of ferric citrate for the treatment of IDA in patients with Stage 3-5 NDD-CKD raises safety signals or fails to demonstrate efficacy despite positive top-line results, we may be unable to submit or receive regulatory approval for an expanded indication for Auryxia.

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of IDA in adults with NDD-CKD. Despite our positive top-line results, the FDA may not concur with our interpretation of our Phase 3 study results, supportive data, conduct of the studies, or any other part of our regulatory submission and could ultimately deny approval of ferric citrate for the treatment of IDA in adults with Stage 3-5 NDD-CKD. Additionally, we may need to conduct significant additional research and human testing before we receive regulatory approval. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product. It requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. Negative, inconclusive, or insufficient results or medical events during a pre-clinical or clinical trial could cause us to delay or terminate our development efforts. Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies.

Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding and liver toxicities that have been seen in some high-dose ferric citrate canine studies, may require us to perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. While both the FDA and EC have previously reviewed the data from our Phase 3 clinical program for CKD patients on dialysis and Phase 2 study in NDD-CKD patients, we can provide no assurance that the FDA will not raise any safety concerns in the future from these studies. Drug candidates in the later stages of clinical development may fail to show the desired traits of safety and efficacy despite positive results in earlier clinical testing. The risk also remains that a clinical program conducted by one of our partners may raise efficacy or safety concerns that may prevent approval of the drug. In addition, qualitative, quantitative and statistical interpretation of any of the prior pre-clinical and clinical safety and efficacy data of our drug may be viewed as flawed by the FDA. In addition, there can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted by us or our consultants, which in subsequent, larger studies might appear and prevent approval of such drug candidate.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving what appeared to be promising results in earlier trials. We experienced such a setback with our Phase 3 KRX-0401 (perifosine) trial results in April 2012, and we can provide no assurance that we will not experience such setbacks with ferric citrate or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we engage, from time to time, clinical research organizations with experience in conducting regulatory trials, errors in the conduct, monitoring, data capture and analysis, and/or auditing could potentially invalidate the results.

Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these license rights would prevent us from developing and further commercializing Auryxia.

We do not own our drug, Auryxia. We have licensed and sublicensed the rights, patent or otherwise, to Auryxia from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Auryxia) and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement (including upon certain insolvency events), Panion could terminate the agreement, and we would lose the rights to Auryxia. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current drug and any future drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug or drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drugs. Finally, our rights to develop and commercialize Auryxia, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Auryxia and the licenses and sublicenses we grant to others.

Our reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or a failure to complete, clinical trials if such CROs fail to perform under our agreements with them.

In the course of product development, we engage CROs and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs or applicable vendors fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory or timely manner, we may face significant delays in completing our clinical trials, submitting our regulatory filings, or approval, as well as the commercialization of one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidate(s).

Other risks related to our business

Any acquisitions we make may require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company's relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the diversion of our management's attention from our core business; and
- the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

Health care reform measures could adversely affect our business.

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare products and services in the United States or internationally, the reimportation of drugs into the United States from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third-party payors. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

Furthermore, in the United States, health care reform legislation titled the Patient Protection and Affordable Care Act, or PPACA, was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court's decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the "donut hole"), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our product.

For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delayed by two years the implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2016. In April

2014, the United States Congress passed legislation known as Protecting Access to Medicare Act of 2014, which, among other things, delays by eight years the implementation of oral-only ESRD related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2025. If phosphate binders are included in the bundle beginning in 2025, or earlier, separate Medicare reimbursement will no longer be available for phosphate binders, as it is today under Medicare Part D. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders, which could significantly reduce the commercial potential of Auryxia.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies approved by the FDA. The FDA's exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other things, renew the drug user fee program, expand the FDA's inspection records access and require manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance. On November 27, 2013, the Drug Quality and Security Act, which includes the Drug Supply Chain Security Act, was signed into law to, among other things, build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Requirements for the tracing of products through the pharmaceutical distribution supply chain took effect on January 1, 2015 for manufacturers and building internal systems to ensure compliance with this law will require dedication of resources. In addition, this law requires engaging in transactions only with authorized trading partners and could limit our pool of available trading partners.

We face product liability risks and may not be able to obtain adequate insurance.

The use of our drug or future drug candidates in clinical trials, and the future sale of any approved drug and new technology, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug product or limit commercialization of any approved product.

We have expanded our insurance coverage to include the commercial sale of Auryxia; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;
- injury to our reputation;
- our inability to continue to develop a drug candidate;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material to our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of Auryxia patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Risks related to our financial condition

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our business plan. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales, the build-up of inventory and capacity expansion, and the timing, design and conduct of, and results from, clinical trials for Auryxia. As a result of these factors, we will need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Auryxia, and to develop and commercialize any drug candidates we may in-license or acquire.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales;
- the timing and expenditures associated with the build-up of inventory and capacity expansion;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the recent interruption in its supply;
- the timing, design and conduct of, and results from, clinical trials for Auryxia;
- the timing of expenses associated with manufacturing and product development of Auryxia and those proprietary drug candidates that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the timing and expenditures associated with commercial activities related to launching Fexeric in Europe, either by us or through a commercialization partner;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangement;
- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;
- the timing and expenses associated with building our own commercial infrastructure to manufacture, market and sell our drug and those that may be in-licensed, partnered or acquired; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights or defending against claims of infringement initiated by third parties in respect of their intellectual property rights.

If our cash is insufficient to meet our future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us, or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, including pursuant to our Controlled Equity Offering℠ Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

Risks related to our intellectual property and third-party contracts

If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third-party challenges. We seek to protect our proprietary products and technology by filing patent applications in the United States and certain foreign jurisdictions. The process for obtaining patent protection is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a cost effective or timely manner. In addition, we may fail to identify patentable subject matter before it is too late to obtain patent protection. Further, license agreements with third parties may not allow us to control the preparation, filing and prosecution of patent applications, or the maintenance or enforcement of patents. Such third parties may decide not to enforce such patents or enforce such patents without our involvement. Thus, these patent

applications and patents may not under these circumstances be prosecuted or enforced in a manner consistent with the best interests of the company.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Changes in the patent laws or the interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. Accordingly, the patents we own or license may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug product and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that any related patent may expire prior to, or remain in existence for only a short period following, commercialization, thus reducing any advantage of the patent. The patents we own or license may be challenged or invalidated or may fail to provide us with any competitive advantage. Since we have licensed or sublicensed many patents from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. For example, claims in a patent application directed to methods of treatment of the human body are not patentable or are restricted in many non-U.S. countries. Further, we may not pursue or obtain patent protection in all major markets. In addition, in jurisdictions outside the United States where we own or license patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

Generally, the first to file a patent application is entitled to the patent if all other requirements of patentability are met. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Since 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, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, the laws enacted by the Leahy-Smith America Invents Act of 2011, or the Act, which reformed certain patent laws in the United States, are still being interpreted and those laws introduce procedures that permit competitors to challenge our patents in the USPTO after grant, including *inter partes* review and post grant review.

We may become involved in addressing patentability objections based on third party submission of references, or we may become involved in defending our patent rights in oppositions, derivation proceedings, reexamination, *inter partes* review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse result in any such 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged on such a basis in the courts or patent offices in the United States and abroad. As a result of such challenges, we may lose exclusivity or freedom-to-operate, or patent claims may be narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent third parties from using or commercializing similar or identical products, or limit the duration of the patent protection for our products.

In addition, patents protecting our product candidate might expire before or shortly after such candidate is commercialized. Thus, our patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to ours.

We also rely on trade secrets and know-how to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, licensees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to our drug product and

technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

The intellectual property that we own or have licensed relating to our drug, Auryxia, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia.

The patent rights that we own or have licensed relating to Auryxia are limited in ways that may affect our ability to exclude third parties from competing against us. For example, a third party may design around our owned or licensed composition of matter patent claims or not market a product for methods of use covered by our owned or licensed patents.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute to others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Auryxia, increase the risk that a generic version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Auryxia. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent.

In addition, any limitations of our patent protection described above may adversely affect the value of our drug product and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

In addition to patent protection, we may utilize, if granted by the FDA, pediatric exclusivity or other provisions of the FDCA, as amended, such as new chemical entity exclusivity, or NCE, or new formulation exclusivity, to provide market exclusivity for a drug candidate.

In the United States, the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired.

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 NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) 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 associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full ANDA; however, an applicant submitting a full ANDA would be required to conduct sufficient studies to demonstrate that their generic product is bioequivalent to Auryxia.

We cannot assure that Auryxia or any drug candidates we may acquire or in-license, will obtain such pediatric exclusivity, NCE exclusivity or any other market exclusivity in the United States, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection. We also cannot assure that Auryxia or any drug candidates we may acquire or in-license will obtain patent term extension.

Litigation or third-party claims could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our product.

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. In addition, third parties may have or may obtain patents in the future and claim that Auryxia or any other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensor or us that seeks damages or an injunction of our commercial activities relating to Auryxia or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Auryxia or such technologies, and/or require our licensor or us to obtain a license to continue to use Auryxia or other technologies. We cannot predict whether our licensor or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

A number of our employees were previously employed at universities, or pharmaceutical or biotechnology companies, some of which may be a competitor or potential competitor. We try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us. Nonetheless, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. As a result, litigation may be necessary to defend against these claims.

In addition, although we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Such assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

In the event that we fail in prosecuting or defending any such claims, we may need to pay monetary damages as well as lose valuable intellectual property rights or personnel. However, regardless of the success in prosecuting or defending against such claims, such litigation may result in substantial costs and distract management.

Risks related to our common stock

The Baupost Group, L.L.C, or Baupost, our largest stockholder, may have significant influence over our company and may cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or the best interest of our other stockholders.

As of December 31, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If Baupost converts all of the convertible notes it holds into shares of our common stock, Baupost would beneficially own approximately 42% of our issued and outstanding common stock. Baupost, through its equity interests, may have significant influence over matters submitted to our stockholders for approval and other corporate actions, such as:

- election of directors;
- timing and manner of dividend distributions;
- approval of contracts between us and Baupost or its respective affiliates, which could involve conflicts of interest;
- open market purchase programs or other purchases of our common shares;
- delay, defer or prevent a change in who controls us;
- discourage bids for our shares at a premium over the market price; and
- adversely affect the market price of our common shares.

Moreover, because large stockholders have potential power to direct or influence our corporate actions, we may be required to engage in transactions that may not be agreeable to our other stockholders or that may not be in the best interest of our other stockholders. In conjunction with the financing, we increased the number of directors on our Board to eight, as Baupost has the right to appoint a director to our Board. Baupost also has the right to appoint an observer to our board.

Future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or make it more difficult for us to raise funds through the sale of equity in the future.

In November 2016, we entered into a Sales Agreement with Cantor Fitzgerald, as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of

up to $75.0 million. We filed a registration statement on Form S-3 (No. 333-214513), which the SEC declared effective on December 6, 2016, which registered the issuance of up to $250.0 million of our securities, including the $75.0 million of common stock issuable pursuant to the Sales Agreement.

In October 2015, we raised $125 million through the private placement of Convertible Senior Notes, due 2020, with funds managed by Baupost. The zero-coupon notes will mature in October 2020 unless converted into shares of our common stock in accordance with their terms prior to such date. Keryx does not have the right to redeem the notes prior to maturity. The conversion price of the notes shall be equal to the closing price of Keryx's common stock on the day prior to closing, October 14, 2015, or $3.74 per share, subject to certain adjustments under the terms of the notes.

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the SEC.

We will need to seek additional financings to provide cash necessary to execute our current operations, including, but not limited to, beyond the continued commercialization of Auryxia, and to develop and commercialize any drug candidates we may in-license or acquire. Future issuances of common stock could depress the market for our common stock.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders' holdings may be significantly diluted. In addition, stockholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments involving us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in quarterly or annual operating results;
- developments relating to the marketing, safety and efficacy of our drug product, and regulatory filing and approvals for us or our competitors;
- expectations regarding our financial condition;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- expectations or investor speculation regarding the strength of our intellectual property position, or the availability of other forms of regulatory exclusivity;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- negative comments and sentiment in the media; and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. For example, following our August 1, 2016 announcement of the supply interruption of Auryxia, four purported class action lawsuits were filed against us and certain of our current and former executive officers alleging false and/or misleading statements concerning the company and its business operations and future prospects, and two stockholder derivative complaints were filed against certain of our current and former executive officers and members of our board of directors. These litigations and any other litigation instituted against us could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business.

Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate office is located in Boston, Massachusetts. In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94-month term that commenced on May 1, 2015 for new office space to serve as our corporate headquarters.

ITEM 3. LEGAL PROCEEDINGS.

For a description of our legal proceedings, see Note 13 - Commitments and Contingencies to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

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 is listed on the Nasdaq Capital Market and trades under the symbol "KERX."

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

	High	Low
Fiscal Year Ended December 31, 2016		
Fourth Quarter	$ 6.41	$ 4.16
Third Quarter	$ 7.53	$ 4.10
Second Quarter	$ 6.76	$ 4.54
First Quarter	$ 5.38	$ 3.17

	High	Low
Fiscal Year Ended December 31, 2015		
Fourth Quarter	$ 5.81	$ 3.19
Third Quarter	$ 10.31	$ 3.38
Second Quarter	$ 12.51	$ 9.32
First Quarter	$ 14.68	$ 10.87

Holders

The number of record holders of our common stock as of February 10, 2017 was 52.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors. Further, in accordance with the Indenture (as defined in Note 8 to the Consolidated Financial Statements included in this annual report on Form 10-K), we are restricted from making payments of cash dividends.

Securities Authorized for Issuance Under Equity Compensation Plans

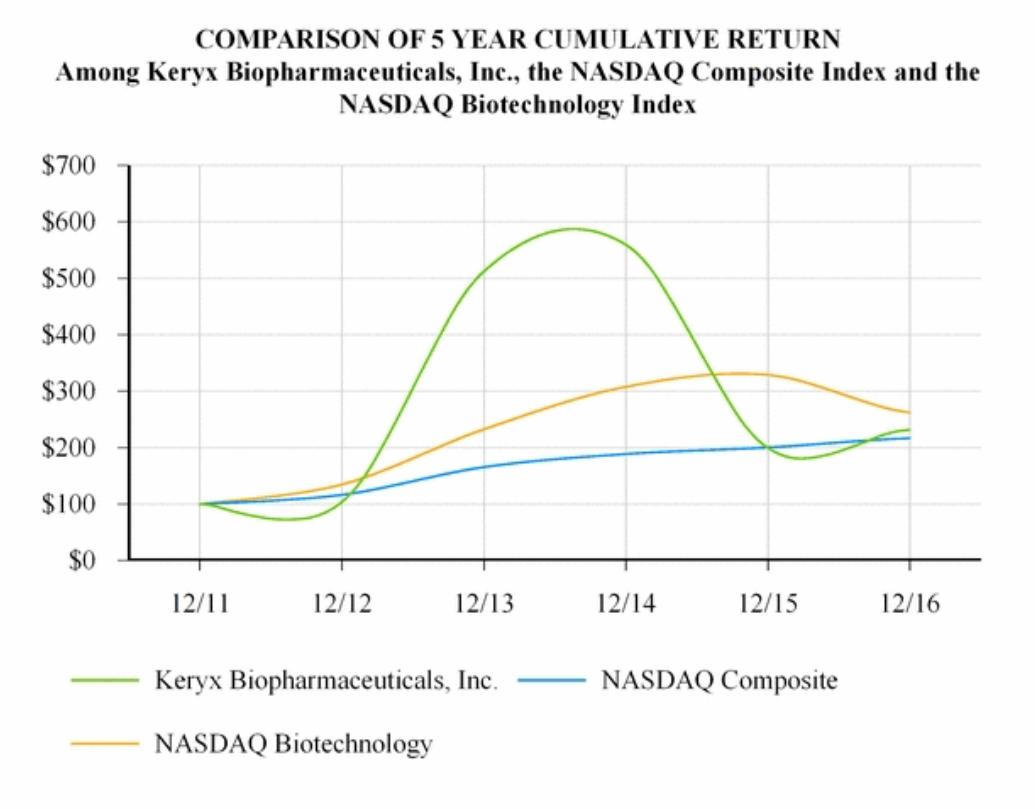
The following table provides information as of December 31, 2016, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, 2004 Long-Term Incentive Plan, 2007 Incentive Plan, 2009 CEO Incentive Plan and 2013 Incentive Plan, as amended.

	Equity Compensation Plan Information		
Plan Category	**Number of securities to be issued upon exercise of outstanding options**	**Weighted-average exercise price of outstanding options**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
	(a)	**(b)**	**(c)**
Equity compensation plans	8,677,998	$ 7.28	7,124,389

For information about all of our equity compensation plans, see Note 9 to our Consolidated Financial Statements included in this report.

COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2011 through December 31, 2016, with the cumulative total return over such period on (i) the U.S. Index of The Nasdaq Stock Market and (ii) the Biotechnology Index of the Nasdaq Stock Market. The graph assumes an investment of $100 on December 31, 2011, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.



ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2016, 2015, 2014, 2013 and 2012, and Balance Sheet Data as of December 31, 2016, 2015, 2014, 2013 and 2012, as set forth below are derived from our audited consolidated financial statements. This financial data should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data” contained elsewhere in this annual report on Form 10-K.

	Years ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Statement of Operations Data:					
Net U.S. Auryxia product sales	$ 27,173	$ 10,141	$ —	$ —	$ —
License revenue	4,810	3,539	10,825	7,000	—
Total revenues	31,983	13,680	10,825	7,000	—
Costs and expenses:					
Cost of goods sold	37,803	4,520	—	—	—
License expenses	2,886	2,124	495	—	—
Research and development	29,504	36,694	51,502	34,734	20,031
Selling, general and administrative	84,553	81,410	70,057	19,349	7,048
Total costs and expenses:	154,746	124,748	122,054	54,083	27,079
Operating loss	(122,763)	(111,068)	(111,229)	(47,083)	(27,079)
Other (expense) income:					
Amortization of debt discount	(34,227)	(11,357)	—	—	—
Other (expense) income, net	(4,025)	(630)	411	351	1,719
Total other (expense) income	(38,252)	(11,987)	411	351	1,719
Loss before income taxes	(161,015)	(123,055)	(110,818)	(46,732)	(25,360)
Income taxes	80	90	700	—	—
Loss before extraordinary gain	(161,095)	(123,145)	(111,518)	(46,732)	(25,360)
Extraordinary gain	—	—	—	—	2,639
Net loss	$ (161,095)	$ (123,145)	$ (111,518)	$ (46,732)	$ (22,721)
Basic and diluted loss per common share:					
Continuing operations	$ (1.52)	$ (1.19)	$ (1.23)	$ 0.58	$ (0.36)
Extraordinary gain	—	—	—	—	0.04
Basic and diluted loss per common share	$ (1.52)	$ (1.19)	$ (1.23)	$ 0.58	$ (0.32)

	As of December 31,				
(in thousands)	2016	2015	2014	2013	2012
Balance Sheet Data:					
Cash and cash equivalents, interest receivable and short-term investment securities	$ 111,810	$ 200,290	$ 85,840	$ 55,696	$ 14,677
Working capital	111,346	171,688	69,285	41,600	7,068
Total assets	141,427	258,685	103,628	60,766	18,569
Convertible senior notes	125,000	90,773	—	—	—
Total liabilities	149,723	171,751	30,144	15,366	8,075
Total stockholders' equity (deficit)	(8,296)	86,934	73,484	45,400	10,494

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

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in this report under the heading "Item 1A. Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with "Item 6. Selected Financial Data," "Item 8. Financial Statements and Supplementary Data," and our consolidated financial statements beginning on page F-1 of this report.

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, and approved in Europe as Fexeric. We are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent, CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that help patients with kidney disease. We use the brand name Auryxia only when we refer to the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines for the treatment of people with kidney disease to the market that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is a non-chewable, orally-administered phosphate binder for patients on dialysis. Auryxia is being marketed in the United States to renal care teams through our specialty salesforce and commercial infrastructure. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to continue to drive commercial adoption of Auryxia in the dialysis setting following the return of this medicine to patients in November 2016.

We also believe that we can maximize the potential of ferric citrate through potential label expansion for the treatment of IDA, NDD-CKD patients. We completed a pivotal Phase 3 clinical trial evaluating ferric citrate for this indication and presented results from this trial to the medical community at the American Society of Nephrology's Kidney Week 2016 Annual Meeting. The results from this trial were also published online in the *Journal of the American Society of Nephrology* in January 2017. We submitted a supplemental new drug application, or sNDA, to the U.S. Food and Drug Administration, or FDA, in January 2017 seeking to expand the label for Auryxia to include the treatment of IDA in NDD-CKD patients and expect that the sNDA will be accepted by the FDA for review. We anticipate a standard review cycle for this sNDA and, if approved, could potentially make the medicine available to these patients late in 2017. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist have IDA, NDD-CKD, including approximately 650,000 adults currently being treated by nephrologists for IDA. IDA is common in the NDD-CKD population and the prevalence and severity increases as CKD advances. IDA is symptomatic and can significantly impact quality of life. No oral iron medications are currently FDA-approved to treat IDA, NDD-CKD.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that help patients with kidney disease. Our business development activities include evaluating several clinical-drug candidates and commercial medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that

leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a work force of high-quality and talented people to support our potential growth.

Financial Performance Overview

Net U.S. Auryxia product sales represents the gross product sales of Auryxia in the United Sates less provisions for product sales allowances and accruals. These provisions include trade allowances, rebates, chargebacks and discounts, product returns and other incentives. See "Critical Accounting Policies" below for more information on the components of net U.S. Auryxia product sales.

Our license revenues consist of license fees, royalties and milestone payments arising from our agreement with JT and Torii. Royalty revenue consists of royalties received from our Japanese partner on net sales of Riona in Japan. Based on our agreement with JT and Torii, and in accordance with our revenue recognition policy described below, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred.

Cost of goods sold includes the cost of active pharmaceutical ingredient, or API, for Auryxia on which product sales were recognized during the period, the associated costs for tableting, packaging, shipment, insurance and quality assurance, as well as any idle capacity charges we may incur at our contract manufacturers and write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

Our license expenses consist of royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to license expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the license revenue is recorded. Other expenses are recognized in the period they are incurred.

Our research and development expenses consist primarily of salaries and related personnel costs, including stock-based compensation, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-approval inventory build-up, regulatory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred. Research and development expenses for the years ended December 31, 2016, 2015 and 2014 were $29.5 million, $36.7 million and $51.5 million, respectively.

The following table sets forth the research and development expenses per project, for the periods presented.

	Years ended December 31,		
(in thousands)	2016	2015	2014
Auryxia (ferric citrate)	$ 26,692	$ 32,911	$ 44,735
Other	—	264	388
Stock-based compensation expense	2,812	3,519	6,379
Total	$ 29,504	$ 36,694	$ 51,502

Our selling, general and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executive, finance, sales, marketing and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities, pre-commercial/commercial activities and facilities-related expenses.

Our results of operations include stock-based compensation expense as a result of the grants of stock options and restricted stock. Stock-based compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. See "Critical Accounting Policies" below for a discussion of our recognition of stock-based compensation expenses. The expense is

classified by expense categories in the consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis, there is no guarantee that we will be able to record meaningful commercial sales of Auryxia in the future or become profitable. In addition, we expect losses to continue as we continue to fund the development and commercialization of Auryxia, including, but not limited to, sNDA submissions, building of inventory, commercial activities, ongoing and additional clinical trials, and the potential acquisition and development of additional drug candidates in the future. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Years Ended December 31, 2016 and 2015

Net U.S. Auryxia Product Sales. For the year ended December 31, 2016, we recognized $27.2 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $10.1 million for the year ended December 31, 2015.

(in thousands)	2016	Percent of gross Auryxia product sales	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 44,557		$ 16,295	
Less provision for product sales allowances and accruals				
Trade allowances	5,157	12%	1,897	12%
Rebates, chargebacks and discounts	10,703	24%	2,418	15%
Product returns	879	2%	—	—%
Other incentives (1)	645	1%	1,839	11%
Total	17,384	39%	6,154	38%
Net U.S. Auryxia product sales	$ 27,173		$ 10,141	

(1) Includes co-pay assistance and voucher rebates.

We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of filling patient prescriptions. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns. Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers.

Gross Auryxia product sales increased for the year ended December 31, 2016 as compared to the same period in 2015 primarily as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the year ended December 31, 2016 as compared to the same period in 2015 increased primarily as a result of additional rebates and discounts given to our third-party payors. The transition to the ex-factory revenue recognition method resulted in the need to establish an accrual for product returns, which increased the provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales. Our sales of Auryxia in 2016, however, were negatively impacted by the interruption in the supply of Auryxia during portions of the third and fourth quarters of 2016 due to a production-related issue in converting API to finished drug product at our contract manufacturer. In November 2016, the FDA approved a second manufacturer to produce finished Auryxia drug product, after which we made Auryxia available for sale again.

As a result in the change in revenue recognition method during the fourth quarter of 2016, we did not have any deferred revenue at December 31, 2016, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and

chargebacks. We expect net Auryxia product sales to increase in 2017 as compared to 2016 as we continue the commercialization of Auryxia.

The following table sets forth customers or partners who represented 10% or more of our total revenues for 2016 and 2015:

(in thousands)	December 31, 2016	December 31, 2015
McKesson Corporation	31%	23%
AmerisourceBergen Drug Corporation	23%	17%
Fresenius Medical Care Rx	22%	15%
Cardinal Health, Inc.	11%	24%
DaVita Rx	10%	19%

License Revenue. For the year ended December 31, 2016, we recognized $4.8 million in license revenue on royalty payments from sales of Riona in Japan as compared to $3.5 million for the year ended December 31, 2015. This increase was directly attributable to increased sales of Riona in Japan.

Cost of Goods Sold. For the year ended December 31, 2016, we recognized $37.8 million in cost of goods sold as compared to $4.5 million for the year ended December 31, 2015. Cost of goods sold in 2016 includes approximately $25.6 million in write-offs of work-in-process inventory that was determined to be no longer suitable for commercial manufacture. Cost of goods sold during each of 2015 and 2016 also includes $2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production capacity at certain of our third-party manufacturers.

License Expenses. For the year ended December 31, 2016, we recognized $2.9 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $2.1 million for the year ended December 31, 2015. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $7.2 million, or 20%, to $29.5 million for the year ended December 31, 2016, as compared to $36.7 million for the year ended December 31, 2015. The decrease in research and development expenses was primarily due to a $3.0 million decrease in expenses related to clinical trial activity following the completion of our Phase 3 clinical trial of ferric citrate in IDA, NDD-CKD, in early 2016, as well as a decrease of $2.5 million in manufacturing-related expenses that were expensed to research & development as a result of a decrease in development work and fees due to our licensor related to lower API production. Regulatory consulting expenses also decreased by approximately $1.4 million after the completion of our European filing for Fexeric in 2015. We expect our research and development expenses to increase slightly in 2017 related to investigator sponsored research and pediatric studies and other post-marketing clinical trials that are expected to begin in 2017.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $3.2 million, or 4%, to $84.6 million for the year ended December 31, 2016, as compared to $81.4 million for the year ended December 31, 2015. The increase was primarily due to a $16.2 million increase in selling expense related to the commercialization of Auryxia, including an increased sales force for a full year in 2016 versus a partial year in 2015. This was partially offset by decreases in personnel costs as a result of severance payments and related costs incurred in 2015. We expect our selling, general and administrative costs to increase in 2017 as compared to 2016, due to costs associated with preparing for the potential approval of Auryxia in pre-dialysis IDA.

Other (expense) income, net. Other (expense) income, net for the year ended December 31, 2016 was $38.3 million (expense) compared to $12.0 million (expense) for the year ended December 31, 2015. This increase in expense was primarily the result of $34.2 million of expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Convertible Senior Notes, due 2020, or the Notes, in October 2015, as compared to $11.4 million recorded in 2015. Additionally, we recorded $4.7 million of expense in 2016 related to the increase in fair value of the derivative liability associated with the Notes, as compared to $1.1 million in 2015. This derivative liability was recorded in connection with the issuance of the Notes in October 2015 and represents the portion of the Notes that is required to be accounted for separately. See Note 8 - Debt for additional details.

Income Taxes. For the years ended December 31, 2016 and December 31, 2015, we recognized $0.1 million in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized under generally accepted accounting principles in the United States, or GAAP, since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. We continue to maintain a full valuation allowance against our net deferred tax assets.

Years Ended December 31, 2015 and 2014

Net U.S. Auryxia Product Sales. For the year ended December 31, 2015, we recognized $10.1 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks. Our commercial launch of Auryxia occurred in late December 2014. There were no product sales for the year ended December 31, 2014.

(in thousands)	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 16,295	
Less provision for product sales allowances and accruals		
Trade allowances	1,897	12%
Rebates, chargebacks and discounts	2,418	15%
Product returns	-	—%
Other incentives (1)	1,839	11%
Total	6,154	38%
Net U.S. Auryxia product sales	$ 10,141	

(1) Includes co-pay assistance and voucher rebates.

Until the fourth quarter of 2016, we deferred recognition of revenue, until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product), and not based on sales from us to our Customers. At December 31, 2015, we had deferred revenue of $3.5 million, which represented Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable discounts and rebates.

Other incentives include costs associated with patient services programs, including a voucher program that provides a free month of drug to patients as we work to build formulary access for Auryxia.

License Revenue. For the year ended December 31, 2015, we recognized $3.5 million in license revenue on royalty payments from sales of Riona in Japan as compared to $10.8 million for the year ended December 31, 2014. This decrease was due to the one-time recognition of a $10.0 million non-refundable milestone payment in January 2014 related to JT and Torii's achievement of marketing approval of Riona in Japan.

Cost of Goods Sold. For the year ended December 31, 2015, we recognized $4.5 million in cost of goods sold related to product sales of Auryxia. Our commercial launch of Auryxia occurred in late December 2014. There was no cost of goods sold expense recorded for the year ended December 31, 2014. The cost of goods sold for the year ended December 31, 2015 includes $2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production capacity at certain of our third-party manufacturers.

License Expenses. For the year ended December 31, 2015, we recognized $2.1 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.5 million for the year ended December 31, 2014. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $14.8 million, or 29%, to $36.7 million for the year ended December 31, 2015, as compared to $51.5 million for the year ended December 31, 2014. The decrease in research and development expenses was due to an $11.1 million decrease in expenses related to the manufacturing of Auryxia, which were expensed through approval of Auryxia in September 2014 and are now capitalized as inventory following approval, as well as a $6.6 million decrease in regulatory and clinical study expenses related to Auryxia. Stock-based compensation also decreased $2.9 million for the year ended December 31, 2015 as compared to the prior year period,

primarily as a result of the vesting of milestone-based stock options and restricted shares upon the FDA approval and first commercial sale of Auryxia to wholesalers in 2014. These decreases were partially offset by $7.9 million of expenses for medical affairs activities in the year ended December 31, 2015, as the medical affairs group will increasingly be supporting additional research and development of Auryxia in the post-approval setting and, therefore, the associated costs are included in research and development expenses as of January 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $11.3 million, or 16%, to $81.4 million for the year ended December 31, 2015, as compared to $70.1 million for the year ended December 31, 2014. The increase was primarily due to a $12.2 million increase in sales expense related to the commercialization of Auryxia, including an increase in sales force.

Other (expense) income, net. Other (expense) income, net for the year ended December 31, 2015 was $12.0 million (expense) compared to $0.4 million income for the year ended December 31, 2014. This increase in expense was primarily the result of $11.4 million of expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Notes in October 2015. Additionally, we recorded $1.1 million of expense in 2015 related to the increase in fair value of the derivative liability from October 15, 2015 to December 31, 2015. This derivative liability was recorded in connection with the issuance of the Notes in October 2015 and represents the portion of the Notes that is required to be accounted for separately. See Note 8 - Debt for additional details.

Income Taxes. For the year ended December 31, 2015, we recognized $0.1 million in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes, as compared to $0.7 million in income tax expense for the year ended December 31, 2014. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP, since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, from the upfront, royalty and milestone payments from our agreement with JT and Torii, sales of Auryxia, option and warrant exercises, interest income, and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue from the sales of Auryxia in 2015. Even if we successfully commercialize Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the SEC declared effective on December 6, 2016, which registered the issuance from time to time of up to $250.0 million of our securities. We also entered into a Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million. The $75.0 million of common stock issuable pursuant to the Sales Agreement is included as part of the $250.0 million registered on the registration statement referred to above. Subsequent to December 31, 2016, we sold 820,566 shares under the Sales Agreement for aggregate net proceeds of $5.1 million. As of the date of this filing, approximately $69.8 million of shares remained available for sale under the Sales Agreement.

In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. The Notes may be converted into shares of our common stock at the discretion of Baupost at a conversion price of $3.74, subject to adjustment based on the occurrence of certain events. We also entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare such resale registration statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns

may be conducted upon written request from Baupost. In addition, the Registration Rights Agreement provides Baupost certain piggyback registration rights.

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the SEC.

In January 2014, our Japanese partner, JT and Torii, received manufacturing and marketing approval of Riona from the Japanese Ministry of Health, Labour and Welfare. We receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe royalties at a mid-single digit percentage of net sales to the licensor of Auryxia associated with net sales of Riona in Japan.

As of December 31, 2016, we had $111.8 million in cash and cash equivalents, as compared to $200.3 million in cash and cash equivalents at December 31, 2015, representing a decrease of $88.5 million.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for ferric citrate. As a result of these factors, we will need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the continued commercialization of Auryxia, and to develop and commercialize any drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, “Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.”

Net cash used in operating activities for the year ended December 31, 2016 was $86.6 million, primarily attributable to our net loss of $161.1 million, adjusted for non-cash stock-based compensation expense and amortization of the debt discount recognized in connection with the issuance of the Notes, as well as changes in operating assets and liabilities, principally the decrease of deferred revenue and accrued expenses from December 31, 2015. Net cash used in operating activities for the year ended December 31, 2015 was $127.5 million, primarily attributable to our net loss of $123.1 million, adjusted for non-cash stock-based compensation expense and changes in operating assets and liabilities, principally the increase in inventory and decrease in accrued expenses from December 31, 2014.

Net cash used in investing activities for the year ended December 31, 2016 was $2.1 million related to capital expenditures. Net cash provided by investing activities for the year ended December 31, 2015 was $8.7 million, attributable to $11.5 million provided by maturities of short-term investments, partially offset by capital expenditures.

Net cash provided by financing activities for the year ended December 31, 2016 was $0.2 million, attributable to proceeds from the exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2015 was $244.7 million, primarily attributable to net proceeds from the issuance of the Notes in October 2015 and from the public offering of common stock in January 2015. The decrease in cash provided by financing activities from 2015 to 2016 was a result of no public offering of common stock or other financings in 2016.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support, or engages in leasing, hedging, or research and development services on our behalf.

OBLIGATIONS AND COMMITMENTS

As of December 31, 2016, we have known contractual obligations, commitments and contingencies of $135.3 million. The debt obligation in the table below reflects our obligations under the Notes to make a principal payment for the par value of

the Notes at maturity. Any future conversion or settlement of the Notes could impact the timing and amount of our potential cash payments under the Notes (see Note 8-Debt). The remaining $10.3 million relates to our operating lease obligations.

(in thousands)	Payment due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Convertible senior notes	125,000	—	—	125,000	—
Operating leases	10,305	1,601	4,966	3,738	—
Total	$ 135,305	$ 1,601	$ 4,966	$ 128,738	$ —

In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94-month term that commenced on May 1, 2015 and will expire in February 2022, for office space to serve as our corporate headquarters.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our consolidated 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 reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our consolidated financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

Revenue Recognition and Related Sales Allowances and Accruals

Our commercial launch of Auryxia occurred in late December 2014. We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of the pharmacies reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectibility is reasonably assured and (iv) the price is fixed or determinable. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns. Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers. As a result, prior to the fourth quarter of 2016, we deferred Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue was recorded net of discounts, rebates, and chargebacks. We also deferred the related cost of product sales and recorded such amounts as finished goods inventory held by others, which was included in inventory on our consolidated balance sheet, until revenue related to such product sales was recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services. The payment terms for sales to Distributors generally include a prompt-pay discount for

payment made within 35 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts and fees, and deduct the full amount of these discounts and fees from our gross product sales and accounts receivable at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We estimate the rebates, chargebacks and discounts that we will provide to Third-Party Payors and specialty pharmacies based upon (i) our contracts with these Third-Party Payors and specialty pharmacies, (ii) the government-mandated discounts applicable to government-funded programs, and (iii) information obtained from our Customers and other third parties regarding the payor mix for Auryxia.

Product Returns: Consistent with industry practice, we generally offer our Customers a limited right to return our Auryxia based on the product's expiration date. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. We estimate product returns based on the historical return patterns and we track actual returns by individual manufacturing lots. We expect that Distributors and pharmacies will not stock significant inventory due to the cost of the product, the expense to store our products and that our product is readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available. As of December 31, 2016, we have experienced a relatively limited number of product returns; however, our returns experience may change over time. As we continue to gain more historical experience with actual returns, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Other Incentives: Other incentives that we offer to indirect customers include co-pay assistance rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay assistance programs, and vouchers for a small supply of Auryxia at no patient cost. Our co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Auryxia's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, we estimate the average co-pay assistance amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay assistance rebates and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We adjust our accruals for co-pay assistance and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

We recognize license revenue in accordance with Accounting Standards Codification 605, *Revenue Recognition,* or *ASC 605*. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

For arrangements for which royalty revenue information becomes available and collectibility is reasonably assured, we recognize revenue during the applicable period earned. When collectibility is reasonably assured but a reasonable estimate of royalty revenue cannot be made, the royalty revenue is recognized in the quarter that the licensee provides the written report and related information to us.

Stock-Based Compensation

We grant stock options and restricted stock to employees, directors and consultants. We are required to estimate the expected forfeiture rate and only recognize expense for those equity awards that are expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes model has several inputs, including the volatility in the price of our stock, the risk-free interest rate, the expected term of the option, the closing market price of our stock on the grant date and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

The aggregate fair value of restricted stock granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures.

The total stock-based compensation recorded in a given period is dependent upon the assumptions utilized. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options issued to employees, consultants and other third-parties vest upon the achievement of certain performance conditions or milestones, the total expense is uncertain.

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Inventory

Inventory is stated at the lower of cost or estimated realizable value. We determine the cost of our inventory, which include amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management's judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers were included as a component of research and development expense.

Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts, if necessary, are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at December 31, 2016 and 2015.

Accounting Related to Goodwill

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

Accounting for Income Taxes

In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

For the years ended December 31, 2016 and 2015, we recognized under $0.1 million in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized for book purposes since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

RECENTLY ISSUED ACCOUNTING STANDARDS

For a discussion of new accounting standards, see Note 2 - Basis of Presentation and Summary of Significant Accounting Policies to our consolidated financial statements included in this report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of December 31, 2016, our portfolio of financial instruments consists of cash equivalents, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Equity Price Risk

Our Convertible Notes include conversion provisions that are based on the price of our common stock at conversion or at maturity of the notes. The fair values of our Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and the notes thereto, included in Part IV, Item 15, Part 1, are incorporated by reference into this Item 8.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2016, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2016, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2016, our internal control over financial reporting was effective based on these criteria. UHY LLP, our independent registered public accounting firm, has audited the accompanying consolidated balance sheets as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2016, included in this annual report on page F-1. UHY LLP has issued an attestation report on our internal control over financial reporting as of December 31, 2016, which is found below.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of Keryx Biopharmaceuticals, Inc.

We have audited Keryx Biopharmaceuticals, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in Part II, Item 9A of this Form 10-K. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Keryx Biopharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows of Keryx Biopharmaceuticals, Inc., and our report dated March 1, 2017, expressed an unqualified opinion thereon.

/s/ UHY LLP
New York, New York
March 1, 2017

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements

The following consolidated financial statements of Keryx Biopharmaceuticals, Inc. are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. Exhibits

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

Keryx Biopharmaceuticals, Inc.
Consolidated Financial Statements as of December 31, 2016

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of Keryx Biopharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Keryx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2016. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Keryx Biopharmaceuticals, Inc. as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 1, 2017, expressed an unqualified opinion thereon.

/s/ UHY LLP
New York, New York
March 1, 2017

Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of December 31,

(in thousands, except share and per share amounts)

	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 111,810	$ 200,290
Inventory	12,681	41,881
Accounts receivable, net	5,236	3,656
Receivable from landlord	—	637
Other current assets	3,170	2,830
Total current assets	132,897	249,294
Property, plant and equipment, net	4,211	5,083
Goodwill	3,208	3,208
Other assets, net	1,111	1,100
Total assets	$ 141,427	$ 258,685
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,190	$ 26,795
Deferred revenue	—	3,526
Derivative liability	—	46,686
Deferred lease incentive, current portion	244	244
Other current liabilities	117	355
Total current liabilities	21,551	77,606
Convertible senior notes	125,000	90,773
Deferred lease incentive, net of current portion	1,262	1,506
Deferred tax liability	870	790
Other liabilities	1,040	1,076
Total liabilities	149,723	171,751
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)	—	—
Common stock, $0.001 par value per share (180,000,000 and 130,000,000 shares authorized, 105,921,052 and 105,221,555 shares issued, 105,841,104 and 105,141,607 shares outstanding at December 31, 2016 and 2015, respectively)	106	105
Additional paid-in capital	827,053	761,189
Treasury stock, at cost, 79,948 shares at December 31, 2016 and 2015	(357)	(357)
Accumulated deficit	(835,098)	(674,003)
Total stockholders' (deficit) equity	(8,296)	86,934
Total liabilities and stockholders' (deficit) equity	$ 141,427	$ 258,685

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations for the Years Ended December 31,

(in thousands, except share and per share amounts)

	2016	2015	2014
Revenues:			
Net U.S. Auryxia product sales	$ 27,173	$ 10,141	$ —
License revenue	4,810	3,539	10,825
Total revenues	31,983	13,680	10,825
Costs and expenses:			
Cost of goods sold	37,803	4,520	—
License expenses	2,886	2,124	495
Research and development	29,504	36,694	51,502
Selling, general and administrative	84,553	81,410	70,057
Total costs and expenses	154,746	124,748	122,054
Operating loss	(122,763)	(111,068)	(111,229)
Other (expense) income:			
Amortization of debt discount	(34,227)	(11,357)	—
Other (expense) income, net	(4,025)	(630)	411
Total other (expense) income:	(38,252)	(11,987)	411
Loss before income taxes	(161,015)	(123,055)	(110,818)
Income taxes	80	90	700
Net loss	$ (161,095)	$ (123,145)	$ (111,518)
Basic and diluted net loss per common share	$ (1.52)	$ (1.19)	$ (1.23)
Weighted average shares used in computing basic and diluted net loss per common share	105,845,121	103,898,399	91,000,902

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
for the Years Ended December 31, 2016, 2015 and 2014

(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Treasury stock		Accumulated deficit	Total
	Shares	Amount		Shares	Amount		
Balance at January 1, 2014	82,723,145	$ 83	$ 485,014	79,948	$ (357)	$ (439,340)	$ 45,400
Issuance of common stock in public offering (net of offering costs of $7,525)	7,935,000	8	107,524	—	—	—	107,532
Issuance of restricted stock	1,451,558	1	—	—	—	—	1
Forfeiture of restricted stock	(88,859)	— *	—	—	—	—	— *
Issuance of common stock in connection with the exercise of stock options	737,945	1 *	5,053	—	—	—	5,054
Stock-based compensation	—	—	27,015	—	—	—	27,015
Net loss	—	—	—	—	—	(111,518)	(111,518)
Balance at December 31, 2014	92,758,789	$ 93	$ 624,606	79,948	$ (357)	$ (550,858)	$ 73,484
Issuance of common stock in public offering (net of offering costs of $8,216)	10,541,667	10	118,274	—	—	—	118,284
Issuance of restricted stock	1,247,250	1	—	—	—	—	1
Forfeiture of restricted stock	(330,102)	— *	—	—	—	—	— *
Surrender of common stock for tax withholding	(1,625)	— *	(15)				(15)
Issuance of common stock in connection with the exercise of stock options	1,005,576	1	1,462	—	—	—	1,463
Stock-based compensation	—	—	16,862	—	—	—	16,862
Net loss	—	—	—	—	—	(123,145)	(123,145)
Balance at December 31, 2015	105,221,555	$ 105	$ 761,189	79,948	$ (357)	$ (674,003)	$ 86,934
Issuance of restricted stock	974,325	1	—	—	—	—	1
Forfeiture of restricted stock	(341,603)	— *	—	—	—	—	— *
Issuance of common stock in connection with the exercise of stock options	66,775	—	198	—	—	—	198
Reclassification of derivative liability to equity	—	—	51,404				51,404
Stock-based compensation	—	—	14,262	—	—	—	14,262
Net loss	—	—	—	—	—	(161,095)	(161,095)
Balance at December 31, 2016	105,921,052	$ 106	$ 827,053	79,948	$ (357)	$ (835,098)	$ (8,296)

* *Amount less than one thousand dollars.*

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows for the Years Ended December 31,

(in thousands)

	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (161,095)	$ (123,145)	$ (111,518)
Adjustments to reconcile net loss to cash flows used in operating activities:			
Stock-based compensation expense	13,989	16,500	26,957
Amortization of debt discount	34,227	11,357	—
Change in fair value of derivative liability	4,718	1,102	—
Depreciation and amortization	1,005	596	306
Loss on disposal of fixed assets	54	507	—
Write-down of inventory to net realizable value	27,968	—	—
Cash received from landlord	637	1,276	—
Amortization of deferred lease incentive	(244)	(163)	—
Deferred income taxes	80	90	700
Changes in operating assets and liabilities:			
Other current assets	(340)	1,262	(2,860)
Accounts receivable, net	(1,580)	(2,822)	(834)
Accrued interest receivable	—	47	(48)
Inventory	(2,300)	(29,189)	(7,771)
Security deposits	—	(807)	—
Other assets	(11)	355	(11)
Other current liabilities	(238)	—	—
Accounts payable and accrued expenses	88	(8,478)	13,569
Deferred revenue	(3,526)	3,112	414
Other liabilities	(36)	943	95
Net cash used in operating activities	(86,604)	(127,457)	(81,001)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(2,074)	(2,777)	(1,489)
Investment in held-to-maturity short-term securities	—	—	(49,771)
Proceeds from maturity of held-to-maturity short-term securities	—	11,508	38,263
Net cash (used in) provided by investing activities	(2,074)	8,731	(12,997)
Cash flows from financing activities:			
Proceeds from public offerings, net	—	118,284	107,532
Proceeds from issuance of convertible senior notes	—	125,000	—
Proceeds from exercise of stock options	198	1,463	5,054
Surrender of common stock for tax withholding	—	(15)	—
Net cash provided by financing activities	198	244,732	112,586
Net (decrease) increase in cash and cash equivalents	(88,480)	126,006	18,588
Cash and cash equivalents at beginning of year	200,290	74,284	55,696
Cash and cash equivalents at end of year	$ 111,810	$ 200,290	$ 74,284
Supplemental disclosures of non-cash investing and financing activities			
Reclassification of derivative liability to equity	51,404	—	—
Increase of receivable from landlord and deferred lease incentive	—	637	—

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

Keryx Biopharmaceuticals, Inc.
Notes to the Consolidated Financial Statements

Unless the context requires otherwise, references in this report to "Keryx," "Company," "we," "us" and "our" refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

NOTE 1 – DESCRIPTION OF BUSINESS

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, and approved in Europe as Fexeric. We are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent, CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that help patients with kidney disease. We use the brand name Auryxia only when we refer to the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines for the treatment of people with kidney disease to the market that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is a non-chewable, orally-administered phosphate binder for patients on dialysis. Auryxia is being marketed in the United States to renal care teams through our specialty salesforce and commercial infrastructure. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to continue to drive commercial adoption of Auryxia in the dialysis setting following the return of this medicine to patients in November 2016.

We also believe that we can maximize the potential of ferric citrate through potential label expansion for the treatment of IDA, NDD-CKD patients. We completed a pivotal Phase 3 clinical trial evaluating ferric citrate for this indication and presented results from this trial to the medical community at the American Society of Nephrology's Kidney Week 2016 Annual Meeting. The results from this trial were also published online in the *Journal of the American Society of Nephrology* in January 2017. We submitted a supplemental new drug application, or sNDA, to the U.S. Food and Drug Administration, or FDA, in January 2017 seeking to expand the label for Auryxia to include the treatment of IDA in NDD-CKD patients and expect that the sNDA will be accepted by the FDA for review. We anticipate a standard review cycle for this sNDA and, if approved, could potentially make the medicine available to these patients late in 2017. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist have IDA, NDD-CKD, including approximately 650,000 adults currently being treated by nephrologists for IDA. IDA is common in the NDD-CKD population and the prevalence and severity increases as CKD advances. IDA is symptomatic and can significantly impact quality of life. No oral iron medications are currently FDA-approved to treat IDA, NDD-CKD.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that help patients with kidney disease. Our business development activities include evaluating several clinical-drug candidates and commercial medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a work force of high-quality and talented people to support our potential growth.

NOTE 2 – BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance of ASU No. 2014-09 on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,* which clarifies certain aspects of identifying performance obligations and licensing implementation guidance of ASU No. 2014-09. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients,* which amends narrow aspects of Topic 606, including guidance on assessing collectibility, non-cash consideration, contract modifications and completed contracts at transition, and the presentation of sales and other similar taxes collected from customers. In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, which amends certain aspects of the guidance issued in ASU No. 2014-09 including guidance related to loan guarantee fees, contract costs, refund liabilities, advertising costs, as well as the disclosure of remaining performance obligations and prior-period performance obligations. We are currently assessing the method of adoption and the expected impact that Topic 606 will have on our financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This standard explicitly requires management to assess an entity's ability to continue as a going concern and to provide footnote disclosures in certain cases. The standard was effective for us on December 31, 2016. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory*. Under this standard, the measurement principle for inventory will change from lower of cost or market value to lower of cost and net realizable value. The standard defines net realizable value as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The standard is applicable to inventory that is accounted for under the first-in, first-out or average cost method and is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases.* The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The adoption of this standard is expected to have a material impact on our financial position as it will impact the amount of our assets and liabilities. We are currently evaluating the potential impact that this standard may have on our results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.* The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard became effective for us on January 1, 2017. This standard is not expected to have a material impact on our financial position, results of operations or statement of cash flows upon adoption.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.* The new standard addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of

cash flows. The new standard will be effective for us on January 1, 2018. This standard is not expected to have a material impact on our statement of cash flows upon adoption.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include our financial statements and those of our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

USE OF ESTIMATES

The preparation of financial statements in conformity with Generally Accepted Accounting Principles, or GAAP, requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of these consolidated financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to these consolidated financial statements.

CASH AND CASH EQUIVALENTS

We consider liquid investments with original maturities of three months or less at the time of purchase to be cash and cash equivalents. At December 31, 2016, all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

INVENTORY

Inventory is stated at the lower of cost or estimated realizable value. We determine the cost of our inventory, which includes amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management's judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers was included as a component of research and development expense.

ACCOUNTS RECEIVABLE, NET

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable determined to be uncollectible are written off against the allowance for doubtful accounts. Allowances for doubtful accounts, if necessary, are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at December 31, 2016 and 2015.

RECEIVABLE FROM LANDLORD

In April 2015, we signed a new lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94- month term that commenced on May 1, 2015. Our landlord agreed to pay for up to approximately $1.9 million of improvements to the space, which we accounted for as a lease incentive in accordance with Accounting Standards Codification, ASC, 840-20, *Operating Leases*. The remaining amount of the lease incentive was collected from our landlord in 2016.

PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at historical cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets:

	Estimated useful life (years)
Office furniture and equipment	3-7
Computers, software and related equipment	3

Leasehold improvements are depreciated over the shorter of their useful life or the remaining term of the lease exclusive of renewal options.

REVENUE RECOGNITION

Our commercial launch of our only product, Auryxia, in the United States, occurred in late December 2014. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectibility is reasonably assured, and (iv) the price is fixed or determinable. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns. Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers.

Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers. As a result, prior to the fourth quarter of 2016, we deferred Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue was recorded net of discounts, rebates, and chargebacks. We also deferred the related cost of product sales and recorded such amounts as finished goods inventory held by others, which was included in inventory on our consolidated balance sheet, until revenue related to such product sales was recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid rebates, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services. The payment terms for sales to Distributors generally include a prompt-pay discount for payments made within 35 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts, and deduct the full amount of these discounts from our gross product sales and accounts receivable at the time such revenues are recognized. Fees for distribution services are deducted from our gross product sales and we accrue these fees which appear in our accrued expenses on our consolidated balance sheets.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We estimate the rebates, chargebacks and discounts that we will provide to Third-party Payors and specialty pharmacies based upon (i) our contracts with these Third-party Payors and specialty pharmacies, (ii) the government-mandated discounts applicable to government-funded programs and (iii) information obtained from our Customers and other third parties regarding the payor mix for Auryxia.

Product Returns: Consistent with industry practice, we generally offer our Customers a limited right to return our Auryxia based on the product's expiration date. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which generally occurs within a few months before Auryxia is delivered to Customers. We estimate product returns based on the historical return patterns and we track actual returns by individual manufacturing lots. We expect that Distributors and pharmacies will not stock significant inventory due to the cost of the product, the expense to store our product, and that our product is readily available for

distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available. As of December 31, 2016, we have experienced a relatively limited number of product returns; however, our returns experience may change over time. As we continue to gain more historical experience with actual returns, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Other Incentives: Other incentives that we offer to indirect customers include co-pay assistance rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay assistance programs, and vouchers for a small supply of Auryxia at no patient cost. Our co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Auryxia's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, we estimate the average co-pay assistance amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay assistance rebates and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We adjust our accruals for co-pay assistance and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

Classification of product sales allowances and accruals

Allowances against receivable balances primarily relate to prompt-pay discounts and chargebacks and are recorded at the time of sale, resulting in a reduction in product sales revenue and the recording of product sales receivables net of allowances. Accruals related to Medicaid, Medicare Part D and other government and commercial rebates, as well as wholesaler fees and product returns are recorded at the time of sale, resulting in a reduction in product sales and the recording of an increase in accrued expenses.

Our U.S. Auryxia product sales for the years ended December 31, 2016 and 2015 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	2016	Percent of gross Auryxia product sales	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 44,557		$ 16,295	
Less provision for product sales allowances and accruals				
Trade allowances	5,157	12%	1,897	12%
Rebates, chargebacks and discounts	10,703	24%	2,418	15%
Product returns	879	2%	—	—%
Other incentives (1)	645	1%	1,839	11%
Total	17,384	39%	6,154	38%
Net U.S. Auryxia product sales	$ 27,173		$ 10,141	

(1) Includes co-pay assistance and voucher rebates.

We recognize license revenue in accordance with ASC 605, *Revenue Recognition*. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

For arrangements for which royalty revenue information becomes available and collectibility is reasonably assured, we recognize revenue during the applicable period earned. When collectibility is reasonably assured but a reasonable estimate of

royalty revenue cannot be made, the royalty revenue is recognized in the quarter that the licensee provides the written report and related information to us.

The following table sets forth customers or partners who represented 10% or more of our total revenues for 2016 and 2015:

(in thousands)	December 31, 2016	December 31, 2015
McKesson Corporation	31%	23%
AmerisourceBergen Drug Corporation	23%	17%
Fresenius Medical Care Rx	22%	15%
Cardinal Health, Inc.	11%	24%
DaVita Rx	10%	19%

COST OF GOODS SOLD

Cost of goods sold includes the cost of active pharmaceutical ingredient, or API, for Auryxia on which product sales were recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and U.S. product sales recognized during the period.

LICENSE EXPENSES

License expenses include royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to royalty expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the revenue is recorded. Other expenses are recognized in the period they are incurred.

RESEARCH AND DEVELOPMENT COSTS

Research and development costs are expensed as incurred. Pre-approval inventory expenditures are recorded as research and development expense as incurred. The capitalization of inventory for our product candidate(s) commence when it is probable that the product will be approved for commercial marketing. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of our deferred tax assets will not be realized.

We, and our subsidiaries, file income tax returns in the United States federal jurisdiction and in various states. Our subsidiary, Keryx Biopharma UK Ltd., files annual returns and accounts in the United Kingdom. We have tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination.

We recognize interest and penalties related to uncertain income tax positions in income tax expense.

Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

We are not aware of any unrecorded tax liabilities which would materially impact our financial position or our results of operations.

STOCK-BASED COMPENSATION

We grant stock options and restricted stock to employees, directors and consultants. We are required to estimate the expected forfeiture rate and only recognize expense for those equity awards that are expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes model has several inputs, including the volatility in the price of our stock, the risk-free interest rate, the expected term of the option, the closing market price of our stock on the grant date and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the fair value calculation, we assume that no dividends will be paid during the life of the options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

The fair value of restricted stock granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures.

For stock-based awards granted to consultants, we recognize compensation expense over the period during which services are rendered by such consultants until completed. At the end of each financial reporting period prior to completion of the service, we remeasure the fair value of these awards using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The total stock-based compensation recorded in a given period is dependent upon the assumptions utilized. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the stock options issued to employees, consultants and other third-parties vest upon the achievement of certain performance conditions or milestones, the total expense is uncertain.

BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options, as their inclusion would be anti-dilutive. The options outstanding as of December 31, 2016, 2015 and 2014, which are not included in the computation of net loss per share amounts, were 8,677,998, 5,411,557 and 5,132,426, respectively.

ACQUISITIONS

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Acquisition-related costs are expensed

as incurred. Any excess of the consideration transferred over the estimated fair values of the identifiable net assets acquired is recorded as goodwill.

IMPAIRMENT

Long-lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future undiscounted cash flows, an impairment charge is recognized.

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. As of December 31, 2016, 2015 and 2014, management conducted its annual assessments of goodwill and concluded that there were no impairments. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

CONCENTRATIONS OF CREDIT RISK

We do not have significant off-balance-sheet risk or credit risk concentrations. We maintain our cash and cash equivalents with multiple financial institutions. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at December 31, 2016 and 2015 represent amounts due to the Company from customers. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total accounts receivable, net as of December 31, 2016 and 2015:

(in thousands)	December 31, 2016	December 31, 2015
McKesson Corporation	31%	23%
AmerisourceBergen Drug Corporation	23%	17%
Fresenius Medical Care Rx	22%	15%
Cardinal Health, Inc.	11%	24%
DaVita Rx	10%	19%

We currently have three approved sites for the supply of Auryxia drug product. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience additional losses of revenue, which could materially and adversely impact our results of operations.

RECLASSIFICATIONS

Certain amounts in the prior period have been reclassified in order to conform to the current period presentation. Specifically, the caption "Accrued compensation and related liabilities" in our consolidated balance sheets as of December 31, 2015 was reclassified into the "Accounts payable and accrued expenses" caption. See Note 7 - Accounts Payable and Accrued Expenses for further detail.

NOTE 3 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in our statements using a fair value hierarchy. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1—quoted prices in active markets for identical assets and liabilities;

- Level 2—inputs other than Level 1 quoted prices that are directly or indirectly observable; and
- Level 3—unobservable inputs that are not corroborated by market data.

The following table provides the fair value measurements made on a recurring basis of applicable financial assets as of December 31, 2016 and 2015:

	Financial assets at fair value as of December 31, 2016		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Money market funds (1)	$ 107,084	$ —	$ —
Total assets	$ 107,084	$ —	$ —

	Financial assets at fair value as of December 31, 2015		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Money market funds (1)	$ 193,886	$ —	$ —
Total assets	$ 193,886	$ —	$ —
Liabilities:			
Derivative liability	$ —	$ —	$ 46,686
Total liabilities	$ —	$ —	$ 46,686

(1) Included in cash and cash equivalents on our consolidated balance sheets. The carrying amount of money market funds approximates fair value.

The derivative liability was recorded as a result of our issuance of $125 million in Convertible Senior Notes, due 2020, or the Notes, in October 2015. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using unobservable inputs. These inputs include: (1) a simulated share price at the time of conversion of the Notes, (2) assumed timing of conversion of the Notes, (3) the probability of stockholder approval of an increase in authorized shares at our 2016 Annual Meeting of Stockholders to allow for a full conversion of the Notes into our common stock, and (4) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The following table represents a reconciliation of the derivative liability recorded in connection with the issuance of the Notes:

January 1, 2015	$ —
Fair value recognized upon issuance of Notes	45,584
Fair value adjustments	1,102
December 31, 2015	$ 46,686
Fair value adjustments	4,718
Reclassification to equity	(51,404)
December 31, 2016	$ —

The fair value of the derivative liability was determined using a form of the income approach, in which we calculated the fair value of the Notes with the conversion feature as compared to the fair value of the Notes without the conversion feature, with the difference representing the value of the conversion feature, or the derivative liability. The fair value of the Notes without the conversion feature was calculated based on a cash payment for the full par value of the Notes at maturity and was discounted by our calculated pre-tax cost of debt of 7.6%. The fair value of the Notes with the conversion feature was calculated based on two scenarios that were probability-weighted: (1) full conversion of the Notes into shares of common stock at maturity which assumed approval of our stockholders of an increase in authorized shares to allow for such full conversion, and (2) cash settlement and physical settlement of the Notes at maturity which assumed no approval of our stockholders of an

increase in authorized shares. Both of the scenarios used to calculate the fair value of the Notes with the conversion feature included an input for the simulated share price at conversion, and were discounted by our calculated cost of equity of 17.5%.

Debt

In October 2015, we issued the Notes in a private financing to funds managed by Baupost. As of December 31, 2016 and 2015 the fair value of our Notes was $195.9 million and $132.9 million, respectively, which differs from their carrying value. The fair value of our Notes is influenced by our stock price and stock price volatility. See Note 8 – Debt for additional information on our debt obligations.

NOTE 4 – INVENTORY

Inventory consists of the following at December 31, 2016 and 2015:

(in thousands)	December 31, 2016	December 31, 2015
Raw materials	$ 418	$ 495
Work in process	11,430	40,124
Finished goods	833	1,031
Finished goods inventory held by others	—	231
Total inventory	$ 12,681	$ 41,881

During the year ended December 31, 2016, we wrote off approximately $25.6 million of work-in-process inventory that was determined to be no longer suitable for commercial manufacture, which was recorded to cost of goods sold.

Finished goods inventory held by others as of December 31, 2015 represents the cost of goods sold that was deferred to align with our deferral of product sales. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns. Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers. As a result, beginning in the fourth quarter of 2016, cost of goods sold is recognized upon delivery of shipments to wholesalers to align with our revenue recognition and is no longer deferred and recorded as inventory held by others on our consolidated balance sheets.

NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2016	December 31, 2015
Leasehold improvements	$ 3,916	$ 3,943
Office furniture and equipment	747	595
Computers, software and related equipment	787	997
	5,450	5,535
Accumulated depreciation and amortization	(1,239)	(452)
Net book value	$ 4,211	$ 5,083

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was $1.0 million, $0.6 million and $0.3 million, respectively.

NOTE 6 – GOODWILL

On April 6, 2006, ADI, our wholly-owned subsidiary, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. The purchase price of Accumin was $4.0 million. We accounted for the ADI transaction as a purchase. The excess of the purchase price over the net assets acquired in the ADI transaction represented goodwill of approximately $3.2 million, which was allocated to our Products segment based on the proposed synergies with our then existing drug pipeline activities. In September 2008, we terminated our license agreement related to the ADI product.

NOTE 7 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consists of the following at December 31, 2016 and 2015:

(in thousands)	December 31, 2016	December 31, 2015
Accounts payable	$ 2,225	$ 8,434
Accrued compensation and related liabilities	8,190	5,483
Professional, license, and other fees and expenses	6,159	10,522
Commercial rebates, fees and returns	4,616	2,356
Total accounts payable and accrued expenses	$ 21,190	$ 26,795

NOTE 8 – DEBT

In October 2015, we completed the sale of $125 million of Notes due 2020, in a private placement, or the Private Placement, to funds managed by Baupost pursuant to a Notes Purchase Agreement dated October 14, 2015. The Notes were issued under an Indenture dated as of October 15, 2015, with The Bank of New York Mellon Trust Company, N.A. as trustee, or the Trustee. Under the terms of the Indenture, the Notes may be converted into shares of our common stock at the discretion of Baupost. The indenture subjects us to certain financial and business covenants and contains restrictions on the payments of cash dividends.

The Indenture contains customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving us) occurs and is continuing, the Trustee by notice to us, or the holders of at least 25% in aggregate principal amount of the outstanding Notes by written notice to us and the Trustee, may declare 100% of the principal on all of the Notes to be due and payable. Upon such a declaration of acceleration, such principal will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving us, 100% of the principal on all of the Notes will become due and payable automatically.

Further, in connection with the Private Placement, we entered into a Registration Rights Agreement with the purchasers of the Notes (the "Registration Rights Agreement"), pursuant to which we agreed to (i) file a registration statement (the "Resale Registration Statement") with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. Finally, the Registration Rights Agreement affords Baupost certain piggyback registration rights.

The Notes are convertible at the option of Baupost at an initial conversion rate of 267.3797 shares of our common stock per $1,000 principal amount, equal to a conversion price of $3.74 per share, which represents the last reported sale price of our stock on October 14, 2015. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events. Further, upon the occurrence of certain fundamental changes involving us, Baupost may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased.

Per the terms of the Notes, a portion of the Notes was contingently convertible into cash if our stockholders did not approve an increase in the number of authorized shares of our common stock by July 1, 2016. In accordance with accounting guidance for debt with a conversion option, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes initially being partially convertible to cash at the option of Baupost. We

allocated the proceeds between the debt component and the embedded conversion option (the derivative) by performing a valuation of the derivative as of the transaction date, which was determined based on the difference between the fair value of the Notes with the conversion option and the fair value of the Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the initial carrying amount of the convertible notes represented the difference between the proceeds from the issuance of the Notes and the fair value of the derivative liability on the date of issuance. The excess of the principal amount of the debt component over its carrying amount ("debt discount") was amortized to interest expense using the effective interest method over the expected life of the debt.

Our outstanding convertible notes and derivative liability balances as of December 31, 2016 and 2015 consists of the following:

(in thousands)	December 31, 2016	December 31, 2015
Debt component:		
Principal	$ 125,000	$ 125,000
Debt discount	—	(34,227)
Net carrying amount	$ 125,000	$ 90,773
Derivative liability balance	$ —	$ 46,686

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represents the point at which a portion of the Notes was contingently convertible into cash. Accordingly, approximately $34.2 million of interest expense was recognized related to the Notes during the year ended December 31, 2016, all of which was attributable to the amortization of the debt discount. As of December 31, 2016 and 2015, the carrying value of the Notes was $125.0 million and $90.8 million and the fair value of the Notes was $195.9 million and $132.9 million, respectively.

At our 2016 Annual Meeting of Stockholders held on May 25, 2016, the necessary stockholder approval of the increase in authorized shares was obtained. As a result, the entirety of the Notes is now convertible into shares of our common stock. During the year ended December 31, 2016, the derivative liability was reclassified to equity as a result of the Notes no longer being convertible into cash.

NOTE 9 – STOCKHOLDERS' EQUITY

Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, $0.001 par value, with rights senior to those of our common stock.

Common Stock

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under Registration Statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the SEC.

On January 22, 2014, we announced the pricing of an underwritten public offering in which we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.5 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the SEC.

Equity Incentive Plans

We have in effect the following stock option and incentive plans.

a. The 1999 Stock Option Plan was adopted in November 1999. Under the 1999 Stock Option Plan, our board of directors could grant stock-based awards to directors, consultants and employees. The plan authorizes grants to purchase up to 4,230,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of the grant. The plan permits the board of directors or a committee appointed by the board to administer the plan. The administrator has the authority, in its discretion, to determine the terms and conditions of any option granted to a service

provider, including the vesting schedule. As of December 31, 2016, no additional shares of our common stock may be issued under the 1999 Stock Option Plan.

b. The 2004 Long-Term Incentive Plan was adopted in June 2004 by our stockholders. Under the 2004 Long-Term Incentive Plan, the compensation committee of our board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2016, no additional shares of our common stock may be issued under the 2004 Long-Term Incentive Plan.

c. The 2007 Incentive Plan was adopted in June 2007 by our stockholders. Under the 2007 Incentive Plan, the compensation committee of our board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2007 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. The plan expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2016, up to an additional 45,754 shares may be issued under the 2007 Incentive Plan.

d. The 2009 CEO Incentive Plan was adopted in May 2009. Under the 2009 CEO Incentive Plan, our board of directors granted an option to Ron Bentsur, our former Chief Executive Officer, to purchase up to 600,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of grant. During the year ended December 31, 2015, the option was exercised in full.

e. The 2013 Incentive Plan was adopted in June 2013 by our stockholders at our 2013 Annual Meeting of Stockholders. The 2013 Incentive plan was amended by our stockholders at a special meeting of our stockholders in November 2014, which increased the number of authorized shares issuable thereunder from 3,500,000 to 9,500,000, and at our 2016 Annual Meeting of Stockholders held on May 25, 2016, which increased the number of authorized shares issuable thereunder from 9,500,000 to 18,000,000. Under the 2013 Incentive Plan, the Compensation Committee of the Company's Board of Directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2016, up to an additional 7,078,635 shares may be issued under the 2013 Incentive Plan.

Total shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 7,124,389 shares at December 31, 2016.

Stock Options

The following table summarizes stock option activity for all plans for the year ended December 31, 2016:

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term	Aggregate Intrinsic Value
Outstanding at December 31, 2015	5,411,557	10.96	7.20	$ 2,049,329
Granted	4,863,550	4.56		
Exercised	(66,775)	2.99		$ 188,240
Forfeited or Expired	(1,530,334)	11.83		
Outstanding at December 31, 2016	8,677,998	$ 7.28	8.12	$ 8,840,412
Vested and expected to vest at December 31, 2016	7,993,753	$ 7.62	8.02	$ 8,038,699
Exercisable at December 31, 2016	3,178,277	$ 9.82	6.37	$ 2,497,744

The weighted-average grant-date fair value of stock options granted during 2016, 2015 and 2014 was $3.47, $8.47 and $11.81, respectively. The aggregate intrinsic value of options exercised during 2016, 2015 and 2014, measured as of the exercise date, was approximately $0.2 million, $8.6 million and $6.3 million, respectively.

Upon the exercise of stock options, we issue new shares of our common stock. As of December 31, 2016, 2,540,000 options issued to employees are unvested, milestone-based options.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under our equity incentive plans. The time-vesting restricted stock grants vest primarily over a period of three to four years. The following table summarizes restricted stock activity for the year ended December 31, 2016:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,344,747	11.59	$ 6,790,972
Granted	974,325	3.86	
Vested	(452,585)	12.25	$ 2,430,166
Forfeited	(341,603)	8.83	
Outstanding at December 31, 2016	1,524,884	$ 7.07	$ 8,935,820

The weighted-average grant-date fair value of restricted stock granted during 2016, 2015 and 2014 was $3.86, $4.76 and $14.77, respectively. The total fair value of restricted stock that vested during 2016, 2015 and 2014 was $2.4 million, $4.7 million and $28.6 million, respectively.

As of December 31, 2016, 435,000 shares of restricted stock issued to employees are unvested, milestone-based shares.

On September 14, 2009, we entered into an employment agreement with Ron Bentsur, our former Chief Executive Officer, which was amended on January 13, 2012, and further amended on September 11, 2013. The agreement, as amended, terminated on May 20, 2015. As of December 31, 2014, Mr. Bentsur had been granted a total of 1,250,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement, all of which had vested as of December 31, 2014.

As per his employment agreement, in December 2014, 500,000 shares of fully vested common stock were granted to Mr. Bentsur, upon the first commercial sale of Auryxia to wholesalers in the United States. In addition, upon reaching the same milestone, 266,666 shares of restricted stock previously issued to Mr. Bentsur were vested. We recorded $10.1 million of stock-based compensation expense associated with the granting and vesting of the 766,666 shares of restricted stock in December 2014, which is included in selling, general and administrative expenses in the year ended December 31, 2014.

Stock-Based Compensation

The following tables summarize stock-based compensation expense information about equity incentive grants for the years ended December 31, 2016, 2015 and 2014:

	For the years ended December 31,		
(in thousands)	2016	2015	2014
Cost of goods sold	$ 125	$ 14	$ —
Research and development expenses	2,687	3,519	6,379
Selling, general and administrative expenses	11,177	12,967	20,578
	$ 13,989	$ 16,500	$ 26,957

	For the years ended December 31,		
(in thousands)	2016	2015	2014
Stock-based compensation expense associated with restricted stock	$ 4,159	$ 5,073	$ 20,031
Stock-based compensation expense associated with stock options	9,830	11,427	6,926
	$ 13,989	$ 16,500	$ 26,957

Stock-based compensation costs capitalized as part of inventory were immaterial for the years ended December 31, 2016 and 2015.

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	2016	2015	2014
Risk-free interest rates	1.5%	1.7%	1.9%
Dividend yield	—%	—%	—%
Volatility	81.4%	89.2%	103.0%
Weighted-average expected term	6.0 years	6.0 years	6.0 years

The weighted average grant date fair value of options granted was $4.56, $8.47 and $11.81 per option for the years ended December 31, 2016, 2015 and 2014, respectively. We used historical information to estimate forfeitures within the valuation model. As of December 31, 2016, there was $9.1 million and $4.0 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.9 years and 1.1 years, respectively. These amounts do not include, as of December 31, 2016, 2,555,000 options outstanding and 435,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

Sales Agreement

On November 9, 2016, we entered into a Controlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million.

We are not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Capital Market to sell shares from time to time based upon our instructions, including any price, time or size limits specified by us. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. Cantor Fitzgerald's obligations to sell shares under the Sales Agreement are subject to satisfaction of certain conditions. We will pay Cantor Fitzgerald a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for the reasonable and documented fees and expenses of its outside legal counsel, not to exceed $50,000 in the aggregate, in connection with entering into the Sales Agreement.

We filed a registration statement on Form S-3 (No. 333-214513) which was declared effective by the SEC on December 6, 2016, which includes a prospectus covering the sale of the $75.0 million shares which may be sold by Cantor Fitzgerald under the Sales Agreement. The offering of shares of our common stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. We and Cantor Fitzgerald may each terminate the Sales Agreement at any time upon ten days' prior notice.

NOTE 10 – LICENSE AGREEMENTS

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc. ("Panion"). Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of ferric citrate.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan, which is being marketed in the United States under the trade name Auryxia. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective as of June 8, 2009, we entered into an Amended and Restated Sublicense Agreement (the "Revised

Agreement") with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement.

In January 2013, JT and Torii filed its new drug application ("NDA") with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, launched in May 2014 and being marketed in Japan by JT's subsidiary, Torii Pharmaceutical Co., Ltd., under the brand name Riona, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. As a result, we recorded license revenue of $10.0 million in accordance with our revenue recognition policy, which is included in the year ended December 31, 2014. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For the years ended December 31, 2016 and 2015, we recorded $4.8 million and $3.5 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. For the years ended December 31, 2016 and 2015, we recorded $2.9 million and $2.1 million, respectively, in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

NOTE 11 – INCOME TAXES

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable; and therefore, a full valuation allowance is established. The valuation allowance for deferred tax assets was $289.7 million and $232.7 million as of December 31, 2016 and 2015, respectively, an increase of $57.0 million.

As of December 31, 2016, we have U.S. net operating loss ("NOL") carryforwards of approximately $706.5 million, of which approximately $83.8 million were derived from certain stock option exercises and any such benefit realized will be credited to additional paid in capital. For income tax purposes, these NOLs will expire in the years 2019 through 2035. Due to our various equity transactions, the utilization of certain NOLs could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision and/or the separate return limitation year losses limitation.

For the years ended December 31, 2016, 2015 and 2014, we recognized $0.1 million, $0.1 million and $0.7 million, respectively, in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

The income tax provision consists of the following:

(in thousands)	December 31, 2016	December 31, 2015	December 31, 2014
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current	—	—	—
Deferred:			
Federal	73	81	640
State	7	9	60
Total deferred	80	90	700
Total income taxes	$ 80	$ 90	$ 700

Income tax expense differed from amounts computed by applying the U.S. federal income tax rate of 34% to pretax loss as follows:

	For the years ended December 31,		
(in thousands)	2016	2015	2014
Loss before income taxes, as reported in the consolidated statements of operations	$ (161,015)	$ (123,055)	$ (110,818)
Computed "expected" tax benefit	(54,745)	(41,838)	(37,678)
Increase (decrease) in income taxes resulting from:			
Expected (benefit) expense from state & local taxes	(5,222)	(3,991)	(3,594)
Stock-based compensation expense	(17)	(2,328)	(7,178)
Tax impact of derivative liability	—	16,977	—
Permanent differences	3,087	1,445	97
Impact of state NOL carryforward change	—	—	6,726
Prior year true-up	(58)	2,191	70
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	57,035	27,634	42,257
	$ 80	$ 90	$ 700

The significant components of deferred income tax expense (benefit) attributable to loss from operations are as follows:

	For the years ended December 31,		
(in thousands)	2016	2015	2014
Deferred tax benefit	$ (56,955)	$ (44,521)	$ (41,557)
Tax impact of derivative liability	—	16,977	0
Increase in the valuation allowance for deferred tax asset	57,035	27,634	42,257
	$ 80	$ 90	$ 700

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2016 and 2015 are presented below.

(in thousands)	December 31, 2016	December 31, 2015
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 255,809	$ 219,658
Stock-based compensation expense	16,735	13,667
Unrealized / realized loss on securities	—	514
Capitalized inventory	2,044	4,501
Inventory reserves	9,288	—
Research and development	2,087	2,087
Intangible assets due to different amortization methods	2,495	2,702
Tax-deductible goodwill	(870)	(790)
Debt discount	—	(12,748)
Deferred revenue	—	1,313
Other temporary differences	1,241	970
Net deferred tax asset, excluding valuation allowance	288,829	231,874
Less valuation allowance	(289,699)	(232,664)
Net deferred tax liabilities	$ (870)	$ (790)

We file income tax returns in the U.S federal and various state and local jurisdictions. For federal and state income tax purposes, the 2015, 2014 and 2013 tax years remain open for examination under the normal three year statute of limitations. The statute of limitations for income tax audits in the United States will commence upon utilization of net operating losses and will expire three years from the filing of the tax return.

There was no accrual for uncertain tax positions or for interest and penalties related to uncertain tax positions for 2016, 2015 and 2014. We do not believe that there will be a material change in our unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

NOTE 12 – OTHER (EXPENSE) INCOME, NET

The components of other (expense) income, net are as follows:

	For the years ended December 31,		
(in thousands)	2016	2015	2014
Interest income	$ 698	$ 472	$ 290
Interest expense	(34,209)	(11,357)	—
Other (expense) income, net	(4,741)	(1,102)	121
	$ (38,252)	$ (11,987)	$ 411

NOTE 13 – COMMITMENTS AND CONTINGENCIES

As of December 31, 2016, we have known contractual obligations, commitments and contingencies of $135.3 million. The debt obligation in the table below reflects our obligations under the Notes to make a principal payment for the par value of the Notes at maturity. Any future conversion or settlement of the Notes could impact the timing and amount of our potential cash payments under the Notes (see Note 8—Debt). The remaining $10.3 million relates to our operating lease obligations.

(in thousands)	Payment due by period				
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Convertible senior notes	$ 125,000	$ —	$ —	$ 125,000	$ —
Operating leases	10,305	1,601	4,966	3,738	—
Total	$ 135,305	$ 1,601	$ 4,966	$ 128,738	$ —

We enter into contracts in the normal course of business related to the manufacturing of inventory, consulting services and subscription fees, among others. These contracts generally provide for termination on notice, and therefore are cancelable contracts and are not included in the table of contractual obligations and commitments.

Leases

In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94-month term that commenced on May 1, 2015. In order to make the space usable for our operations, substantial improvements were made. Our landlord agreed to pay for up to approximately $1.9 million of the improvements, and we bore all additional costs that were incurred. As such, we have determined that we are the owner of the improvements and account for tenant improvements paid by our landlord as a lease incentive. On May 1, 2015, in accordance with ASC 840-20, *Operating Leases,* we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease, and the receivable was drawn down as cash was received from our landlord. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be depreciated over the assets' useful lives or the remaining lease term, whichever is shorter.

The lease for our New York City office expired on September 30, 2016 and we did not renew our lease.

Total rental expense was approximately $1.9 million, $2.2 million and $1.6 million for the years ended December 31, 2016, 2015, and 2014, respectively. We recognized sublet income of $0.1 million for the year ended December 31, 2014, related to the office sharing agreement which ended in September 2014.

Royalty and Contingent Milestone Payments

Under the license agreement with Panion, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in the United States and of Riona in Japan. We record royalties on net U.S. sales of Auryxia in cost of goods sold and royalties on net sales of Riona in license expense.

Litigation

Four purported class action lawsuits have been filed against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero). Three of these actions have been filed in the United States District Court for the Southern District of New York, captioned respectively Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131 filed on August 2, 2016, Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 2016 and Richard King v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06233 on August 5, 2016. The Jackson complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and August 1, 2016, the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 2016, and the King complaint purports to be brought on behalf of stockholders who purchased our stock between February 25, 2016 and July 29, 2016. On August 26, 2016, the fourth complaint, captioned Tim Karth v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-11745, was filed in the United States District Court for the District of Massachusetts, which complaint was subsequently amended. The Karth complaint purports to be brought on behalf of stockholders who purchased our stock between May 8, 2013 and August 1, 2016. Each complaint generally alleges that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the Company and its business operations and future prospects in light of the August 1, 2016 announcement of an imminent interruption in our supply of Auryxia. Two stockholder derivative complaints were also filed on December 16, 2016 against the Company and certain of its current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero), certain of its current directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers and John P. Butler) and its former directors (Michael P. Tarnok, Joseph Feczko, Jack Kaye and Wyche Fowler, Jr.), in the Superior Court of Massachusetts, one captioned Venkat Vara Prasad Malledi v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3865 and one captioned James Anderson v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3866. Each of these two complaints generally allege that the individual defendants breached their fiduciary duties owed to the Company, unjustly enriched themselves by their actions, abused their control positions with the Company, mismanaged the Company and wasted corporate assets since July 31, 2013 in light of the August 1, 2016 announcement by the Company of an interruption in the supply of the Company's product Auryxia. All of the complaints seek unspecified damages, interest, attorneys' fees, and other costs. We deny any allegations of

wrongdoing and intend to vigorously defend against these lawsuits. There is no assurance, however, that we or the other defendants will be successful in our defense of either of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits adverse to us or the other defendants, however, could have a material effect on our financial position and results of operations in the period in which the particular lawsuit is resolved.

NOTE 14 - BUSINESS SEGMENTS

We have determined that we conduct our operations in one business segment: the manufacture, development and commercialization of products for use in treating human diseases. Long-lived assets consist entirely of property, plant and equipment and are located in the United States for all periods presented.

NOTE 15 – QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2016			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenues:				
Net U.S. Auryxia product sales	$ 5,616	$ 8,279	$ 5,050	$ 8,228
License revenue	1,209	1,009	1,287	1,305
Total revenues	6,825	9,288	6,337	9,533
Costs and expenses:				
Cost of goods sold	1,071	5,099	18,196	13,437
License expenses	726	605	772	783
Research and development	7,616	7,029	8,674	6,185
Selling, general and administrative	20,809	20,188	20,521	23,035
Total costs and expenses	30,222	32,921	48,163	43,440
Operating loss	(23,397)	(23,633)	(41,826)	(33,907)
Other (expense) income:				
Amortization of debt discount	(15,748)	(18,479)	—	—
Other (expense) income, net	(1,799)	(2,519)	150	143
Total other (expense) income:	(17,547)	(20,998)	150	143
Loss before income taxes	(40,944)	(44,631)	(41,676)	(33,764)
Income taxes	20	20	20	20
Net loss	$ (40,964)	$ (44,651)	$ (41,696)	$ (33,784)
Basic and diluted net loss per common share*	$ (0.39)	$ (0.42)	$ (0.39)	$ (0.32)

	2015			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenues:				
Net U.S. Auryxia product sales	$ 422	$ 1,758	$ 3,191	$ 4,770
License revenue	753	756	1,017	$ 1,013
Total revenues	1,175	2,514	4,208	5,783
Costs and expenses:				
Cost of goods sold	76	304	3,065	1,075
License expenses	452	453	611	608
Research and development	9,591	7,963	11,150	7,990
Selling, general and administrative	18,880	20,762	20,205	21,563
Total cost and expenses	28,999	29,482	35,031	31,236
Operating loss	(27,824)	(26,968)	(30,823)	(25,453)
Other income (expense):				
Other income (expense), net	107	114	100	(12,308)
Loss before income taxes	(27,717)	(26,854)	(30,723)	(37,761)
Income taxes	22	23	22	23
Net loss	$ (27,739)	$ (26,877)	$ (30,745)	$ (37,784)
Basic and diluted net loss per common share*	$ (0.28)	$ (0.26)	$ (0.29)	$ (0.36)

* *The aggregate of quarterly computed basic and diluted net loss per common share may not agree with the annual amount due to rounding.*

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SIGNATURES

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

Date: March 1, 2017

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Gregory P. Madison

Gregory P. Madison
Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Gregory P. Madison and Brian Adams, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 1, 2017, and in the capacities indicated:

Signatures	Title
/s/ Gregory P. Madison	Chief Executive Officer and Director
Gregory P. Madison	(principal executive officer)
/s/ Scott A. Holmes	Chief Financial Officer
Scott A. Holmes	(principal financial and accounting officer)
/s/ John P. Butler	Chairman of the Board of Directors
John P. Butler	
/s/ Kevin Cameron	Director
Kevin Cameron	
/s/ Daniel P. Regan	Director
Daniel P. Regan	
/s/ Michael Rogers	Director
Michael Rogers	
/s/ Steven Gilman	Director
Steven Gilman	
/s/ Michael Heffernan	Director
Michael Heffernan	
/s/ Jodie Morrison	Director
Jodie Morrison	

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated December 17, 2003, and the Amendment thereto, dated June 18, 2004, filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated July 24, 2007, filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated June 18, 2013, filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 2, 2013 (File No. 000-30929), and incorporated herein by reference.
3.4	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated May 25, 2016, filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 5, 2016 (File No. 000-30929), and incorporated herein by reference.
3.5	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
4.1	Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.
4.2	Indenture dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and The Bank of New York Mellon Trust Company, N.A., filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.
10.1†	Keryx Biopharmaceuticals, Inc. 1999 Stock Option Plan, as amended, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, filed on May 15, 2003 (File No. 000-30929), and incorporated herein by reference.
10.2†	Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan, filed with the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders on June 10, 2004, filed on April 29, 2004 (File No. 000-30929), and incorporated herein by reference.
10.3†	Amendment to the Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan dated April 11, 2006, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed on August 9, 2006 (File No. 000-30929), and incorporated herein by reference.
10.4†	2007 Incentive Plan, filed as Annex D to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 30, 2007 (File No. 000-30929), and incorporated herein by reference.
10.5†	Keryx Biopharmaceuticals, Inc. Amended and Restated 2013 Incentive Plan, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), and incorporated herein by reference.
10.6†	Keryx Biopharmaceuticals, Inc. Fourth Amended and Restated Directors Equity Compensation Plan, filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), and incorporated herein by reference.
10.7!	Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 12, 2008 (File No. 000-30929), and incorporated herein by reference.
10.8!	First Amendment to Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008, filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 31, 2009 (File No. 000-30929), and incorporated herein by reference.

Exhibit Number	Exhibit Description
10.9!	Amended and Restated Sub-License Agreement dated June 8, 2009, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Japan Torii Pharmaceutical Co. Ltd., filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, filed on August 12, 2009 (File No. 000-30929), and incorporated herein by reference.
10.10!	Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc. dated January 17, 2014, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014 (File No. 000-30929), and incorporated herein by reference.
10.11!	First Addendum to Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc. dated October 24, 2014, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014 (File No. 000-30929), and incorporated herein by reference.
10.12!	Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates dated November 12, 2016, and related Product Agreement dated October 5, 2016, and related Product Agreement dated October 12, 2016.
10.13†	Employment Agreement with Gregory P. Madison dated March 10, 2015, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015 (File No. 000-30929), and incorporated herein by reference.
10.14†	Employment Agreement with Brian Adams dated April 8, 2014, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015 (File No. 000-30929), and incorporated herein by reference.
10.15†	Employment Agreement with John F. Neylan, M.D. dated April 22, 2015, filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015 (File No. 000-30929), and incorporated herein by reference.
10.16†	Employment Agreement with Scott Holmes dated June 26, 2015, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2015 (File No. 000-30929), and incorporated herein by reference.
10.17†	First Amendment to Employment Agreement with Gregory P. Madison dated October 15, 2015, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015 (File No. 000-30929), and incorporated herein by reference.
10.18†	First Amendment to Employment Agreement with Brian Adams dated October 15, 2015, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015 (File No. 000-30929), and incorporated herein by reference.
10.19†	First Amendment to Employment Agreement with Scott Holmes dated October 15, 2015, filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015 (File No. 000-30929), and incorporated herein by reference.
10.20†	First Amendment to Employment Agreement with John F. Neylan, M.D. dated October 15, 2015, filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015 (File No. 000-30929), and incorporated herein by reference.
10.21†	Second Amendment to Employment Agreement with Brian Adams dated December 15, 2016.
10.22†	Second Amendment to Employment Agreement with Scott Holmes dated January 6, 2017.
10.23†	Second Amendment to Employment Agreement with John F. Neylan, M.D. dated January 6, 2017.
10.24†	Employment Agreement with Christine A. Carberry dated January 6, 2017, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 9, 2017 (File No. 000-30929), and incorporated herein by reference.
10.25†	Form of Indemnification Agreement between Keryx Biopharmaceuticals, Inc. and its directors and officers, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed on November 9, 2016 (File No. 000-30929), and incorporated herein by reference.
10.26	Notes Purchase Agreement dated as of October 14, 2015, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.

Exhibit Number	Exhibit Description
10.27	Registration Rights Agreement dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C., filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.
10.28	Controlled Equity Offering[SM] Sales Agreement dated November 9, 2016, by and between Keryx Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co., filed as Exhibit 1.2 to the Registrant's Registration Statement on Form S-3, filed on November 9, 2016 (File No. 333-214513), and incorporated herein by reference.
10.29	One Marina Park Drive Office Lease dated April 29, 2015, by and between Keryx Biopharmaceuticals, Inc. and Fallon Cornerstone One MPD LLC.
21.1	List of Subsidiaries.
23.1	Consent of UHY LLP.
24.1	Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included on the signature to this Annual Report on Form 10-K).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 1, 2017.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 1, 2017.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 1, 2017.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 1, 2017.
101	The following financial information from Keryx Biopharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' (Deficit) Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.

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! Confidential treatment has been granted or is being sought with respect to the omitted portions of this exhibit.

† Indicates management contract or compensatory plan or arrangement.

Confidential Materials Omitted, Designated Herein as [***], and Filed Separately with the Securities and Exchange Commission

Master Manufacturing Services Agreement

September 27, 2016

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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of September 27, 2016 (the "**Effective Date**")

B E T W E E N:

PATHEON MANUFACTURING SERVICES LLC,
a limited liability company existing under the laws of the State of Delaware

("**Patheon**"),

- and -

KERYX BIOPHARMACEUTICALS, INC.
a corporation existing under the laws of the State of Delaware

("**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where Patheon or the Affiliate of Patheon resides. This "master" form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon's global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", **"Active Pharmaceutical Ingredients" or "API"** means the materials listed in a Product Agreement on Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.2(a);

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

"Annual Product Review Report" means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report**" means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

"**Applicable Laws**" means (i) for Patheon, all Laws, including, without limitation, (A) those of the State of North Carolina or the local jurisdiction for Patheon Affiliate, in any event being the jurisdiction where the Manufacturing Site is located, and (B) FDA and EMA regulations, governing or related to any and all activities of Patheon and its Affiliates under this Agreement; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

"**Authority**" means any governmental or regulatory authority, subdivision, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"**Breach Notice**" has the meaning specified in Section 8.2(a);

"Business Day" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the jurisdiction of the applicable manufacturing site;

"**Capital Equipment Agreement**" means a separate agreement that the parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"cGMPs" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) EC Directive 2003/94/EC; and

(c) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"Client Intellectual Property" means (a) Intellectual Property of Client existing prior to the Effective Date, including but not limited to, inventions, ideas, discoveries, developments, technical information, know-how and confidential information existing prior to the Effective Date, (b) Intellectual Property that is developed, discovered or created outside of either Party's performance under this Agreement which is specific to, or dependent upon, Client's Active Material, Product, and/or any Client Confidential Information, and (c) Intellectual Property that is developed, discovered, or created in connection with this Agreement which is specific to, or dependent upon, Client's Active Material, Product, and/or any Client Confidential Information.

"**Client Property**" has the meaning specified in Section 8.4(e);

"**Client-Supplied Components**" means those Components to be supplied by Client or that have been supplied by Client, excluding the API;

"**CMC**" has the meaning specified in Section 7.8(c);

"Components" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**Deficiencies**" have the meaning specified in Section 7.8(d);

"Deficiency Notice" has the meaning specified in Section 6.1(a);

"Delivery Date" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

"Disclosing Party" has the meaning specified in Section 11.1;

"EMA" means the European Medicines Agency;

"FDA" means the United States Food and Drug Administration;

"Firm Orders" have the meaning specified in Section 5.1(c);

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"GST" has the meaning specified in Section 13.16(a)(ii);

"Health Canada" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"**Importer of Record**" has the meaning specified in Section 3.2(a);

"**Initial Product Term**" has the meaning specified in Section 8.1;

"**Initial Set Exchange Rate**" means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the billing currency into the Patheon Manufacturing Site local currency, calculated as the daily average interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"**Initial Term**" has the meaning specified in Section 8.1;

"Intellectual Property" includes, without limitation, rights in patents, patent applications, formulae, trademarks, process, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"Invention" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"Inventory" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"Laws" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"Long Term Forecast" has the meaning specified in Section 5.1(a);

"Manufacturing Services" means the manufacturing, quality control, quality assurance, analytical testing, stability testing, packaging, and related services, as set forth in this Agreement, required to manufacture Product or Products using the Active Materials and Components;

"Manufacturing Site" means the facility owned and operated by Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

"Materials" means all Components and other items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"Maximum Credit Value" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;

"**Minimum Market Requirement**" means the minimum percentage of Client's or its Affiliates' requirements for a Product in the Territory, if any, that must be purchased from Patheon or its Affiliates.

"Minimum Order Quantity" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Competitor**" means (a) in the case of Patheon, a business that derives greater than 50% of its revenues from performing contract pharmaceutical development or commercial manufacturing services and (b) in the case of Client, a business whose primary focus is the research, development and/or commercialization of products that are competitive with the Products;

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to or dependent upon, Client's Active Material, Product, and/or Client Confidential Information, including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

"**Persistent Supply Failure**" means Patheon's failure to supply at least [***] of the quantity of Product ordered by Client (i) for [***] or longer of any forecast period; or (iii) on [***] or more orders during a Year.

"**PPI**" has the meaning specified in Section 4.2(a);

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing costs as set forth in a Product Agreement on Schedule C;

"Product(s)" means the product(s) listed in a Product Agreement on Schedule A;

"**Product Agreement**" means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to E) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site;

"**Product Claims**" have the meaning specified in Section 6.3(d);

"Quality Agreement" means the agreement (the general form of which is set forth in Exhibit B) between the parties entering a Product Agreement that sets out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"Regulatory Authority" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies or Authorities competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"**Remediation Period**" has the meaning specified in Section 8.2(a);

"**Representatives**" means a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives;

"Resident Jurisdiction" has the meaning specified in Section 13.16(a)(i);

"Set Exchange Rate" means the exchange rate to convert one unit of the billing currency into the Patheon Manufacturing Site local currency for each Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"**Shortfall Credit**" has the meaning specified in Section 2.2(b);

"**Specifications**" means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"**Surplus**" has the meaning specified in Section 2.2(c);

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Tax**" or "**Taxes**" have the meaning specified in Section 13.16(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means the geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.16(d);

"**Year**" means in the first year of this Agreement or in the first year of a Product Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

"Yield Tolerance" has the meaning specified in Section 2.2(b); and

"**Zero Forecast Period**" has the meaning specified in Section 5.1(g).

1.4 Currency.

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.5 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, and Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.6 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.7 Appendix 1, Schedules and Exhibits.

Appendix 1 (including the Schedules thereto) and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

Appendix 1 - Form of Product Agreement (Including Schedules A to E)

Exhibit A - Technical Dispute Resolution
Exhibit B - Commercial Quality Agreement
Exhibit C - Monthly Active Materials Inventory Report
Exhibit D - Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield

Exhibit E - Example of Price Adjustment Due to Currency Fluctuation

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C to manufacture Products for Client. Schedule B to a Product Agreement sets forth a list of cost items that are included or not included in the Price for Products; all cost items that are not included in the Price are subject to additional fees to be paid by the Client. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. Unless otherwise agreed in a Product Agreement, the Minimum Market Requirement shall be [***] of Client's annual commercial requirements for Products offered for sale in the Territory for any Year. Patheon shall have the right, and the obligation, to supply the Minimum Market Requirement, provided that the Minimum Market Requirement shall be reduced to [***] in the event of any Persistent Supply Failure. Subject to any applicable Minimum Market Requirement, this Agreement is non-exclusive and nothing in this Agreement shall prevent Client from obtaining services from third parties that are equivalent or similar to the Manufacturing Services. To the extent specified in a Product Agreement, Patheon will be entitled to any applicable manufacturing tax credits that arise from performing the Manufacturing Services under this Agreement. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Prior to shipment of Products to Client, Patheon will provide to Client a certificate of analysis, certificate of origin (BSE / TSE statement) and a certificate of compliance, including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client Quality Assurance will review such documents prior to release. For routine or standard batches with no major issues or only minor deviations, Client will use good faith efforts to release the batches within 5 Business Days, or as otherwise agreed. Client will have sole responsibility to authorize a shipment from the manufacturing site and for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property. Notwithstanding the foregoing, Client may make reasonable requests and shall be entitled to review the raw testing data, and other information set forth in the Quality Agreement.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon's expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. The parties will use good faith efforts to determine the root cause of any failures and to allocate the costs. Patheon will give Client all stability test data and results at Client's request.

(e) Packaging and Artwork. Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers, expiration dates, serialization numbers, and 2D bar codes will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. At least 90 days prior to the Delivery Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon, final camera ready artwork for all packaging Components to be used in the manufacture of the Product that meet the Specifications. For the avoidance of doubt, the parties acknowledge and agree that Client will be responsible for complying with any and all regulatory requirements for the labeling of the Product.

(f) Active Materials and Client-Supplied Components. At least [***] before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010), at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received [***] before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. For Active Materials or Client-Supplied Components which may be subject to import or export, Client agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

(g) Intentionally omitted.

(h) Validation Activities (if applicable). Patheon shall assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees for this service are not included in the Price and will be set out separately in Schedule C to a Product Agreement.

(i) Additional Services. If Client requests services other than those expressly set forth herein or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), Patheon will provide a good faith and reasonable written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be set forth in a separate agreement signed by the parties. If so agreed by the parties, the terms and conditions of this Agreement will apply to these services. Such additional services or items not included in the costs may include, but are not limited to, third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable) and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components.

2.2 Active Material Yield.

(a) Reporting. Patheon will give Client a monthly inventory report of the Active Materials held by Patheon using the inventory report form set out in Exhibit C, which will contain the following information for the month by lot number:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products including Active Materials lost in the warehouse prior to and during dispensing, and will not include any [***].

Quantity Converted: The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within [***] after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit D including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

After Patheon has produced a minimum of [***] successful commercial production batches of Product and has produced commercial production batches for at least [***] at the Manufacturing Site, the parties will agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). If the parties are unable to agree upon the Target Yield, they will resolve the matter pursuant to the technical dispute process set forth in Section 12.2. The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Credit Calculation. If the Actual Annual Yield falls more than the Yield Tolerance (set forth in the Product Agreement) below the respective Target Yield, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall Credit = [(Target Yield – Yield Tolerance) – AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Surplus Calculation. If the Actual Annual Yield is more than the respective Target Yield in a Year, then the surplus for that Year (the "Surplus") will be determined based on the following calculation:

Surplus = [AAY – Target Yield] * Active Materials Credit Value * Quantity Dispensed

(d) Credits.

Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than [***] after the end of the Year. Each credit under this Section 2.2(d) will be summarized on the reconciliation report form set forth in Exhibit D. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

Surplus Credit. If there is a Surplus for a Product in a Year, then Patheon will be entitled to apply the amount of the Surplus as a credit against any Shortfall for that Product which may occur in the next Year. If there is no Shortfall in the next Year the Surplus credit will expire.

Each credit under this Section 2.2 will be summarized on the reconciliation report prepared in the form set forth in Exhibit D. Upon expiration or termination of a Product Agreement, any remaining Shortfall credit amount owing under this Section 2.2 will be paid to Client.

(e) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 for any Product in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to a Product Agreement.

(f) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) solely because the Actual Annual Yield is less than the Target Yield, so long as the Shortfall is not the result of Patheon failing to meet any obligation set forth in this Agreement.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under other parts of this Agreement.

3.2 Active Materials and Qualification of Additional Sources of Supply.

(a) Client will at its sole cost and expense deliver the Active Materials to Patheon in accordance with Section 2.1(f). If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "**Importer of Record**" for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services. Client will be responsible for paying for all rejected Product that arises from defects in the Active Materials which could not be reasonably discoverable by Patheon using the test methods set forth in the Specifications.

(b) If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon may agree to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will agree on the scope of work to be performed by Patheon at Client's cost. For an Active Material, this work may include: (i) laboratory testing to confirm the Active Material meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on three months accelerated stability; and (iii) manufacture of three full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale). Section 6.1(d) will apply to all Product manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

(b) Patheon will promptly advise Client if it encounters supply problems, including delays and/or delivery of non-conforming Active Material or Components from a Client designated additional source; and (ii) Patheon and Client will cooperate to reduce or eliminate any supply problems from these additional sources of supply. Client will be obligated to certify all Client designated sources of supply on an annual basis at its expense and will provide Patheon with copies of these annual certifications, as further set forth in the Quality Agreement, and pursuant to Patheon's standard certification form. If Patheon agrees to certify a Client designated additional sources of supply on behalf of Client, it will do so at Client's expense.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The Price for the first Year will be listed in Schedules B and C in a Product Agreement and will be subject to the adjustments set forth in Sections 4.2 and 4.3. The Price may also be increased or decreased by Patheon at any time upon written notice to Client if there are changes to the underlying manufacturing, packaging or testing assumptions set forth in Schedule B of the Product Agreement that result in an

increase or decrease in the cost of performing the Manufacturing Services. Patheon shall provide documentation as to why such Price for the first year is being increased or decreased; provided however, Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year of the Product Agreement, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States or Puerto Rico, Patheon may adjust the conversion component of the Price and the annual stability testing costs for inflation, based upon the preliminary number for any increase in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing ("**PPI**") published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. On or before [***], Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. For Products manufactured outside the United States or Puerto Rico, Patheon may similarly adjust the Price for inflation using an inflation index to be agreed by the parties in a Product Agreement.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs at Patheon's actual cost. If Patheon obtains a decrease in Component costs during the Year, it will decrease the Price for the next Year to pass through [***] of the cost savings to the Client. On or before [***], Patheon will give Client information about the increase or decrease in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase or decrease is justified. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if the specified Minimum Order Quantity changes or if the Annual Volume is not ordered in a Year. For greater certainty, if Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year whether as a result of a decrease in estimated Annual Volume or otherwise and, as a result of the reduction, Patheon demonstrates to Client that its costs to perform the Manufacturing Services or to acquire the Components for the Product will increase on a per unit basis (including the amount of the increase), then Patheon may increase the Price by an amount sufficient to absorb the documented increased costs. On or before [***], Patheon will give Client a statement and sufficient justification setting forth the information to be applied in calculating those cost increases for the next Year, and the parties will use good faith efforts to approve any such increases. Such cost increase must be approved by Client in advance of cost increases going into effect; provided however, the price increase will not be unreasonably denied if the foregoing process is used and justified. Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(d) Adjustments Due to Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for a Canadian Manufacturing Site invoiced in USD) is set forth in Exhibit E.

(e) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon the Client's volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the [***] forecast provided in [***]. Within [***], Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment [***] or will issue payment to the Client for the overpayment [***]. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment [***]. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement [***], the matter will be handled under Section 12.1.

(f) For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or before [***] a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year. If in any Year Patheon would have been entitled to increase the Price based on any of the provisions of this Section 4.2 but Patheon did not exercise its right to do so, then solely at the expiry of the next subsequent Year, Patheon will be entitled to make a cumulative adjustment for the two year period going forward as if it had made adjustments for each of the two Years. Under no circumstance shall Patheon be entitled to make a price adjustment hereunder for a Year by going back past the immediately prior Year (if no such adjustment had been made for such immediately prior Year). It is not the intention of this section for any such adjustments to be applied retroactively.

4.2.1 The Parties acknowledge that Sterile Products are not included in this Agreement.

4.3 Price Adjustments – Current Year Pricing.

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases or Decreases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases or decreases [***] of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases or decreases [***] of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B to the Product Agreement.

4.4 Adjustments Due to Technical Changes or Regulatory Authority Requirements.

(a) Technical Changes to Requirements. Technical changes requested by Client will only be implemented following a technical and cost review that Patheon will perform and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Technical changes requested by Patheon will only be implemented following an assessment by Patheon and the Client regarding the technical changes that may have an effect on certain areas including, but not limited to Regulatory filings, fees, etc. All technical changes requested by Patheon require the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications and the associated scope of work will be implemented at Client's cost. All costs relating to the technical changes, including re-validations of the process, or stability program shall be determined by the parties after good faith discussions, and the Price change will become effective only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory for Firm Orders used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client.

(b) Regulatory Changes to Authority Requirements. Regulatory changes to the Specifications requested by Client will be implemented immediately, and will be followed by a good faith effort from both parties to evaluate the cost impact. Regulatory changes to the Manufacturing Site will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. The cost of any such changes shall be agreed to in advance by the parties after good faith discussions.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Long Term Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [***] forecast of Client's volume requirements for the Product for the [***] of the term of the Product Agreement (the "**Long Term Forecast**"). The Long Term Forecast will thereafter be updated annually, [***]. If Patheon is unable to accommodate any portion of the Long Term Forecast, it will notify Client and the parties will agree on any revisions to the forecast.

(b) Rolling [***] Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [***] forecast of the volume of Product that Client expects to order in the [***] of commercial manufacture of the Product. This forecast will then be updated by Client on or before the [***] on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [***]. The most recent [***] forecast will prevail.

(c) Firm Orders. On a rolling basis during the term of the Product Agreement, Client will issue an updated [***] forecast on or before the [***]. This forecast will start on [***]. Unless otherwise agreed in the Product Agreement, the first [***] of this updated forecast will be considered binding firm orders. Concurrent with the [***] forecast, Client will issue a new firm written order in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not be less than [***] following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client. Further, for [***] of the [***] forecast, Client commits that its Firm Orders for each of those months will be no less than [***], respectively, of the forecasted amounts for [***]. If Client orders less than the agreed volume, the parties will meet to discuss how to smooth production to meet demand. If it is not possible to smooth production to meet forecasted demand, Client will compensate Patheon for not meeting the Firm Order commitment by paying the [***] for the shortfall between what Client actually ordered and its Firm Order commitment as set forth above or as otherwise provided for in the applicable Product Agreement. The forgoing shall be Patheon's sole and exclusive remedy for Client's failure to meet the Firm Order commitment. No amounts shall be payable to Patheon if Client is unable to make the Firm Order commitment because of Force Majeure or because the Product is taken off the market due in response to an action by an Authority or otherwise as required by Applicable Law. Patheon commits to make [***] of the forecasted amounts available to Client, and will reserve [***] of its capacity to meet that commitment. Patheon shall notify Client as soon as possible of impending capacity constraints in relation to Client's forecasts and/or changes in Client's demands.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [***] of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(f). If Patheon fails to acknowledge receipt of a Firm Order within the [***] period, the Firm Order will be deemed to have been accepted by Patheon.

(e) Cancellation of a Firm Order. Except for [***], if Client cancels a Firm Order, Client will pay Patheon the [***] for the Firm Order. For purposes of this provision, [***] . Patheon will use commercially reasonable efforts to mitigate all costs related to a cancellation of a Firm Order and to deploy its resources to other clients.

(f) On Time Delivery.

(i) Patheon and the Client understand that there may be uncertainties and necessary adjustments in production schedules during the first 6 months of Manufacturing. The parties agree that they will work together closely to expedite deliveries and manage the scheduling of the initial Product launch.

(ii) If, [***], Patheon is unable to deliver the quantity of Product ordered under a Firm Order [***] of the Delivery Date due to an act or omission by Patheon (a "**Late Delivery**"), [***]. Nothing herein shall preclude Client from exercising any other rights it may have under this Agreement in connection with Patheon's failure to timely delivery Product.

(iii) A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2. If Patheon has [***] Late Deliveries in any [***], the parties will meet as necessary to amicably resolve the reasons for the Late Deliveries. The parties will agree on a delivery improvement plan [***]. If, after the delivery improvement plan is in place, Patheon has [***] Late Deliveries in any [***], Client may exercise its right to terminate this Agreement for cause under Section 8.2(a) without a further opportunity to cure.

(iv) For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials (provided that Patheon ordered Materials with sufficient lead time for such Materials to be delivered on a timely basis), a delay in Product release approval from Client, inaccurate Client forecasts, or receipt of non-conforming API or Components supplied by Client.

(g) Zero Volume Forecast. If Client forecasts zero volume for [***] (the "**Zero Forecast Period"**), then Patheon will have the option, at its sole discretion, to provide a [***] notice to Client of Patheon's intention to terminate the Product Agreement on a stated day within the Zero Forecast Period. Client thereafter will have [***] to either (i) withdraw the zero forecast and re-submit a reasonable volume forecast, or (ii) negotiate other terms and conditions on which the Product Agreement will remain in effect. Otherwise, Patheon will have the right to terminate the Product Agreement at the end of the [***] notice period.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a) (b) and (c) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products [***] contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon under Firm Orders or under Section 5.2(a) that are not included in finished Products manufactured for Client within six months after the forecasted month for which the purchases have been made (or for

a longer period as the parties may agree) or if the Components have expired or are rendered obsolete due to changes in artwork or applicable regulations during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's cost to purchase (plus a [***] handling fee) and destroy the Obsolete Stock. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(c) If Client fails to take possession or arrange for the destruction of non-expired Components (whose purchase was authorized by Client per Section 5.2 (a)) [***] or, in the case of the delivery of conforming finished Product not accepted by Client [***], Client will pay Patheon [***] per pallet, per month thereafter for storing the Components or finished Product. During the parties' normal quarterly reviews, Patheon will detail all potential storage costs. To the extent applicable, storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [***]per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than [***] to the Client at Client's expense on [***] written notice to the Client.

5.3 Minimum Orders.

Client may only order Manufacturing Services for batches of Products at or greater than the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 Delivery and Shipping.

Upon acceptance from Client's Quality Assurance Department, the Product will be delivered to Client after it has been manufactured and released to the Client by Patheon and released by Client; provided however that such acceptance release by Client shall be within [***] of receipt of all required batch documentation and release to ship by Patheon. Delivery of Products will be made EXW (Incoterms 2010) Patheon's shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk, (i) arrange for shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 Invoices and Payment.

Invoices will be sent by email to the email address given by Client to Patheon in writing. Invoices will be issued when the Product is manufactured and released by Patheon and Client. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [***] of the date of Client's receipt of an undisputed invoice. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at [***] per month which is equal to an annual rate of [***].

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject any portion or all of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws within [***] after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [***] after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [***] period, then the delivery will be deemed to have been accepted by Client on the [***] after delivery or discovery, as applicable. Patheon will have no liability for any deviations for which it has not received notice within the applicable [***] period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have [***] to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within ten days after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, or Applicable Laws, then the parties will mutually select an independent qualified investigator and/or laboratory to evaluate if the Products deviate from the Specifications, cGMPs, or Applicable Laws. This evaluation will be binding on the parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Client will be deemed to have accepted delivery of the Products on [***] after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on [***] after discovery thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) Shortages and Price Disputes. Claims for shortages in the amount of Products shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be deemed waived if it has not been presented within [***] of the date of a compliant invoice meeting the requirements of this Agreement.

(d) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon. If after a full investigation as set forth in Section 6.1(b), it is determined that Patheon manufactured Product in accordance with the agreed upon in-

process specifications, cGMP, the batch production record, Patheon's standard operating procedures for manufacturing and the other requirements of the Agreement and the applicable Product Agreement, and a batch or portion of batch of Product does not meet a finished Product Specification, Client will pay Patheon [***] for the non-conforming Product. Patheon will be responsible for the materials and Client will be responsible for the API. The API in the non-conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a). If it is determined that the Product failure is due to error on Patheon's part, Patheon will pay for product disposal, provide a certificate of destruction to the Client, and the API in the non-conforming Product will be excluded from the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any affected Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any Authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws, or the other requirements of this Agreement or the applicable Product Agreement) Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefore under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater clarity, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2. Patheon shall promptly reimburse Client for all costs related to the production and shipment of the Client-Supplied Components to Patheon related to the defective Product.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to provide Product that conforms with the Specifications, cGMPs, Applicable Laws or the other requirements of this Agreement or the applicable Product Agreement, in addition to the amounts described under Section 6.3(a), Patheon will also be responsible for the documented out-of-pocket expenses of the Recall or return. For greater clarity, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Replacement Product. If (i) Client rejects Product under Section 6.3(a) and Patheon or (ii) (A) an independent laboratory pursuant to Section 6.1 determines that or (B) Product is recalled because the Product manufactured and released by Patheon deviates from the Specifications, GMPs, Applicable Laws, or any other requirement of this Agreement or the applicable Product Agreement, Client shall have the right to avail itself of the remedies set forth in Section 6.3(a) above.

(d) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) results from a defect in the Active Materials, Client-Supplied Components or Components supplied by a Client designated additional source that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP's, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 [***] and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6, along with any termination rights permitted under this Agreement, will be Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen. At each Quarterly Review, Patheon should prepare and provide Client data and reports relating to manufacturing, yield performance, analytical results, inventory, forecasts, and any other matters reasonably requested by Client. Also, Patheon should provide all of the past and on-going quality issues specifically related to Client's Products including Out Of Trend (OOT), Out Of specifications (OOS), deviation investigations and reports.

7.2 Governmental Agencies.

Subject to Section 7.8, except as otherwise required by Applicable Law, Client (or its designated representatives) shall be the sole communicator with any Authority, including but not limited to governmental agencies, such as the FDA and EMA, responsible for granting regulatory approval for the Products, regarding the Products. Except as otherwise required by Applicable Law or otherwise permitted in this Section 7, Patheon shall not initiate contact with any Authority regarding the Products or respond to any inquiry or communication from any Authority regarding the Products without Client's prior written approval. If Client is required to submit to an Authority any information concerning the Products or any services provided hereunder, Patheon will provide Client copies of such documentation, data and other information as shall be necessary or reasonably desirable for such submission to the Authorities and such other information in such form as Client may reasonably request. Patheon shall also cooperate and consult as reasonably requested by Client and/or required by the Authorities for development of additional data or performance of studies concerning the Product. Client shall pay Patheon's reasonable costs and fees for performance under this section. Patheon shall also provide, if required by the Authorities, information concerning its laboratory, manufacturing, quality control procedures and CMC matters with respect to its activities under this Agreement, including any Product Agreement. Patheon shall provide Client all documentation, data and information referred to in this Section 7.2 reasonably in advance of their required submission to allow for Client's review and comment. Patheon shall endeavor in good faith to satisfactorily resolve/incorporate all Client comments prior to submission.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Further information regarding the Records and Accounting by Patheon is set forth in the parties' Quality Agreement.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 Access.

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws, including reasonable access to the appropriate manufacturing areas while Client products are being manufactured. But, with the exception of "for-cause" audits, Client will be limited each Year to [***] cGMP-type audit, lasting no more than [***], and involving no more than [***]. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of [***] for each additional audit day and [***] per audit day for each additional auditor. The right of access set forth in Sections 7.4 and 7.5 will not include a right to access or inspect Patheon's financial records.

7.6 Notification of Regulatory Inspections.

Patheon will notify Client as soon as possible but no more than [***] of receipt of any inspections by any Authority specifically involving the Products or otherwise relating to quality matters at the Manufacturing Site or the other facilities in which the Manufacturing Services

are performed. Patheon will also notify Client of receipt of any form 483's or warning letters or any other significant regulatory action or communication from any Authority that relate to the Products or the facility in which the Manufacturing Services are performed or could otherwise reasonably be expected to impact Patheon's ability to perform hereunder, and provide Client with a copy of such FDA Form 483s, warning letter or any other documents relating to significant regulatory action or communication from any Authority. In connection with any response by Patheon to such Authority related to Products, Patheon shall provide Client all relevant documentation, data and information reasonably in advance of the required submission to allow for Client's review and comment. Patheon shall endeavor in good faith to satisfactorily resolve/incorporate all Client comments prior to submission

7.7 Reports.

Patheon will supply [***] all Product data in its control, including release test results, change controls, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 Regulatory Filings.

(a) Regulatory Authority. Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the relevant portions of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon will promptly review the proposed submission and in no event shall take more than [***] (or such shorter period as required to meet the submission date for the relevant document) to perform this review and the parties may agree to a shorter time for the review as needed.

(c) Verification of CMC. Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls (all such documentation herein referred to as "**CMC**") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a redacted copy of the Drug-Product portion of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires [***] to perform this review but the parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all FDA filings at the time of submission which contain CMC information regarding the Product.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) Client Responsibility. For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client.

7.9 Inspection by Regulatory Authorities.

If Client does not give Patheon the documents requested under clause 7.7(b) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2021 (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement at least 24 months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of five Years from the start of commercial manufacture at the Manufacturing Site for the Product unless the parties agree to a different number of Years in the applicable Product Agreement (each, an "**Initial Product Term**"). Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least 24 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement or the Product Agreement and in the case of curable material breaches within 60 days following receipt of a written notice (the "**Remediation Period**") of the breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement or a

Product Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period in the case of remediable breaches (where the breach has not been remedied) and if the termination right in connection with such remediable material breach is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from researching, developing, importing, exporting, purchasing, selling or otherwise commercializing the Product (an "**Authority Action**"). But if this occurs, Client must still fulfill all of its obligations under Section 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Either party may terminate this Agreement or a Product Agreement upon six months' prior written notice if the other party assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of the non-assigning party acting reasonably, is (i) not a credit worthy substitute for the other party or (ii) a Competitor of the non-assigning party.

8.3 Product Discontinuation.

Client will give at least [***] advance notice (or such shorter period if required pursuant to an Authority Action) if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market.

8.4 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's cost plus [***] handling fee, the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given; provided that Patheon will make commercially reasonable efforts to mitigate any costs payable by Client in connection therewith, which may include canceling any pending orders for such Components, returning or selling items in the Inventory back to its supplier(s) if possible, or otherwise utilizing such Inventory or Components with other Patheon clients or otherwise in Patheon's business;

(c) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2, and thereafter Client will have sole right, title and interest in and to such Components;

(d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site;

(e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), [***], all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property [***] following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon [***] per pallet, per month, one pallet minimum (except, if applicable, Client will pay [***] per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property; provided that no such charges shall be applicable and payable by Client if Client notifies Patheon to destroy/dispose of such Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.5 of this Agreement;

(f) Pursuant to a reasonable written request from Client to Patheon, Patheon shall transfer to Client and/or its designee any and all Client Intellectual Property in Patheon's possession and shall provide to Client and/or its designee Patheon Intellectual Property, so as to permit Client and/or its designee(s) to produce/manufacture Products with such technical assistance being provided in accordance with a plan provided to Patheon by Client. To the extent transferable, Patheon shall also transfer any license(s) obtained specifically for the production/manufacture of Products under this Agreement. Patheon hereby grants to Client [***] any and all Patheon Intellectual Property to make, have made, use, offer for sale, sell, and import Products, which license shall survive termination of this Agreement. However, no Competitor of Patheon in the business of contract development or manufacture of drug products will be permitted to have access to Patheon's manufacturing site. The third party manufacturer will be required to sign a customary and appropriate confidentiality agreement with Patheon concerning the nondisclosure of Patheon confidential information that may be involved in the transfer;

(g) Except to the extent necessary to complete performance pursuant to subsection (f) or to exercise rights that survive the termination of this Agreement, each party as a receiving party shall deliver to the disclosing party such disclosing party's Confidential Information in the receiving party's possession or control. Notwithstanding anything in this Agreement that may be to the contrary, Client (and its designees) may continue to retain and use Patheon Confidential Information that is required to maintain marketing approval for a Product and/or is useful to production/manufacture of the Product;

(h) Promptly following any notice of termination of expiration, Patheon will update and confirm the technical information and specifications for the Product as set forth in the Specifications (Schedule A), Stability Testing protocols and procedures (Schedule C) and the Quality Agreement (Exhibit B) as applicable, to the extent required to reflect any needed changes to manufacturing and validation methods;

(i) Each party will continue to comply with their obligations under Applicable Law which survive termination of this Agreement;

Any termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, termination of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10, 11, 12 and 13 and Sections 1.3, 1.5, 1.6, 1.7, 6.2, 6.3, 6.4, 6.5, 6.6, 7.2, 7.3, 7.4, 7.5, 7.6, 7.8, and 8.4, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client, and (C) to the knowledge of Client does not infringe and will not infringe any Third Party Rights;

(iii) the performance of the Manufacturing Services by Patheon for any Product under this Agreement or any Product Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or under any Product Agreement, to the knowledge of Client, does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings against Client, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws may be lawfully sold and distributed in every jurisdiction in which Client markets the Products; and

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws;

(b) it has or shall have and shall maintain all necessary licences, permits, and approvals required by any Regulatory Authority for the manufacture of the Product;

(c) it has disclosed and will disclose to Client all warnings or other notices from any applicable Regulatory Authority it has received relating to its Manufacturing Site to the extent that such notice or warning would affect Patheon's ability to perform the Manufacturing Services in accordance with this Agreement;

(d) it shall not at any time without Client's prior written consent:

(i) make any changes to the manufacturing, packaging, testing, or storage of the Product; or

(ii) knowingly take any actions which would likely affect the validation status or quantity of the Product

(e) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not knowingly infringe and will not knowingly infringe any Third Party Rights;

(f) the Product when delivered will be in compliance with the certificate of analysis provided by Patheon to Client with respect thereto;

(g) all right, title and interest in the Product will be transferred to Client free of any and all liens, security interests or other encumbrances (provided however, Client has provided all API and Client Supplied Components to Patheon free of any and all liens, security interests or other encumbrances; and

(h) the Manufacturing Services and other work performed hereunder will be performed in a professional, expeditious and workmanlike manner, consistent with industry standards.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the *Federal Food, Drug, and Cosmetic Act* (United States).

9.5 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

EACH PARTY HERETO MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT, INCLUDING ANY IMPLIED REPRESENTATION OR WARRANTY WITH RESPECT TO (I) MERCHANTABILITY, NON-INFRINGEMENT, SUITABILITY OR FITNESS FOR A PARTICULAR PURPOSE, (II) THE LIKELIHOOD OF SUCCESS OF ANY APPLICATION FOR MARKETING AUTHORIZATION RELATING TO ANY PRODUCTS CURRENTLY IN DEVELOPMENT OR FOR WHICH MARKETING AUTHORIZATION HAS NOT YET BEEN GRANTED EITHER IN THE U.S. OR IN ANY OTHER COUNTRY, OR (III) THE PROBABLE SUCCESS OR PROFITABILITY OF ANY PRODUCTS AFTER THE EFFECTIVE DATE.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except in connection with [***] provisions of this Agreement (all the foregoing the "**Exceptions**"), under no other circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind

incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Defective or Recalled Product. Other than in the case of the Exceptions, Patheon's maximum aggregate liability to Client for any obligation to (i) refund, offset or replace any defective Product under Section 6.3(a) or (ii) replace any recalled Products under Section 6.3(b), will not [***]. This Section 10.2(a) will not be subject to Section 10.2(c).

(b) Active Materials. Except (i) as expressly set forth in Section 2.2, (ii) in connection with the Exceptions, (iii) [***] and (iv) as otherwise provided under this Agreement, Patheon will not be responsible for any loss or damage to the Active Materials and Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(c) Maximum Liability. Other than in the case of the Exceptions, [***] and as provided under Section 10.2(a) above, Patheon's maximum liability to Client under this Agreement or any Product Agreement for any reason whatsoever will not exceed on a per Product basis [***].

(d) Nothing in this Agreement is intended to limit either party's liability for death or personal injury caused by its negligence or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify and hold harmless Client, its officers, employees, Affiliates and agents against all losses, damages, fines, penalties, costs, expenses (including reasonable attorneys' fees and court costs), claims, suits, proceedings, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) (all the foregoing, "**Third-Party Claims**") resulting from, or relating to (i) any claim that is the result of a failure by Patheon to perform its obligations under this Agreement, including that the Manufacturing Services were not performed in accordance with the Specifications, cGMPs, and Applicable Laws and the other requirements of this Agreement and the applicable Product Agreement, (ii) the gross negligence or willful misconduct of Patheon or any of its personnel, representatives, Affiliates or subcontractors or, (iii) any claim of infringement or alleged infringement of any Third Party Rights regarding the use of Patheon Intellectual Property pursuant to this Agreement (but excluding any Client Intellectual Property included or utilized in connection therewith) except to the extent that such Third Party Claims are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates.

(b) If a Third-Party Claim occurs for which indemnification is sought under the foregoing, Client will: (a) promptly notify Patheon of the Third-Party Claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the Third-Party Claim (at Patheon's sole cost and expense); and (d) permit Patheon to control the defense and settlement of the Third-Party Claim, all at Patheon's cost and expense. Client and the other indemnitees may participate in the defense and settlement of any Third-Party Claim using counsel of its own choice at its own expense. Patheon shall not settle any Third-Party Claim in a manner that adversely affects the rights of the Client or any other indemnitee without the Client's or such other indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. The Client's or any other indemnitee's failure to perform any obligations under this Section shall not relieve Patheon of its obligations hereunder, except to the extent that Patheon can demonstrate that it has been materially prejudiced as a result of such failure.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify and hold harmless Patheon, its officers, employees, and agents against all Third-Party Claims resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof (but excluding any Patheon Intellectual Property included or utilized in connection therewith), or any claim that is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, except to the extent that the Third-Party Claims are due to the negligence or wrongful act(s) of Patheon, its officers, employees, Affiliates or agents.

(b) If a Third-Party Claim occurs for which indemnification is sought under the foregoing, Patheon will: (a) promptly notify Client of the Third-Party Claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the Third-Party Claim (at Client's sole cost and expense); and (d) permit Client to control the defense and settlement of the Third-Party Claim, all at Client's cost and expense. Patheon and the other indemnitees may participate in the defense and settlement of any Third-Party Claim using counsel of its own choice at its own expense. Client shall not settle any Third-Party Claim in a manner that adversely affects the rights of Patheon or any other indemnitee without Patheon's or such other indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. Patheon's or any other indemnitee's failure to perform any obligations under this Section shall not relieve Client of its obligations hereunder, except to the extent that the Client can demonstrate that it has been materially prejudiced as a result of such failure.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing

Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. Furthermore, any data, reports, information, deliverables, test results, and materials related to the Product generated or made by Patheon under this Agreement (all the foregoing, "**Deliverables**") and Product shall be deemed Confidential Information of Client.

For the purposes of this ARTICLE 11, a party or its Representative receiving Confidential Information under this Agreement is a "**Recipient**," and a party or its Representative disclosing Confidential Information under this Agreement is the **"Disclosing Party**."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using all reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient, after due inquiry, to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Except as required by Law, neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out herein. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

Furthermore, no provision of this Agreement shall be construed so as to preclude disclosure of Patheon Confidential Information by Client as may be reasonably necessary or useful for Client to secure from any Authority necessary marketing or other approvals or licenses for a Product.

Client may disclose this Agreement to one or more third parties (i) in connection with a proposed sale, merger, financing, loan, investment or similar transaction (each a "**Potential Transaction**") so long as those third parties subject to obligations of confidentiality and are limited to using information derived from this Agreement solely for purposes of evaluating whether to enter into one or more of the Potential Transactions and no other purpose.

11.6 Marking.

The Disclosing Party agrees to use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form. Notwithstanding the foregoing, any information which by its nature is confidential and would be judged so under a reasonable standard, or is disclosed, or provided, under circumstances reasonably indicating it is confidential or proprietary, shall be considered Confidential

Information regardless of whether a party has marked the Confidential Information as “Confidential” or “Proprietary” or has otherwise identified the information as being confidential.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Agreement and agree that the non-breaching party will be entitled to seek specific performance, injunctive and/or other equitable relief (without the need to post bond or other security or to otherwise demonstrate monetary damages) to prevent breaches of this Agreement and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Agreement but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within ten Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the ten Business Day period set forth above, the dispute will immediately be referred to the Chief Executive Officer (in the case or Client) or to the Chief Operating Officer (in the case of Patheon), or another officer as he/she may designate, of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.17.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as possible and in any event no later than ten Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within 30 Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Exhibit A. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

12.3 Injunctive Relief.

Nothing in this Article 12 above shall prevent a party from seeking and obtaining temporary or preliminary injunctive or equitable relief to protect the interests of such party pending the outcome of the dispute resolution proceedings set forth above.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client’s Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for Client.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use, and sale of Client’s Product that is the subject of the Manufacturing Services along with all Deliverables (such Intellectual Property and Deliverables collectively, “**Client Arising Intellectual Property**”), will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client [***] to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions. Each party will cooperate with the other party in the filing and prosecution of patent applications related to Inventions in which such other party has an ownership interest as a result of activities under this Agreement or otherwise in the registering, perfecting or recording its rights in or to its respective Intellectual Property. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits for

the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications, and causing its personnel (including all subcontractors) to irrevocably waive, to the extent permitted by Law, any and all claims such personnel (including all subcontractors) may now or hereafter have in any jurisdiction to so-called "moral rights" or rights of droit moral.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

(f) Patheon agrees, and will cause its personnel (including all subcontractors) to agree, that with respect to any Client Arising Intellectual Property that may qualify as "work made for hire" as defined in 17 U.S.C. §101, such Client Arising Intellectual Property are hereby deemed a "work made for hire" for Client. To the extent that any of the Client Arising Intellectual Property do not constitute a "work made for hire", Patheon hereby irrevocably assigns, and shall cause its personnel (including all subcontractors) to irrevocably assign to Client, in each case without additional consideration, all right, title and interest throughout the world in and to the Client Arising Intellectual Property, including all intellectual property rights therein.

13.2 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party, including any storage obligations, under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than (i) $[***] for each occurrence for personal injury or property damage liability; and (ii) $[***] in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties. A party shall have no authority to bind or act on behalf of the other Party. This Agreement shall not entitle Patheon to participate in any benefit plan or program of Client. Patheon shall be responsible for, and agrees to comply with, obligations under all applicable tax laws for payment of income and, if applicable, self-employment tax. Patheon is not entitled to worker's compensation coverage by Client, and Patheon hereby waives any and all rights Patheon may have to be covered under Client's worker's compensation policies.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will not be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement with the consent of Client, not to be unreasonably delayed or withheld. Further it is specifically agreed that Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to any of its Affiliates.

(b) Subject to Section 13.6(a), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable hereunder. Any partial assignment of this Agreement or a Product Agreement will be subject to Patheon's cost review of the assigned Products, such review to be performed on an expeditious basis. Client will reimburse Patheon for any costs incurred by Patheon in connection with the partial assignment including any expenses incurred by Patheon for any due diligence audits in connection with the partial assignment.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes, riots, quarantines, communicable disease

outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right provided that that any of these affect the ability to produce or manufacture the Product (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. The parties may agree to excuse a party from the timelines for payment under this Agreement do to a Force Majeure Event, but such event shall not relieve a party from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.8 Additional Product.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, D, and E as applicable.

13.9 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by express delivery (like FedEx, UPS, DHL), by sending the same by certified first class mail, postage prepaid (return receipt requested) to the respective addresses set forth below:

If to Client:

Keryx Biopharmaceuticals, Inc.
One Marina Park Drive, 12th Floor
Boston, MA 02210
Attention: CEO

With a copy (which will not constitute notice) to:

Keryx Biopharmaceuticals, Inc.
One Marina Park Drive, 12th Floor
Boston, MA 02210
Attention: General Counsel

If to Patheon:

[***]

With a copy to:

[***]

or to any other addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner. Routine notices relating to invoices, purchase orders and forecasts may be sent by email.

13.10 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, together with the applicable Product Agreement, and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.14 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client.

13.16 Taxes.

(a) The Client will bear all taxes, duties, levies and similar charges (and any related interest and penalties) ("**Tax**" or "**Taxes**"), however designated, imposed as a result of the provision by the Patheon of Services under this Agreement, except:

(i) any Tax based on net income or gross income that is imposed on Patheon by its jurisdiction of formation or incorporation ("**Resident Jurisdiction**");

(i) any Tax based on net income or gross income that is imposed on Patheon by jurisdictions other than its Resident Jurisdiction if this tax is based on a permanent establishment of Patheon; and

(ii) any Tax that is recoverable by Patheon in the ordinary course of business for purchases made by Patheon in the course of providing its Services, such as Value Added Tax (as more fully defined in subparagraph (d) below), Goods & Services Tax ("**GST**") and similar taxes.

(b) If the Client is required to bear a tax, duty, levy or similar charge under this Agreement by any state, federal, provincial or foreign government, including, but not limited to, Value Added Tax, the Client will pay the tax, duty, levy or similar charge and any additional amounts to the appropriate taxing authority as are necessary to ensure that the net amounts received by Patheon hereunder after all such payments or withholdings equal the amounts to which Patheon is otherwise entitled under this Agreement as if the tax, duty, levy or similar charge did not exist.

(c) Patheon will not collect an otherwise applicable tax if the Client's purchase is exempt from Patheon's collection of the tax and a valid tax exemption certificate is furnished by the Client to Patheon.

(d) If subparagraph 13.16 (a)(iii) does not apply, any payment due under this Agreement for the provision of Services to the Client by Patheon is exclusive of value added taxes, turnover taxes, sales taxes or similar taxes, including any related interest and penalties (hereinafter all referred to as "**VAT**"). If any VAT is payable on a Service supplied by Patheon to the Client under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) the Client. If VAT on the supplies of Patheon is payable by the Client under a reverse charge procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), the Client will ensure that Patheon will not effectively be held liable for this VAT by the relevant taxing authorities or other parties. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to the Client are issued in such a way that these invoices meet the requirements for deduction of input VAT by the Client, if the Client is permitted by law to do so.

(e) Unless consented to by Patheon (such consent not to be unreasonably withheld, conditioned or delayed), any Tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon pursuant hereto may not be offset against sums due by Client to Patheon whether due pursuant to this Agreement or otherwise. Further, for any Tax remitted by Client but as to which Patheon is liable hereunder, if so requested by Client, Patheon shall promptly reimburse Client for such amounts paid on Patheon's behalf.

13.17 Governing Law.

This Agreement and any Product Agreement, unless otherwise agreed by the parties in the Product Agreement, will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein, without application of conflicts of laws provisions that would otherwise apply the substantive law of another jurisdiction. Subject to the alternative dispute resolutions provision set forth in Article 12 above, any legal suit, action or proceeding arising out of or related to this Agreement or the services provided hereunder shall be instituted exclusively in the federal courts of the United States or the courts of the State of New York, in each case located in New York County, New York, and each party irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON MANUFACTURING SERVICES LLC

By: /s/ [***]

Name: [***]

Title: Director, Business Management

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Greg Madison

Name: Greg Madison

Title: President & CEO

APPENDIX 1

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to E)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated **[insert date]** between Patheon Manufacturing Services LLC and Keryx Biopharmaceuticals, Inc. (the "**Master Agreement**"), and is entered into **[insert effective date]** (the "**Effective Date**"), between Patheon Manufacturing Services LLC, a limited liability company existing under the laws of the State of Delaware, having a principal place of business at 5900 Martin Luther King Jr. Highway, Greenville, NC 27834 **[or Patheon Affiliate address]** ("**Patheon**") and Keryx Biopharmaceuticals, Inc. a corporation existing under the laws of the State of Delaware, having a principal place of business at One Marina Park Drive, 12th Floor, Boston, MA 02210 ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)

2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)

3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)

4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)

5. **Territory**: (insert the description of the Territory here)

6. **Manufacturing Site**: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)

7. **Governing Law**: (if applicable under Section 13.17 of the Master Agreement)

8. **Inflation Index:** (if applicable under Section 4.2(a) of the Master Agreement for Products manufactured outside of the Unites States or Puerto Rico)

9. **Currency**: (if applicable under Section 1.4 of the Master Agreement)

10. **Initial Set Exchange Rate**: (if applicable under Section 4.2(d) of the Master Agreement)

11. **Initial Product Term:** (if applicable under Section 8.1 of the Master Agreement)

12. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

13. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

_____

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON MANUFACTURING SERVICES LLC

By: _____

Name: _____

Title: _____

KERYX BIOPHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

1.

The following cost items are included in the Price for the Products:

[***]

The following cost items are not included in the Price for the Products:

[***]

SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

[***]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier*

*** In the future Client may supply Patheon with the API from other suppliers which are not yet listed above.**

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Client's actual cost for Active Materials not to exceed $____ per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement **[for any Product]** in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
	[***] per Year to Patheon under this Product Agreement.

(a)

SCHEDULE E

REPORTING REQUIREMENTS

[End of Product Agreement]

EXHIBIT A

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1.**Appointment of Expert**. Within ten Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable neutral expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the ten Business Day period, or in the event of disclosure of a conflict by an expert which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2.**Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the Federal Arbitration Act, 9 U.S.C. §§ 1-16, or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit A.

3.**Procedure**. Where an expert is appointed:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 3(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(e) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself

indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

EXHIBIT B

COMMERCIAL QUALITY AGREEMENT

EXHIBIT C

MONTHLY ACTIVE MATERIALS INVENTORY REPORT

TO: KERYX BIOPHARMACEUTICALS, INC.

FROM: PATHEON MANUFACTURING SERVICES LLC

RE: Active Materials monthly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated • (the "**Agreement**")

Reporting month: _____

Active Materials on hand
at beginning of month:_____ kg (A)

Active Materials on hand
at end of month:_____ kg (B)

Quantity Received during month:_____ kg (C)

Quantity Dispensed during month:_____ kg
(A + C – B)

Quantity Converted during month:_____ kg
(total Active Materials in Products produced
and not rejected, recalled or returned)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE:_____

PATHEON MANUFACTURING SERVICES LLC

Per: _____
Name:
Title:

EXHIBIT D

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: KERYX BIOPHARMACEUTICALS, INC.

FROM: PATHEON MANUFACTURING SERVICES LLC

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated • (the "**Agreement**")

Reporting Year ending: _____

Active Materials on hand
at beginning of Year:_____ kg (A)

Active Materials on hand
at end of Year:_____ kg (B)

Quantity Received during Year:_____ kg (C)

Quantity Dispensed during Year:_____ kg (D)
(A + C - B)

Quantity Converted during Year:_____ kg (E)
(total Active Materials in Products produced
and not rejected, recalled or returned)

Active Materials Credit Value:$_____ / kg (F)

Target Yield:_____% (G)

Actual Annual Yield:_____ % (H)
((E/D) * 100)

Shortfall:$_____ (I)
(((G – Yield Tolerance) - H)/100) * F * D(if a negative number, insert zero)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $_____.

Surplus Credit: $ (J)
(H – G/100) * F * D

Based on the foregoing reimbursement calculation Patheon may carry forward one Year a Surplus Credit in the amount of $.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON MANUFACTURING SERVICES LLC

Per: _____
Name:
Title:

EXHIBIT E

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(d)

Time period: 10/01/11 to 09/30/12.

Average (365 days):

0.998

-- "Set Exchange Rate"

SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate:

1.000

CAD/USD

Set Exchange Rate:

0.998

CAD/USD

Initial Price:

3.59

Revised Price (FX):

3.70

(Material price and PPI adjustments)

Calculation:

[Revised Price (After FX)] = [Revised Price (Before FX)] X [Initial Exchange Rate] / [Set Exchange Rate]

= 3.70 X [1.000 / 0.998]

= 3.71

Confidential Materials Omitted, Designated Herein as [***], and Filed Separately with the Securities and Exchange Commission

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated September 27, 2016 between Patheon Manufacturing Services LLC and Keryx BioPharmaceuticals (the "**Master Agreement**"), and is entered into October 5, 2016 (the "**Effective Date**"), between Patheon Manufacturing Services LLC, a limited liability company existing under the laws of the State of Delaware, having a principal place of business at [***] ("**Patheon**") and Keryx BioPharmaceuticals, Inc., a corporation existing under the laws of Delaware, having a principal place of business at One Marina Park Drive, 12th Floor, Boston, MA 02210 ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

3. **Product List and Specifications** (See Schedule A attached hereto)
4. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Client Supply Chain Inventory Documentation Requirements** (See Schedule E attached hereto)
6. **Yearly Forecasted Volume:** Not applicable
7. **Territory**: USA
8. **Manufacturing Site**: [***]
9. **Governing Law**: New York per the Master Agreement
10. **Inflation Index:** Per Section 4.2(a) of the Master Agreement
11. **Currency**: $ USD
12. **Initial Set Exchange Rate**: Not applicable
13. **Initial Product Term:** From the Effective Date until December 31, 2021.
14. **Notices**: Per Section 13.9 of the Master Agreement
15. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON MANUFACTURING SERVICES LLC

By: /s/ [***]

Name: [***]

Title: Director, Business Management

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Greg Madison

Name: Greg Madison

Title: President & CEO

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Auryxia [***]

Specifications

[***]

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[***]

SCHEDULE C

ANNUAL STABILITY TESTING

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Auryxia, Fexeric	[***]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Auryxia, Fexeric	Ferric Citrate	[***]

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement **[for any Product]** in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Auryxia, Fexeric	[***] per Year to Patheon under this Product Agreement.

YIELD TOLERANCE

[***]

SCHEDULE E

Client Supply Chain Inventory Documentation Requirements

[***]

Confidential Materials Omitted, Designated Herein as [***], and Filed Separately with the Securities and Exchange Commission

PRODUCT AGREEMENT

FOR FERRIC CITRATE IR TABLETS (BRC)

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated 27 September 2016 between Patheon Manufacturing Services LLC and Keryx BioPharmaceuticals (the "**Master Agreement**"), and is entered into 12 October 2017 (the "**Effective Date**"), between Patheon UK Limited, a corporation existing under the laws of England, having a principal place of business at [***] ("**Patheon**") and Keryx BioPharmaceuticals, Inc., a corporation existing under the laws of Delaware, having a principal place of business at One Marina Park Drive, 12th Floor, Boston, MA 02210 ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

5. **Product List and Specifications** (See Schedule A attached hereto)
6. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Client Supply Chain Inventory Documentation Requirements** (See Schedule E attached hereto)
6. **Yearly Forecasted Volume:** Not applicable
7. **Territory**: EU and USA
8. **Manufacturing Site**: [***]
9. **Governing Law**: New York per the Master Agreement
10. **Inflation Index:** Per Section 4.2(a) of the Master Agreement
11. **Currency**: $ USD
12. **Initial Set Exchange Rate**: Not applicable
13. **Initial Product Term:** From the Effective Date until December 31, 2021.
14. **Notices**: [***]
15. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

The first sentence of Section 2.1(f) of the Master Agreement will be modified for purposes of this Product Agreement only as follows until such time as the API full testing is not required, following which time the first sentence of such section shall govern again.

"[***], Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010), at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date."

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON UK LIMITED

By: /s/ [***]

Name: [***]

Title: Sr. Dir. GCS

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Greg Madison

Name: Greg Madison

Title: President & CEO

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Ferric Citrate IR Tablets, [***]

Specifications

[***]

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[***]

SCHEDULE C

ANNUAL STABILITY TESTING

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

[***]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Auryxia, Fexeric	[***]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Auryxia, Fexeric	Ferric Citrate	[***]

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement **[for any Product]** in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Auryxia, Fexeric	[***] per Year to Patheon under this Product Agreement.

YIELD TOLERANCE

[***]

SCHEDULE E

Client Supply Chain Inventory Documentation Requirements

[***]

AMENDMENT TWO TO
EMPLOYMENT AGREEMENT

This Amendment Number Two (the "Amendment") to the Employment Agreement dated April 8, 2014, as amended by Amendment Number One to the Employment Agreement dated October 15, 2015 (the Employment Agreement, as amended, referred to herein as the "Employment Agreement") is made and entered into this 15th day of December, 2016 by and between Keryx Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), and Brian Adams ("Executive"), to be effective immediately.

BACKGROUND

WHEREAS, the Company currently employs Executive under the terms of the Employment Agreement;

WHEREAS, the Company desires to amend the terms upon which it has engaged Executive in accordance with the terms of the Employment Agreement and this Amendment; and

WHEREAS, Executive is willing to serve as such in accordance with the terms and conditions of the Employment Agreement and this Amendment.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Section 2 of the Employment Agreement shall be amended by deleting the following text located in the first sentence of such section:

> "; provided, however, that if Executive does not commence employment by April 14, 2014 for any reason, then this Agreement shall become null and void and neither Executive nor the Company shall have any obligations hereunder other than as expressly set forth in Section 7(e) hereof."

2. Section 3 of the Employment Agreement shall be amended by deleting said section in its entirety and replacing it with this following:

> Employment Period. The Company agrees to continue to employ Executive, and Executive agrees to continue to serve the Company, on an "at will" basis, which means that, subject to the payment obligations imposed on the Company pursuant to this Agreement, either the Company or Executive may terminate Executive's employment with the Company at any time, with or without Cause, as provided in Section 6 below. The period commencing with the Start Date and ending on the effective date of any termination of employment in accordance with the provisions hereof shall constitute the term of this Agreement (the "Employment Period").

3. Section 7 of the Employment Agreement shall be amended by deleting Sections 7(d) and 7(e) (and references to same in the Table of Contents) in their entirety, and such Sections 7(d) and 7(e) shall terminate and no longer be of any force or effect.

4. Except as modified in this Amendment, the Employment Agreement and all terms, covenants and conditions thereof shall remain in full force and effect.

IN WITNESS WHEREOF, Executive has hereunto set Executive's hand and, pursuant to the authorization from the Board, the Company has caused these presents to be executed in its name on its behalf, all as of the day and year first above written.

Executive:

/s/ Brian Adams

Name: Brian Adams
Title: General Counsel & Secretary

KERYX BIOPHARMACEUTICALS, INC.

/s/ Gregory P. Madison

By: Gregory P. Madison
Title: President & CEO

AMENDMENT TWO TO
EMPLOYMENT AGREEMENT

This Amendment Number Two (the "Amendment") to the Employment Agreement dated June 26, 2015, as amended by Amendment Number One to the Employment Agreement dated October 15, 2015 (the Employment Agreement, as amended, referred to herein as the "Employment Agreement") is made and entered into this 6th day of January, 2017 by and between Keryx Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), and Scott Holmes ("Executive"), to be effective immediately.

BACKGROUND

WHEREAS, the Company currently employs Executive under the terms of the Employment Agreement;

WHEREAS, the Company desires to amend the terms upon which it has engaged Executive in accordance with the terms of the Employment Agreement and this Amendment; and

WHEREAS, Executive is willing to serve as such in accordance with the terms and conditions of the Employment Agreement and this Amendment.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Section 2 of the Employment Agreement shall be amended by deleting the following text located in the first sentence of such section:

> "; provided, however, that if Executive does not commence employment by August 3, 2015 for any reason, then this Agreement shall become null and void and neither Executive nor the Company shall have any obligations hereunder other than as expressly set forth in Section 7(e) hereof."

2. Section 3 of the Employment Agreement shall be amended by deleting said section in its entirety and replacing it with this following:

> Employment Period. The Company agrees to continue to employ Executive, and Executive agrees to continue to serve the Company, on an "at will" basis, which means that, subject to the payment obligations imposed on the Company pursuant to this Agreement, either the Company or Executive may terminate Executive's employment with the Company at any time, with or without Cause, as provided in Section 6 below. The period commencing with the Start Date and ending on the effective date of any termination of employment in accordance with the provisions hereof shall constitute the term of this Agreement (the "Employment Period").

3. Section 7 of the Employment Agreement shall be amended by deleting Sections 7(d) and 7(e) (and references to same in the Table of Contents) in their entirety, and such Sections 7(d) and 7(e) shall terminate and no longer be of any force or effect.

4. Except as modified in this Amendment, the Employment Agreement and all terms, covenants and conditions thereof shall remain in full force and effect.

IN WITNESS WHEREOF, Executive has hereunto set Executive's hand and, pursuant to the authorization from the Board, the Company has caused these presents to be executed in its name on its behalf, all as of the day and year first above written.

Executive:

/s/ Scott Holmes

Name: Scott Holmes
Title: Chief Financial Officer

KERYX BIOPHARMACEUTICALS, INC.

/s/ Gregory P. Madison

By: Gregory P. Madison
Title: President & CEO

AMENDMENT TWO TO
EMPLOYMENT AGREEMENT

This Amendment Number Two (the "Amendment") to the Employment Agreement dated April 22, 2015, as amended by Amendment Number One to the Employment Agreement dated October 15, 2015 (the Employment Agreement, as amended, referred to herein as the "Employment Agreement") is made and entered into this 6th day of January, 2017 by and between Keryx Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), and John F. Neylan, MD ("Executive"), to be effective immediately.

BACKGROUND

WHEREAS, the Company currently employs Executive under the terms of the Employment Agreement;

WHEREAS, the Company desires to amend the terms upon which it has engaged Executive in accordance with the terms of the Employment Agreement and this Amendment; and

WHEREAS, Executive is willing to serve as such in accordance with the terms and conditions of the Employment Agreement and this Amendment.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Section 2 of the Employment Agreement shall be amended by deleting the following text located in the first sentence of such section:

> "; provided, however, that if Executive does not commence employment by April 27, 2015 for any reason, then this Agreement shall become null and void and neither Executive nor the Company shall have any obligations hereunder other than as expressly set forth in Section 7(e) hereof."

2. Section 3 of the Employment Agreement shall be amended by deleting said section in its entirety and replacing it with this following:

> Employment Period. The Company agrees to continue to employ Executive, and Executive agrees to continue to serve the Company, on an "at will" basis, which means that, subject to the payment obligations imposed on the Company pursuant to this Agreement, either the Company or Executive may terminate Executive's employment with the Company at any time, with or without Cause, as provided in Section 6 below. The period commencing with the Start Date and ending on the effective date of any termination of employment in accordance with the provisions hereof shall constitute the term of this Agreement (the "Employment Period").

3. Section 7 of the Employment Agreement shall be amended by deleting Section 7(d) (and references to same in the Table of Contents) in their entirety, and such Section 7(d) shall terminate and no longer be of any force or effect.

4. Except as modified in this Amendment, the Employment Agreement and all terms, covenants and conditions thereof shall remain in full force and effect.

IN WITNESS WHEREOF, Executive has hereunto set Executive's hand and, pursuant to the authorization from the Board, the Company has caused these presents to be executed in its name on its behalf, all as of the day and year first above written.

Executive:

/s/ John F. Neylan, MD

Name: John F. Neylan, MD
Title: Chief Medical Officer

KERYX BIOPHARMACEUTICALS, INC.

/s/ Gregory P. Madison

By: Gregory P. Madison
Title: President & CEO

ONE MARINA PARK DRIVE
OFFICE LEASE

THIS LEASE (this "Lease"), made as of April 29, 2015, by and between **FALLON CORNERSTONE ONE MPD LLC**, a Delaware limited liability company ("Landlord"), and **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation ("Tenant").

INDEX

EXHIBITS

Exhibit A	Space/Floor Plan Showing Premises
Exhibit B	Tenant's Work Exhibit
Exhibit B-1	Tenant's Conceptual Space Plan
Exhibit C	Form of Sublease Consent
Exhibit D	Building's Rules and Regulations and Janitorial Specifications
Exhibit E	Description of Base Building Condition
Exhibit F	Option to Extend Term
Exhibit G	Form of SNDA
Exhibit H	Pro Forma Budget of FPOC Expenses
Exhibit I	Memorandum Outlining Landlord's Sustainable Design Strategies
Exhibit J	OTIS
Exhibit K	Form of Commencement Date Confirmation

ARTICLE 1.

BASIC PROVISIONS

A. Tenant's Trade Name:	Keryx Biopharmaceuticals, Inc. (or such other trade name as Tenant may select from time to time, provided that Tenant shall promptly provide Landlord with written notice of any such trade name change)
B. Tenant's Address:	Prior to Tenant's occupancy of the Premises: One Marina Park Drive, 10th Floor Boston, Massachusetts 02210 Attention: General Counsel On and after Tenant's occupancy of the Premises: One Marina Park Drive, Suite 1200 Boston, Massachusetts 02210 Attention: General Counsel
C. Building Name and Address:	One Marina Park Drive Boston, Massachusetts 02210
D. Premises:	Suite 1200, comprising the entire (12th) floor of the Building and consisting of 27,323 rentable square feet, as shown on the space plan attached hereto as Exhibit A.
E. Landlord:	Fallon Cornerstone One MPD LLC
F. Landlord's Address:	c/o Cornerstone Real Estate Advisers LLC 180 Glastonbury Boulevard, Suite 200 Glastonbury, Connecticut 06033 Attention: Linda C. Houston, Senior Vice President

G. Building Manager Name and Address:	CB Richard Ellis – N.E. Partners LP One Marina Park Drive Boston, Massachusetts 02210

H. Commencement Date:	The later of (i) the date of full execution of this Lease, and (ii) the date on which possession of the Premises is delivered to Tenant in the Delivery Condition (as defined in Article 5.A. of this Lease).	
I. Rent Commencement Date:	March 1, 2016	
J. Expiration Date:	February 28, 2023, unless the Term (as hereinafter defined) is sooner terminated or further extended as provided in this Lease.	
K. Security Deposit:	$788,951.64, to be held by Landlord subject to periodic reduction and other terms and conditions set forth in Article 23 of this Lease.	
L. Monthly Base Rent:	Time Period	Monthly Base Rent
	Lease Year 1 (March 1, 2016 through February 28, 2017)	$131,491.94
	Lease Year 2 (March 1, 2017 through February 28, 2018)	$133,768.85
	Lease Year 3 (March 1, 2018 through February 28, 2019)	$136,045.77
	Lease Year 4 (March 1, 2019 through February 29, 2020)	$138,322.69
	Lease Year 5 (March 1, 2020 through February 28, 2021)	$140,599.60
	Lease Year 6 (March 1, 2021 through February 28, 2022)	$142,876.52
	Lease Year 7 (March 1, 2022 through February 28, 2023)	$145,153.44
M. Tenant's Pro Rata Share:	5.80% (based on 27,323 rentable square feet/470,949 rentable square feet, which is the rentable square footage of the Office Component as provided in Article 29.M. of this Lease)	

N. Normal Business Hours of Building:	Monday through Friday: 8:00 a.m. to 6:00 p.m. Saturday: 8:00 a.m. to 1:00 p.m. (upon written request by Tenant only, but at no additional cost) Sunday: None (Excepting local and national holidays)
O. Permitted Use:	General office use, and for no other purpose.
P. Broker(s):	CB Richard Ellis – N.E. Partners L.P., representing Landlord, and Transwestern RBJ, representing Tenant.
Q. Parking Access Rights:	Nine (9) parking access devices for unreserved parking spaces in the Parking Garage (as hereinafter defined), subject to the terms and conditions of Article 26 of this Lease.
R. Base Year:	Calendar year 2016 for Operating Expenses (as hereinafter defined), and fiscal year 2016 for Taxes (as hereinafter defined).

S. Allowance:	$70.00 per rentable square feet of the Premises, subject to the terms and conditions of Exhibit B attached hereto.

The foregoing provisions shall be interpreted and applied in accordance with the other provisions of this Lease set forth below. The capitalized terms, and the terms defined in Article 29, shall have the meanings set forth herein or therein (unless otherwise modified in the Lease) when used as capitalized terms in other provisions of the Lease.

Landlord and Tenant hereby agree that the Premises contain the number of rentable square feet specified in Article 1 above.

ARTICLE 2.

PREMISES, TERM AND COMMENCEMENT DATE

Subject to the terms and conditions set forth herein, Landlord hereby leases and demises to Tenant and Tenant hereby leases from Landlord the Premises identified in Article 1 above for a term ("Term") commencing on the Commencement Date and ending on the Expiration Date set forth in Article 1, unless sooner terminated as provided herein. Such date shall be confirmed by execution of the Commencement Date Confirmation in the form as set forth in Exhibit K, which Tenant shall execute and return to Landlord within fifteen (15) days after receipt thereof. Tenant shall be permitted to extend the original Term hereof in accordance with the provisions of Exhibit F attached hereto.

ARTICLE 3.

RENT

A. Monthly Base Rent. Commencing on the Rent Commencement Date, Tenant shall pay Monthly Base Rent in advance on or before the first (1st) day of each month of the Term without demand, setoff or deduction except as otherwise expressly set forth in this Lease. If the Term shall end on a day other than the first (1st) day of a month, the Monthly Base Rent for the last partial month of the Term shall be prorated on a per diem basis.

B . Additional Rent. All costs and expenses, other than Monthly Base Rent, which Tenant assumes or agrees to pay and any other sum payable by Tenant pursuant to this Lease, including, without limitation, its Pro Rata Share of Taxes and Operating Expenses (both as hereinafter defined), shall be deemed Additional Rent.

C. Rent. Monthly Base Rent, Additional Rent, and any other amounts of every nature which Tenant is or becomes obligated to pay Landlord under this Lease are herein referred to collectively as "Rent," and all remedies applicable to the nonpayment of Rent shall be applicable thereto. Landlord may apply payments received from Tenant to any obligations of Tenant then accrued and due, without regard to such obligations as may be designated by Tenant.

D . Place of Payment, Late Charge, Default Interest. Rent and other charges required to be paid under this Lease, no matter how described, shall be paid by Tenant to Landlord without offset, deduction, credit or the like, at the Building Manager's address listed in Article 1, or to such other person and/or address as Landlord may designate in writing. In the event Tenant fails to pay Rent due under this Lease within ten (10) business days of the due date of said Rent, Tenant shall pay to Landlord a late charge of three percent (3%) of the amount overdue; provided, however, that no such late charge will be charged for the first (1st) late payment in any rolling twelve (12) month period during the Term. Any Rent not paid within ten (10) business days of the due date of said Rent shall also bear interest at the Default Rate from and after the date due through the date on which Landlord receives payment. This provision shall in no way be construed to modify Tenant's obligation to pay Rent on or before the first (1st) day of the month.

ARTICLE 4.

TAXES AND OPERATING EXPENSES

A . Payment of Taxes and Operating Expenses. Commencing upon the expiration of the Base Year (i.e., January 1, 2017 for Operating Expenses and July 1, 2016 for Taxes) and for each year, or portion thereof, thereafter during the Term (hereinafter each referred to as a "Comparison Year"), Tenant shall pay Landlord an amount equal to Tenant's Pro Rata Share of increases in Operating Expenses and Taxes over the Operating Expenses and Taxes for the relevant Base Year (collectively, the "Escalation Increase"). Landlord shall have the right to change the Comparison Year from a calendar year to a fiscal year from time to time (or vice versa), provided that equitable adjustment is made so that Tenant shall not be charged more than once for the same period. Commencing with the first (1st) month of the first (1st) Comparison Year and on the first (1st) day of each month thereafter during the original Term or any extension thereof, Tenant shall pay Escalation Increases to Landlord, as Additional Rent due concurrently with Monthly Base Rent, in installments equal to one-twelfth (1/12) of Landlord's commercially reasonable estimate of any projected Escalation Increase for the particular Comparison Year (the "Estimated Escalation Increase"). A final adjustment ("Escalation Reconciliation") shall be made by Landlord and Tenant as soon as practicable (but in any event within one hundred twenty (120) days) following the end of each Comparison Year. In computing the Estimated Escalation Increase for any particular Comparison Year, Landlord shall take into account any prior increases in Tenant's Pro Rata Share of Taxes and Operating Expenses. Landlord's Estimated Escalation Increase for Taxes in any Comparison Year will not exceed the Taxes then reflected on Landlord's real estate tax bill from the City of Boston. If any Estimated Escalation Increase is less than the Estimated Escalation Increase for the immediately preceding Comparison Year, the payments to be paid by Tenant for the new Comparison Year attributable to said Estimated Escalation Increase shall be decreased accordingly; provided, however, in no event will the Rent paid by Tenant hereunder ever be less than the Monthly Base Rent.

B . Escalation Reconciliation. Within one hundred twenty (120) days after the last day of such Comparison Year, Landlord shall submit to Tenant a statement setting forth the actual Escalation Increase for the Comparison Year which was just completed and the Estimated Escalation Increase for the current Comparison Year (the "Escalation Statement"). To the extent that the actual Escalation Increase exceeds the Estimated Escalation Increase paid by Tenant for the Comparison Year just completed, Tenant shall pay Landlord the difference, in cash within thirty (30) days following receipt by Tenant from Landlord of the Escalation Statement. If the actual Escalation Increase for the Comparison Year just completed is less than the Estimated Escalation Increase paid by Tenant for such year, then Tenant shall receive a credit on future Rent owing under this Lease (or cash, if there is no future Rent owing hereunder). Until Tenant receives the Escalation Statement, Tenant's Estimated Escalation Increases for the new Comparison Year shall continue to be paid at the rate being paid for the particular Comparison Year just completed. Tenant shall commence payment to Landlord of the Estimated Escalation Increase for the then current Comparison Year, beginning on the first (1st) day of the month following the month in which Tenant receives the applicable Escalation Statement. Any amount described in this Article 4 that is not billed to Tenant within two (2) years after the end of the Comparison Year in question shall be deemed forever waived by Landlord, and Tenant shall have no further obligation therefor.

C. Changes in Escalations During the Lease Year. In addition to the above, if, during any particular Comparison Year, there is a change in the information upon which the then current Estimated Escalation Increase is based, Landlord shall be permitted (but in no event more than one time in any calendar year) to revise such Estimated Escalation Increase by notifying Tenant, and such adjustment shall be made in the payment of Estimated Escalation Increases, commencing on the first day of the month following the delivery of such notice to Tenant. When the Escalation Statement for the Comparison Year in which this Lease terminates is delivered to the Tenant, Tenant shall pay to Landlord within thirty (30) days after Landlord's delivery of the same, any additional amounts due as calculated pursuant to this Article 4. Landlord's and Tenant's responsibilities with respect to Escalation Increases shall survive the expiration or early termination of this Lease.

If the Building is less than ninety-five percent (95%) occupied during the Base Year or any particular Comparison Year, Landlord shall adjust those particular components of Operating Expenses which are affected by Building occupancy for the Base Year or the particular Comparison Year, or portion thereof, as the case may be, to reflect an occupancy of not less than ninety-five percent (95%) of all such rentable area of the Building.

D . Disputes Over Taxes or Operating Expenses. If Tenant disputes the amount of an Estimated Escalation Increase or an actual Escalation Increase, Tenant shall give Landlord written notice of such dispute within one hundred fifty (150) days after Landlord delivers the applicable Escalation Statement. Tenant's failure to give such notice shall waive its right to audit the amounts so determined. Tenant shall not be entitled to audit the foregoing amounts if an Event of Default by Tenant then exists and remains

uncured. Said audit will be conducted at Tenant's expense by a certified public accountant or by a qualified and reputable real estate professional, in either case paid on an hourly basis unrelated to actual savings identified. Tenant shall only be permitted to conduct such a review during regular business hours at Landlord's office, after Tenant gives Landlord twenty (20) days prior written notice, and no more than once with respect to any one Comparison Year. If such review discloses that the charges actually incurred by Landlord are less than those used by Landlord in calculating Escalation Increases, then Landlord shall reimburse Tenant for the amount Tenant paid in excess of Tenant's actual Escalation Increases. If any such review discloses that the charges for Operating Expenses or Taxes used by Landlord in calculating the Escalation Increases exceeds the actual charges for Operating Expenses and Taxes (the "Actual Expenses") by five percent (5%) or more of the Actual Expenses for such Comparison Year, then Landlord shall pay the reasonable costs of such review. If Tenant does not review Landlord's records within two hundred seventy (270) days after receipt of the Escalation Statement, Tenant shall have no further right to review Landlord's records for the applicable period. No subtenant shall have the right to conduct an audit and no assignee shall conduct an audit for any period during which such assignee was not in possession of the Premises.

In the event Tenant elects to exercise its audit rights hereunder, Tenant shall nevertheless timely pay Landlord the amount of the prior year's Escalation Reconciliation and continue to pay Estimated Escalation Increases (without prejudice to Tenant's position) as set forth in the then applicable Escalation Statement until the parties have agreed as to the appropriate adjustment.

E. Building as Part of Multi-Building Development. Tenant acknowledges that the Building is part of the Project. As a result thereof, any Operating Expenses and Taxes attributable in part to the Building and in part to other portions of the Project, including, without limitation, the Building Common Areas (as hereinafter defined), shall be allocated to the Building and said other portions of the Project pursuant to the Declaration or any other applicable reciprocal easement agreement and otherwise on an equitable basis. In addition, any Operating Expenses and Taxes attributable in part to the Office Component and in part to the Retail Component shall be allocated to the Office Component or the Retail Component, as the case may be, on an equitable basis.

F. Tenant's Taxes. Tenant shall pay, prior to delinquency, all taxes assessed against or levied upon trade fixtures, furnishings, equipment and all other personal property of Tenant located in the Premises and any excise, sales or use taxes related to Tenant's business. In the event any or all of Tenant's trade fixtures, furnishings, equipment and other personal property shall be assessed and taxed with property of Landlord, or if the cost or value of any leasehold improvements in the Premises exceeds the cost or value of a standard build out for general office use and, as a result, real property taxes for the Building are increased, Tenant shall pay to Landlord its share of such taxes within thirty (30) days after delivery to Tenant by Landlord of a statement in writing setting forth the amount of such taxes applicable to Tenant's property or above-standard improvements. Tenant shall pay directly to the party or entity entitled thereto all business license fees, gross receipts taxes and similar taxes and impositions which may from time to time be assessed against or levied upon Tenant, as and when the same become due and before delinquency. Notwithstanding anything to the contrary contained herein, any sums payable by Tenant under this Article 4 shall not be included in the computation of "Taxes."

ARTICLE 5.

DELIVERY OF PREMISES, TENANT'S WORK, ALTERATIONS AND ADDITIONS

A. Delivery of Premises. On the next business day following the execution and delivery of this Lease by Landlord and Tenant, Landlord shall deliver, and Tenant shall accept, the Premises in the "Delivery Condition," which shall mean that the Premises will be delivered vacant and broom clean, free of construction debris, tools and other personal property, and free of any unlawful Hazardous Materials (as hereinafter defined), but otherwise in their current "as is," "where is" condition. Landlord shall have no obligation to construct any improvements in and to the Premises or to perform any other work therein, the parties acknowledging and agreeing that Tenant shall be solely responsible for improving the Premises as provided in Article 5.B. below and Exhibit B attached hereto, provided that the foregoing shall in no event derogate from or diminish Landlord's ongoing repair and maintenance obligations under this Lease. Notwithstanding anything contained herein to the contrary, Landlord hereby represents and warrants to Tenant that, as of the Commencement Date, the Common Areas of the Building and the Base Building Condition of the Premises comply with all applicable Laws, including, without limitation, the ADA (as hereinafter defined) and all other applicable laws and rules governing access to and use of facilities by people with disabilities, including the Massachusetts Architectural Access Board regulations. The "Base Building Condition" is as described on Exhibit E attached hereto.

B. Tenant's Work. On and after the Commencement Date, Tenant shall be entitled to construct certain initial improvements in and to the Premises and prepare same for occupancy in accordance with the terms and conditions of the work exhibit attached hereto as Exhibit B (collectively, "Tenant's Work").

C. Alterations. Except as otherwise provided in Article 5.B. above and Exhibit B attached hereto, Tenant shall make no alterations or additions to the Premises ("Alterations") without the prior written consent of Landlord, which consent may be withheld in Landlord's sole discretion as to Alterations which adversely affect or impair the structural integrity of or the efficient and proper operation of the operating systems of the Building, and which consent shall not be unreasonably withheld, delayed or conditioned as to all other Alterations. Any Alterations shall only be performed by contractors or mechanics approved by Landlord in writing (which approval shall not be unreasonably withheld, conditioned or delayed), and only upon the approval by Landlord in writing of fully detailed and dimensioned plans and specifications pertaining to the Alterations in question (to the extent such plans and/or

specifications would customarily be prepared for work of such nature), to be prepared and submitted by Tenant, at its sole cost and expense, which approval shall not be unreasonably withheld, conditioned or delayed. Tenant shall, at its sole cost and expense, obtain all necessary approvals and permits pertaining to any Alterations approved by Landlord. Tenant hereby indemnifies, defends and agrees to hold Landlord free and harmless from all liens and claims of lien, and all other liability, claims and demands arising out of any work done or material supplied to the Premises by or at the request of Tenant in connection with any Alterations. If permitted Alterations are made by, on behalf of, or at the request of, Tenant, they shall be made at Tenant's sole cost and expense and shall be and become the property of Landlord, except that Landlord may, by written notice to Tenant given at the time of approval of such Alterations, require Tenant, at Tenant's expense, to remove all partitions, counters, railings and other Alterations installed by Tenant, and to repair any damages to the Premises caused by such removal. Unless Landlord notifies Tenant in writing of such removal obligation at the time of Landlord's approval of the plans and specifications therefor in accordance with the terms and conditions of Exhibit B attached hereto, Tenant shall not be required to remove any alterations or improvements made to prepare the Premises for Tenant's initial occupancy; provided, however, that Landlord agrees that Tenant shall not be obligated to remove any of the improvements conceptually shown on the space plan hereto as Exhibit B-1, subject to the terms and conditions of Exhibit B attached hereto. Any and all costs attributable to or related to the applicable building codes of the City of Boston (or any other authority having jurisdiction over the Building) arising from Tenant's plans, specifications, improvements, Alterations or otherwise shall be paid by Tenant at its sole cost and expense. With regard to repairs, Alterations or any other work arising from or related to this Article 5, Landlord shall be entitled to receive a commercially reasonable administrative/supervision fee, not to exceed three percent (3%) of the so-called "hard" costs of any such work, to compensate Landlord for costs and expenses arising from Landlord's review and approval processes.

D. Liens. Tenant will not cause or permit any mechanic's, materialman's or similar liens or encumbrances to be filed or exist against the Premises or the Building or Tenant's interest in this Lease in connection with work done under this Article 5 or in connection with any other work, and Tenant agrees to defend, indemnify and hold harmless Landlord from and against any such lien or claim or action thereon, together with costs of suit and reasonable attorneys' fees incurred by Landlord in connection with any such claim or action. Tenant shall remove any such lien or encumbrance by bond or otherwise within twenty (20) days from the date of receipt of notice of its existence. If Tenant fails to do so, Landlord may, without being responsible to investigate the validity or lawfulness of the lien, pay the amount or take such other action as Landlord deems necessary to remove any such lien or encumbrance or require that Tenant deposit with Landlord in cash and lawful money of the United States, one hundred ten percent (110%) of the amount of such claim, which sum may be retained by Landlord until such claim shall have been removed of record or until judgment shall have been rendered on such claim and such judgment shall have become final, at which time Landlord shall have the right to apply such deposit in discharge of the judgment on said claim and any costs, including attorneys' fees incurred by Landlord, and shall remit the balance thereof to Tenant. The amounts so paid and costs incurred by Landlord shall be deemed Additional Rent under this Lease and payable in full upon demand, but shall be applied only to the lien or judgment in question, and any excess will be refunded to Tenant.

E. Compliance with ADA. Landlord represents and warrants to Tenant that, as of the Commencement Date hereof, the Building and the Premises are in compliance with ADA (as defined below). Landlord and Tenant agree that responsibility for compliance with the Americans With Disabilities Act of 1990, as amended (the "ADA") shall be allocated as follows: (i) Landlord shall be responsible for compliance with the provisions of Title III of the ADA for all Building Common Areas, including exterior and interior areas of the Building not included within the Premises or the premises of other tenants; (ii) Landlord shall be responsible for compliance with the provisions of Title III of the ADA for any construction, renovations, alterations and repairs made within the Premises if such construction, renovations, alterations or repairs are made by Landlord for the purpose of improving the Building generally; and (iii) Tenant shall be responsible for compliance with the provisions of Title III of the ADA for any construction, renovations, Alterations and repairs made within the Premises if such construction, renovations, Alterations and repairs are made by Tenant, its employees, agents or contractors, at the direction of Tenant or done pursuant to final construction plans and specifications prepared or provided by Tenant or Tenant's architect or space planner.

F. Labor Covenant. As a condition precedent to any proposed construction work or Alteration, Tenant shall deliver to Landlord evidence satisfactory to Landlord that Tenant shall cause such construction, alteration or service contract work to be performed solely by contractors whose employees are represented by unions and such employment will conform to the traditional craft jurisdictions in the area (the "Labor Covenant"). Tenant shall include the Labor Covenant in each of its contracts for such construction or alteration work and in each of its service contracts for any maintenance, repair and services relating to, or to be performed for the benefit of, the Premises. Tenant shall also provide such evidence as Landlord may reasonably require, from time to time during the course of such construction or alteration work or the performance of such services, that the Labor Covenant is being fully and faithfully observed and Tenant shall include the obligation to provide such evidence in each contract entered into by Tenant for such construction or alteration work or service being provided to the Premises. Tenant further agrees that it shall incorporate the foregoing requirements in any sublease of the Premises. Tenant improvement or Alteration work requiring specialized skills that are not available through unionized contractors may be exempted from the Labor Covenant, subject to prior approval by Landlord.

G. Building Sustainability Strategies. Landlord has received LEED-Core and Shell Gold Certification, a rating established by the U.S. Green Building Council. A memorandum outlining Landlord's "Sustainable Design Strategies" is attached hereto as Exhibit I.

ARTICLE 6.

TENANT'S USE, RESTRICTIONS AND COMPLIANCE WITH LAWS

A. Tenant's Use. Tenant shall use the Premises for the Permitted Use as provided in Article 1 above, and for no other purpose whatsoever, subject to and in compliance with all other provisions of this Lease, including without limitation the Building's Rules and Regulations attached as Exhibit D hereto. Tenant and its invitees shall also have the non-exclusive right, along with other tenants of the Building, others authorized by Landlord, and others having the right to the use thereof, to use the Building Common Areas subject to the Project Documents and such rules and regulations as Landlord may impose from time to time in its sole discretion provided the same are enforced in a non-discriminatory manner. Landlord makes no representation that the Premises are suitable for Tenant's purposes.

B. Tenant's Restrictions. Tenant shall not at any time use or occupy, or suffer or permit anyone to use or occupy, the Premises or do or permit anything to be done in the Premises which: (a) causes or is liable to cause injury to persons, to the Building or its equipment, facilities or systems; (b) impairs the character, reputation or appearance of the Building as a first class office building; (c) impairs the proper and economic maintenance, operation and repair of the Building or its equipment, facilities or systems; or (d) would invalidate or increase the cost of any fire and extended coverage insurance policy covering the Building and/or the property located therein. Tenant shall comply with all rules, orders, regulations and requirements of any organization which sets out standards and requirements commonly referred to by major fire insurance underwriters. Landlord shall notify Tenant if Landlord reasonably believes that Tenant's use of the Premises is in violation of any such standard or requirement. Tenant shall promptly, upon demand, reimburse Landlord for any additional premium charges for any such insurance policy assessed or increased by reason of Tenant's failure to comply with the provisions of this Article 6.

C. Tenant's Compliance with Laws. Tenant shall, at Tenant's sole cost and expense, keep and maintain the Premises, its use thereof and its business in compliance with all Laws now in force or which may hereafter be in force or effect. Tenant shall comply with all Laws relating to the Premises and Tenant's use or occupancy thereof, including without limitation Laws in connection with the health, safety and building codes, and any permit or license requirements. Tenant shall not be required to make any alterations to the Premises in order to comply with laws or codes that are applicable to the operation and maintenance generally of a commercial rental property such as the Project, as opposed to Tenant's specific use of the Premises or any Alterations or other work by Tenant.

ARTICLE 7.

SERVICES

A. Climate Control. Landlord shall furnish heat or air conditioning to the Premises during Normal Business Hours of the Building as set forth in Article 1, as required in Landlord's reasonable judgment for the comfortable use and occupancy of the Premises and otherwise in accordance with the standards attached hereto as Exhibit J (such standards being referred to herein as "OTIS" or "OTIS standards"). If Tenant requires heat or air conditioning at any other time ("After Hours Services"), Landlord shall use reasonable efforts to furnish such After Hours Services upon at least twenty-four (24) hours advance notice by Tenant, and Tenant shall pay Landlord, as Additional Rent, the then current rate for such After Hours Services that is applicable to office tenants of the Building generally. The current estimated rate for After Hours Services is Fifty Dollars ($50.00) per hour, which rate is subject to change from time to time in Landlord's sole, but reasonable discretion.

The performance by Landlord of its obligations under this Article 7 is subject to Tenant's compliance with the terms of this Lease regarding any connected electrical load reasonably established by Landlord, and Landlord shall promptly notify Tenant of any respect in which Landlord reasonably believes Tenant is not so complying. Tenant shall not use the Premises or any part thereof in a manner exceeding the heating, ventilating or air-conditioning ("HVAC") design conditions (including any occupancy or connected electrical load conditions) set forth in OTIS, including the rearrangement of partitioning which may interfere with the normal operation of the HVAC equipment, or the use of computer or data processing machines or other machines or equipment in excess of the capacities (if any) and standards set forth in OTIS. If any such use of the Premises by Tenant requires changes in the HVAC or plumbing systems or controls servicing the Premises or portions thereof in order to provide comfortable occupancy in accordance with OTIS standards, such changes may be made by Landlord at Tenant's expense, and Tenant agrees to promptly pay any such amount to Landlord as Additional Rent.

If Tenant shall install supplemental HVAC equipment in the Premises to serve its needs, chilled water/condenser water shall be made available to Tenant in accordance with OTIS standards.

B. Elevator Service. Landlord, during Normal Business Hours of the Building, shall furnish passenger and freight elevator service to Tenant to be used in common with others. At least one (1) passenger elevator shall remain in service during all other hours. Landlord may designate a specific elevator for use as a service elevator.

C. Janitorial Services. Landlord shall provide janitorial and cleaning services to the Premises, substantially as described in Exhibit D attached hereto. Tenant shall pay to Landlord within thirty (30) days after receipt of an invoice therefor the actual and reasonable costs incurred by Landlord for (i) any cleaning of the Premises in excess of the specifications in Exhibit D for any reason, including, without limitation, cleaning required because of (A) unreasonable misuse or neglect on the part of Tenant or Tenant's agents,

contractors, invitees, employees and customers, (B) the use of portions of the Premises for special purposes requiring greater or more difficult cleaning work than office areas, (C) unusual quantities of interior glass partitions or interior glass surfaces, and (D) non-building standard materials or finishes installed by Tenant or at its request; and (ii) removal from the Premises of any refuse and rubbish of Tenant in excess of that ordinarily accumulated in general office occupancy or at times other than Landlord's standard cleaning times as reflected on such Exhibit D.

D . Water and Electricity. Landlord shall make available domestic water in reasonable quantities to the Building Common Areas and cause electric service sufficient for lighting the Premises and for the operation of Ordinary Office Equipment. "Ordinary Office Equipment" shall mean equipment not exceeding the standards and capacities set forth in OTIS. Landlord shall have the exclusive right to make any replacement of lamps, fluorescent tubes and lamp ballasts in the Premises (provided, however, that replacements of specialty lighting shall be at Tenant's sole cost and expense). Landlord may adopt a system of re-lamping and ballast replacement periodically on a group basis in accordance with good management practice. Tenant's use of electric energy or water in the Premises shall not at any time exceed the capacity of any of the risers, piping, electrical conductors and other equipment in or serving the Premises. In order to insure that such capacity is not exceeded and to avert any possible adverse effect upon the Building's electric system, Tenant shall not, without Landlord's prior written consent in each instance, connect appliances or heavy duty equipment, other than Ordinary Office Equipment, to the Building's electric system or make any alteration or addition to the Building's electric system. Should Landlord grant its consent in writing, which Landlord may withhold in its sole discretion, all additional risers, piping and electrical conductors or other equipment therefor shall be provided by Landlord and the cost thereof shall be paid by Tenant within thirty (30) days of Landlord's demand therefor. As a condition to granting such consent, Landlord may require Tenant to agree to a reasonable increase in Monthly Base Rent to offset the expected cost to Landlord of such additional service, that is, the cost of the additional electric energy to be made available to Tenant based upon the estimated additional capacity of such additional risers, piping and electrical conductors or other equipment. If Landlord and Tenant cannot agree thereon, such cost shall be determined by an independent electrical engineer, to be selected by Landlord and reasonably approved by Tenant and paid equally by both parties.

E . Separate Meters. As part of Tenant's Work, by no later than the thirtieth (30th) day following the Commencement Date, Tenant shall cause the Premises to be separately metered for lights, plugs and power and the electricity to power the VAV boxes in the Premises, and Tenant shall pay a monthly electricity charge to the applicable electricity provider, based on Tenant's separately metered use and consumption of such electricity in the Premises. If a direct metering arrangement is not reasonably feasible, then Tenant shall install a so-called submeter for electricity and Tenant shall pay a monthly electricity charge to Landlord, as Additional Rent, based on usage as indicated by such submeter and calculated at Landlord's actual rate(s) for such electricity (without add-on or mark-up). If the Premises are separately metered for any other utility, Tenant shall pay a utility charge directly to the utility company (or, if such arrangement is not reasonably feasible, to Landlord, as Additional Rent) based upon Tenant's actual consumption as measured by the meter. Landlord also reserves the right (at its expense) to install separate meters for the Premises to register the usage of all or any one of the utilities, and, in such event, Landlord shall pay the cost of installation and Tenant shall pay for the cost of utility usage as metered to the Premises. As to the separate metering of any service or utility, the cost of which was previously included in the Monthly Base Rent and/or Base Year for Operating Expenses or Taxes, there shall be a reasonable and equitable adjustment to Monthly Base Rent and Operating Expenses (for the Base Year and each subsequent year) following such separate metering to reflect that Tenant will thereafter be paying the cost of such service or utility directly. The term "utility" for purposes hereof may refer to but is not limited to gas, water, sewer, steam, fire protection system, telephone or other communication or alarm service, as well as HVAC, and all taxes or other charges thereon.

F. Interruptions. Landlord does not represent or warrant that any of the services referred to above, or any other services which Landlord may supply, will be free from interruption and Tenant acknowledges that any one or more of such services may be suspended by reason of accident, repairs, inspections, alterations or improvements necessary to be made, or by Force Majeure. Any interruption, reduction or discontinuance of service shall not be deemed an eviction or disturbance of Tenant's use and possession of the Premises, or any part thereof, nor, except as otherwise set forth herein, render Landlord liable to Tenant for damages, nor relieve Tenant from performance of Tenant's obligations under this Lease. Landlord shall however, exercise reasonable diligence to restore any service so interrupted.

Notwithstanding the foregoing, if any essential services to be supplied by Landlord under this Lease are interrupted, and such interruption has resulted from an act or omission of Landlord and as a result of such cessation of service, the Premises, or a material portion thereof, is rendered untenantable (meaning that Tenant is unable to use and gain reasonable access to the Premises, or such material portion thereof, in the normal course of its business) and Tenant provides written notice of such interruption to Landlord, Tenant shall be entitled to an abatement of a proportionate share of the Monthly Base Rent and all Additional Rent and charges, allocable to the affected material portion of the Premises commencing on the third (3rd) consecutive business day of the interruption following the date on which Tenant notifies Landlord of the cessation of such service, and ending on the date such essential services and Tenant's access and use of the Premises are restored. If any such interruption continues for fifteen (15) business days after the date of such notice, then for each day thereafter that the interruption continues, Tenant shall be granted a credit of one and one-half (1.5) days' Monthly Base Rent and Additional Rent, to be applied following the resumption of such services. If such interruption continues for twenty-five (25) business days after the date of such notice, then for each day thereafter that the interruption continues, Tenant shall be granted a credit of two (2) days' Monthly Base Rent and Additional Rent, instead of the prior one and one-half (1.5) day rent credit, to be applied following the resumption of such services.

G. Additional Utilities Provided by Tenant. Tenant shall make application in Tenant's own name for all utilities not provided herein by Landlord and shall: (i) comply with all utility company regulations for such utilities, including requirements for the installation of meters, and (ii) obtain such utilities directly from, and pay for the same when due directly to, the applicable utility companies. The term "utilities" for purposes hereof shall include but not be limited to telephone and other communication and alarm services, and all taxes or other charges thereon. Tenant shall install and connect all equipment and lines required to supply such additional utilities to the extent not already available at or serving the Premises, or at Landlord's option shall repair, alter or replace any such existing items. Tenant shall maintain, repair and replace all such items, operate the same, and keep the same in good working order and condition. Tenant shall not install any equipment or fixtures, or use the same, so as to exceed the safe and lawful capacity of any utility equipment or lines serving the same. The installation, alteration, replacement or connection of any utility equipment and lines shall be subject to the requirements for Alterations of the Premises set forth in Article 5, and Tenant will have the right to use, in common with other tenants and occupants of the Building, common ducts, chases, conduits, and pipes in order to make necessary connections with the Premises. Tenant shall ensure that all of Tenant's HVAC equipment that is installed by, on behalf of, or at the request of, Tenant is installed and operated at all times in a manner to prevent roof leaks, damage, or noise due to vibrations or improper installation, maintenance or operation. Except as specifically provided in this Article 7, Tenant agrees to pay for all utilities and other services utilized by Tenant and additional services furnished to Tenant not uniformly furnished to all tenants of the Office Component at the rate actually paid by Landlord to the utility provider.

H. Additional Installations. If any lights, machines or equipment (including but not limited to computers) used by Tenant in the Premises materially and adversely affect the temperature otherwise maintained by the air conditioning system, or generate substantially more heat in the Premises than would be generated by the building standard lights and Ordinary Office Equipment, and if such adverse effect continues for more than ten (10) business days after notice thereof from Landlord, Landlord shall have the right to install any machinery and equipment which Landlord reasonably deems necessary to restore temperature balance, including but not limited to modifications to the standard air conditioning equipment, and the cost thereof, including the cost of installation and any additional cost of operation and maintenance occasioned thereby, shall be paid by Tenant to Landlord upon demand by Landlord. Landlord shall not be liable under any circumstances for loss of or injury to property, however occurring, through or in connection with or incidental to failure to furnish any of the foregoing.

I. Access to Building Common Areas. Tenant shall have access to the Building Common Areas twenty-four (24) hours per day, seven (7) days per week, three hundred sixty-five (365) days per year. Upon initial occupancy, Tenant will be entitled to one (1) access card or other access device per employee for use at the Building turnstiles and elevators. Thereafter, additional access cards or devices may be obtained at the rate of Twenty-Five and 00/100 Dollars ($25.00) per additional card or device, which rate is subject to change from time to time in Landlord's sole but reasonable discretion.

ARTICLE 8.

INSURANCE

A. Required Insurance. Tenant shall, at all times during the Term of this Lease, and at its own cost and expense, maintain insurance policies, with responsible companies licensed to do business in the Commonwealth of Massachusetts and reasonably satisfactory to Landlord, naming Landlord, the Building Manager, Cornerstone Real Estate Advisers LLC, Tenant and any Mortgagee of Landlord, as their respective interests may appear, including: (i) a policy of standard fire, extended coverage and special extended coverage property insurance which shall be primary on the lease improvements referenced in Article 5 and Tenant's property, including its goods, equipment and inventory, in an amount adequate to cover their insurable replacement cost, including a vandalism and malicious mischief endorsement, and sprinkler leakage coverage; (ii) business interruption insurance, loss of income and extra expense insurance covering the failure of Tenant's telecommunications equipment and all other perils, failures or interruptions; (iii) commercial general liability insurance on an occurrence basis with limits of liability in an amount not less than Two Million Dollars ($2,000,000) combined single limit for each occurrence, and Three Million Dollars ($3,000,000) in the annual aggregate; and (iv) Worker's Compensation Coverage as required by law. The commercial general liability policy shall include contractual liability, provided that contractual liability coverage shall not provide coverage for losses arising from the negligence or willful misconduct of an additional insured.

On or before the Commencement Date, Tenant shall furnish to Landlord and the Building Manager, certificates of insurance evidencing the insurance coverage set forth above, including naming Landlord, Cornerstone Real Estate Advisers LLC and the Building Manager as additional insureds. Renewal certificates must be furnished to Landlord at least ten (10) days prior to the renewal or replacement of such insurance policies showing the above coverage to be in full force and effect.

The foregoing policy sets forth minimum limits of liability and Tenant's procurement and maintenance thereof shall in no event limit the liability of Tenant under this Lease. All such general liability insurance policies carried by Tenant shall be with companies having a rating of not less than A-VIII in Best's Insurance Guide. All such policies shall be endorsed to agree that Tenant's policy is primary and that any insurance covered by Landlord is excess and not contributing with any Tenant insurance requirement hereunder. Tenant agrees that if Tenant does not take out and maintain such insurance or furnish Landlord with renewals or binders, Landlord may (but shall not be required to) procure said insurance on Tenant's behalf and charge Tenant the cost thereof, which amount shall be payable by Tenant upon demand with interest from the date such sums are extended. Tenant agrees that no policy required hereunder

will be canceled except upon thirty (30) days prior written notice (except ten (10) days in the case of non-payment of premium) from Tenant or its insurance agent or consultant. Tenant shall comply with all reasonable and generally applicable rules and directives of any insurance board, company or agency determining rates of hazard coverage for the Premises, including but not limited to the installation of any equipment and/or the correction of any condition necessary to prevent any increase in such rates such as may result from a violation by Tenant.

B . Landlord's Insurance. During the Term of this Lease, Landlord shall maintain "Special Form" property and commercial general liability insurance covering the Building. The Special Form property insurance policy shall cover all structures and improvements for full replacement value, with replacement cost endorsement, above foundation walls. Landlord's Commercial General Liability Insurance shall be written on an occurrence basis with minimum limits of liability in an amount of not less than $5,000,000.00, combined single limit, for bodily injury or death including personal injury, and with respect to damage to the property of others, including legal liability arising out of any one occurrence, which insurance shall contain contractual liability insurance coverage. The commercial general liability insurance shall insure against claims for bodily injury and property damage occurring in or about the Building. Such insurance may be included in blanket policies carried by Landlord so long as such blanket policies do not reduce the amount of insurance available to pay any claim with respect to the Building.

C. Waiver of Subrogation. Landlord and Tenant each agree that neither Landlord nor Tenant will have any claim against the other for any loss, damage or injury which is covered by insurance carried by either party and for which recovery from such insurer is made, notwithstanding the negligence of either party in causing the loss, and each agree to have their respective insurers issuing the insurance described in this Article 8 waive any rights of subrogation that such companies may have against the other party. Each party agrees to use commercially reasonable efforts to obtain such an agreement from its insurer if the policy does not expressly permit a waiver of subrogation.

D . Waiver of Claims. Except for claims arising from Landlord's willful misconduct or negligence that are not covered by Tenant's insurance required hereunder, Tenant waives all claims against Landlord for injury or death to persons, damage to property or to any other interest of Tenant sustained by Tenant or any party claiming, through Tenant resulting from: (i) any occurrence in or upon the Premises; (ii) leaking of roofs, bursting, stoppage or leaking of water, gas, sewer or steam pipes or equipment, including sprinklers; (iii) wind, rain, snow, ice, flooding, freezing, fire, explosion, earthquake, excessive heat or cold, or other casualty; (iv) the Building, Premises, or the operating and mechanical systems or equipment of the Building, being defective, or failing; and (v) vandalism, malicious mischief, theft or other acts or omissions of any other parties including, without limitation, other tenants, contractors and invitees at the Building. In no event will Landlord or Tenant be responsible for any consequential damages incurred by the other party, including but not limited to, lost profits or interruption of business as a result of any alleged default hereunder; provided, however, that no remedies or damages expressly provided in this Lease shall be considered indirect or consequential, and that the provisions of this Article 8.D. shall not apply to Articles 15 and 27 of this Lease.

ARTICLE 9.

INDEMNIFICATION

A . Tenant Indemnity of Landlord. Except to the extent resulting from the willful misconduct or negligence of Landlord or its agents, employees or contractors, and subject to Article 8.C., Tenant shall defend, indemnify and hold harmless Landlord and its agents, successors and assigns, including the Building Manager, from and against any and all injury, loss, costs, expenses, liabilities, claims or damage (including attorneys' fees and disbursements) to any person or property (i) arising from, related to, or in connection with any use or occupancy of the Premises by Tenant, or (ii) arising from, related to, or in connection with any negligent or willful and wrongful act or omission (including, without limitation, construction and repair of the Premises arising out of any Alterations) of Tenant, its agents, contractors, employees, customers, and invitees, or (iii) or arising from any uncured default by Tenant under this Lease. This indemnification shall survive the expiration or termination of the Lease Term.

B . Landlord Indemnity of Tenant. Landlord shall defend, indemnify and hold Tenant harmless from and against all claims, causes of action, liabilities, losses, costs and expenses arising from or in connection with (i) any injury or other damage to any person or property resulting from any act or omission of Landlord, or (ii) any uncured default by Landlord under this Lease. This indemnification shall survive the expiration or termination of the Lease Term.

C . Indemnity Limitations. The indemnity obligations set forth in Sections A. and B. above shall not apply (i) to any costs or expenses not reasonably incurred by the indemnitee, or (ii) to any claims, causes of action, liabilities, losses, costs and expenses resulting from a default by the indemnitee hereunder.

D . Indemnitees; Acceptable Attorneys . Whenever, in this Article 9 and throughout this Lease, Landlord or Tenant is required to defend, indemnify and hold the other harmless, such obligations shall extend to the successors, assigns, officers, partners, members, managers, directors, employees and other agents of the indemnitee. In any instance where this Lease requires either party to defend the other, such defense shall involve an attorney or attorneys reasonably acceptable to the indemnitee.

E . Limitation on Liability. Landlord shall not be liable to Tenant for any damage by or from any act or negligence of any tenant or other occupant of the Building, or by any owner or occupants (other than Landlord or its affiliated entities) of adjoining or

contiguous property. Landlord shall not be liable for any injury or damage to persons or property resulting in whole or in part from the criminal activities or willful misconduct of others. Subject to Article 8.C. above, Tenant agrees to pay for all damage to the Building, as well as all damage to persons or property of other tenants or occupants thereof, caused by the negligence, fraud or willful misconduct of Tenant or any of its agents, contractors, employees, customers (while located in the Premises) and invitees (while located in the Premises). Nothing contained herein shall be construed to relieve Landlord from liability for any personal injury resulting from its negligence, fraud or willful misconduct and that of its agents, employees or contractors.

F . Surveillance. Tenant acknowledges that Landlord's election to provide mechanical surveillance or to post security personnel in the Building is subject to Landlord's sole discretion. Except to the extent resulting from the willful misconduct or negligence of Landlord or its agents, employees or contractors, and then subject to Article 8.C. above, Landlord shall have no liability in connection with the decision whether or not to provide such services and Tenant hereby waives all claims based thereon. Landlord shall not be liable for losses due to theft, vandalism, or like causes.

ARTICLE 10.

CASUALTY DAMAGE

Tenant shall promptly notify Landlord or the Building Manager of any fire or other casualty to the Premises, or, to the extent it knows of damage, to the Building. In the event the Premises or any substantial part of the Building is wholly or partially damaged or destroyed by fire or other casualty which is covered by the insurance that Landlord is required to carry hereunder, Landlord will proceed to restore the same to substantially the same condition existing immediately prior to such damage or destruction unless Landlord notifies Tenant (the "Casualty Notice") that (i) such damage or destruction is incapable of repair or restoration within three hundred sixty-five (365) days from commencement thereof as reasonably determined by Landlord's architect; or (ii) the insurance proceeds recovered by reason of the damage or destruction (together with the amount of any deductible) are, in Landlord's commercially reasonable judgment, inadequate to complete the restoration of the Building; or (iii) Landlord elects not to repair or restore the Building; in any of which events Landlord or Tenant may, by written notice given to the other party within twenty (20) days of Tenant's receipt of the Casualty Notice, declare this Lease terminated as of the happening of such damage or destruction. Any Casualty Notice must be delivered within forty-five (45) days after the date of such damage. To the extent after fire or other casualty that Tenant shall be deprived of the use and occupancy of the Premises or any portion thereof as a result of any such damage, destruction or the repair thereof, providing Tenant did not intentionally cause the fire or other casualty, then Tenant shall be relieved of the same ratable portion of the Monthly Base Rent and all additional rent due under this Lease as the amount of damaged or useless space in the Premises bears to the rentable square footage of the Premises until such time as the Premises may be restored. Landlord shall reasonably determine the amount of damaged or useless space and the square footage of the Premises referenced in the prior sentence and whether or not its insurance covers the payment of Rent. Tenant may elect to terminate this Lease: (a) if the Casualty Notice states that it will take greater than three hundred sixty-five (365) days to complete the restoration or repair from the time that such restoration or repair commences, provided that Tenant gives such notice within thirty (30) days after delivery of the Casualty Notice; or (b) if the restoration or repair is not completed within three hundred sixty-five (365) days (or such longer period as is specified in the Casualty Notice, plus an additional contingency period equal to twenty percent (20%) of such scheduled period) of the casualty, plus an additional period of up to sixty (60) days on account of Force Majeure; provided however, that if such restoration or repair is completed within thirty (30) days following receipt of Tenant's notice of termination, then such notice of termination shall be deemed null and void and of no further force or effect.

ARTICLE 11.

CONDEMNATION

In the event of a condemnation or taking of the entire Premises by a public or quasi-public authority, this Lease shall terminate as of the date title vests in the public or quasi-public authority. In the event of (i) a taking or condemnation of fifteen percent (15%) or more (but less than the whole) of the Building and without regard to whether the Premises are part of such taking or condemnation; (ii) a taking or condemnation which results in Landlord electing not to restore the Building; or (iii) a taking or condemnation which results in Landlord electing to change the use of the land upon which the Building is located, Landlord may elect to terminate this Lease by giving notice to Tenant within sixty (60) days of Landlord receiving notice of such condemnation. In the event of a partial taking as described in this Article 11, or a sale, transfer or conveyance in lieu thereof, which does not result in the termination of this Lease, Rent shall be apportioned according to the ratio that the part of the Premises remaining usable by Tenant bears to the total area of the Premises. All compensation awarded for any condemnation shall be the property of Landlord, whether such damages shall be awarded as a compensation for diminution in the value of the leasehold or to the fee of the Premises, and Tenant hereby assigns to Landlord all of Tenant's right, title and interest in and to any and all such compensation; provided, however that in the event this Lease is terminated, Tenant shall be entitled to make a separate claim for the taking of Tenant's personal property (including fixtures paid for by Tenant), and for costs of moving, provided that any such award to Tenant is payable separately and does not diminish the award available to Landlord or any Lender of Landlord. Any additional portion of such award shall belong to Landlord. Tenant hereby waives any and all rights, imposed by law, statute, ordinance, governmental regulation or requirement of the United States, the Commonwealth of Massachusetts or any local government authority or agency or any political subdivision thereof, now or hereafter in effect, it might otherwise have to petition a court to terminate the Lease. In the event that any portion of the Premises shall be the subject to

condemnation or a taking and Tenant determines that the remainder, even after restoration, would not be reasonably suitable for Tenant's continued use, then this Lease may be terminated at the election of Tenant, which election shall be made by giving of notice by Tenant to Landlord within thirty (30) days after the date of the condemnation or taking.

ARTICLE 12.

REPAIR AND MAINTENANCE

A. Tenant's Obligations. Tenant shall keep the Premises in good working order, repair (and in compliance with all Laws now or hereafter adopted) and condition (which condition shall be neat, clean and sanitary) and shall make all necessary non-structural repairs thereto and any repairs to non-Building standard mechanical, HVAC, electrical and plumbing systems or components located in and exclusively serving the Premises. Tenant's obligations hereunder shall include, but not be limited to, Tenant's trade fixtures and equipment, security systems, signs, interior decorations, floor-coverings, wall-coverings, entry and interior doors, interior glass, light fixtures and bulbs, keys and locks, and Alterations to the Premises whether installed by Tenant or Landlord. Landlord may make any repairs which are not promptly made by Tenant after Tenant's receipt of written notice and the reasonable opportunity of Tenant to make said repair within five thirty (30) days from receipt of said written notice, and charge Tenant for the cost thereof, which cost shall be paid by Tenant within thirty (30) days from invoice therefor from Landlord. Tenant waives all rights to make repairs at the expense of Landlord, or to deduct the cost thereof from Rent.

B. Landlord's Obligations. Landlord shall maintain, in a condition similar to other first-class office buildings in the Boston market and in material compliance with all applicable Laws (other than those Laws applicable to a tenant's unique use and occupancy of its premises or to any alterations or other work performed by, on behalf of, or at the request of, such tenant), (i) the foundations, roof, perimeter walls and exterior windows and all structural aspects of the Building, and (ii) all nonstructural aspects of the Building which relate to the Building Common Areas or to more than one tenant's premises, or which no tenant of the Building is required to maintain and repair, including all systems and facilities necessary for the operation of the Building and the provision of services and utilities as required herein (except to the extent that any of the foregoing items are installed by or on behalf of, or are the property of, Tenant). Landlord shall also make all necessary structural repairs to the Building and any necessary repairs to the Building standard mechanical, HVAC, electrical, and plumbing systems in or servicing the Premises (the cost of which shall be included in Operating Expenses to the extent permitted under Article 4), excluding repairs required to be made by Tenant pursuant to this Article 12. Landlord shall have no responsibility to make any repairs unless and until Landlord receives written notice of the need for such repair or otherwise becomes aware. Landlord shall not be liable for damages arising from any failure to make repairs or to perform any maintenance unless such failure shall persist for an unreasonable period of time after written notice of the need for such repairs or maintenance is received by Landlord from Tenant or after Landlord otherwise becomes aware. Landlord shall make every reasonable effort to perform all such repairs or maintenance in such a manner (in its judgment) so as to cause minimum interference with Tenant and the Premises but Landlord shall not be liable to Tenant (except as may otherwise be expressly provided in this Lease) for any interruption or loss of business pertaining to such activities. Landlord shall have the right to require (subject to Article 8.C.) that any damage caused by the willful misconduct of Tenant or any of Tenant's agents, contractors or employees, be paid for and performed by the Tenant (without limiting Landlord's other remedies herein).

C. General Obligations. Alterations to the Premises required from time to time to comply with applicable Laws, requirements of any board of property insurance underwriters or similar entity, or reasonable requirements of Landlord's or Tenant's insurers shall be made by the party to this Lease responsible for maintaining and repairing the applicable aspect of the Premises hereunder, provided that Landlord shall be responsible for any such alteration that is not required solely on account of Tenant's particular use (other than general business offices) of the Premises or Alterations to the Premises. Landlord warrants to Tenant that, as of the Commencement Date, all aspects of the Premises comprising the Base Building Condition shall comply with all applicable Laws, with the requirements of Landlord's insurers, and with the requirements of all boards of property insurance underwriters and similar entities.

D. Signs and Obstructions. Tenant shall not obstruct or permit the obstruction of lights, halls, Building Common Areas, roofs, parapets, stairways or entrances to the Building or the Premises and will not affix, paint, erect or inscribe any sign, projection, awning, signal or advertisement of any kind to any part of the Building outside of the Premises, including the inside or outside of the windows or doors, or within the Premises if same can be seen from outside of the Premises, without the written consent of Landlord. If such work is done by Tenant through any person, firm or corporation not approved by Landlord, or without the express written consent of Landlord, Landlord shall have the right to remove such signs, projections, awnings, signals or advertisements without being liable to the Tenant by reason thereof and to charge the cost of such removal to Tenant as Additional Rent, payable within ten (10) days of Landlord's demand therefor. Tenant shall be entitled to Building-standard lobby directory signage, in common with other tenants of the Building, at no additional cost.

E. Outside Services. Tenant shall not permit, except by Landlord or a person or company reasonably satisfactory to and approved by Landlord: (i) the servicing of Tenant's supplemental heating, ventilating and air conditioning equipment in the Premises and (ii) window cleaning, janitorial services or similar work in or about the Premises.

F. Condition of Premises. Except as otherwise provided herein to the contrary (including without limitation Landlord's ongoing repair and maintenance obligations), Tenant hereby agrees that the Premises shall be taken "as is," "with all faults," and

"without any representations or warranties," and Tenant hereby acknowledges and agrees that it has investigated and inspected the condition of the Premises and the suitability of same for Tenant's purposes, and except for matters or conditions that could not reasonably be detected by a reasonably careful inspection, Tenant does hereby waive and disclaim any objection to, cause of action based upon, or claim that its obligations hereunder should be reduced or limited because of the condition of the Premises or the Building or the suitability of same for Tenant's purposes. Tenant acknowledges that neither Landlord nor any agent nor any employee of Landlord has made any representation or warranty with respect to the suitability of the Premises or the Building for the conduct of Tenant's business and Tenant expressly represents and warrants that Tenant has relied solely on its own investigation and inspection of the Premises and the Building in its decision to enter into this Lease and let the Premises in an "As Is" condition. The Premises shall be initially improved by Tenant as provided in, and subject to, the terms and conditions of Exhibit B attached hereto and made a part hereof. The Tenant Improvements (as defined in Exhibit B), together with any subsequent Alterations during the Term of this Lease, may be collectively referred to herein as the "Premises Improvements." The taking of possession of the Premises by Tenant shall conclusively establish that the Premises and the Building were at such time in satisfactory condition.

Landlord reserves the right from time to time, but subject to payment by and/or reimbursement from Tenant as otherwise provided herein: (i) to install, use, maintain, repair, replace and relocate for service to the Premises and/or other parts of the Building pipes, ducts, conduits, wires, appurtenant fixtures, and mechanical systems, wherever located in the Premises or the Building, (ii) to alter, close or relocate any facility in the Premises or the Building Common Areas or otherwise conduct any of the above activities for the purpose of complying with a general plan for fire/life safety for the Building or otherwise and (iii) to comply with any Law with respect thereto or the regulation thereof not currently in effect. Landlord shall attempt to perform any such work with the least inconvenience to Tenant as possible, but, except as otherwise expressly provided herein, so long as the activities by Landlord set forth in (i) and (ii) do not unreasonably interfere with Tenant's operations in the Premises, Tenant shall not be permitted to withhold or reduce Rent or other charges due hereunder as a result of same or otherwise make claim against Landlord for interruption or interference with Tenant's business and/or operations.

ARTICLE 13.

INSPECTION OF PREMISES

Tenant shall permit the Landlord, the Building Manager and its authorized representatives to enter the Premises upon at least twenty-four (24) hours' advance notice to show the Premises during Normal Business Hours of the Building (provided, however, that Landlord's right to show the Premises to prospective tenants shall be limited to the last twelve (12) months of the Term) and at other reasonable times to inspect the Premises, to clean the Premises, to serve or post notices as provided by law or which Landlord reasonably deems necessary for the protection of Landlord or Landlord's property, and to make such repairs, improvements, alterations or additions in the Premises or in the Building of which they are a part as Landlord may deem necessary or appropriate and at any time in the event of an emergency. If Tenant shall not be personally present to open and permit an entry into the Premises at any time when such an entry is necessary or permitted hereunder, Landlord may enter by means of a master key or may enter forcibly, only in the case of an emergency, without liability to Tenant and without affecting this Lease. Landlord shall (except in cases of emergency) use commercially reasonable efforts to avoid unnecessary interruption of Tenant's use of the Premises in any entry authorized hereby. Except in cases of emergency, Landlord will cooperate with Tenant to schedule such entry in a manner so as to minimize interference with Tenant's operations, and, if Tenant requests and pays for any incremental premium cost actually incurred by Landlord as a result of such request, Landlord will enter after hours.

ARTICLE 14.

SURRENDER OF PREMISES

Upon the expiration of the Term, or sooner termination of the Lease, Tenant shall quit and surrender to Landlord the Premises, broom clean, in good order and condition, normal wear and tear and damage by fire and other casualty which are Landlord's obligation excepted. All Premises Improvements and other fixtures, such as light fixtures and HVAC equipment, wall coverings, carpeting and drapes, in or serving the Premises, whether installed by Tenant or Landlord, shall be Landlord's property and shall remain, all without compensation, allowance or credit to Tenant; provided that Tenant shall, at its expense, remove any Alterations made by tenant after completion of the Tenant Improvements and that were required to be so removed by Landlord in any notice given to Tenant at the time of approval of such Alterations in accordance with Article 5.C. above and/or Exhibit B attached hereto, and repair any damages to the Premises caused by such removal, all at Tenant's sole cost and expense. Unless Landlord has otherwise directed Tenant to do so in writing under Exhibit B attached hereto at the time of Landlord's approval, Tenant shall not be required to remove any of the Tenant Improvements. Upon the expiration or earlier termination of this Lease, Tenant shall remove from the Premises all of Tenant's furniture, trade fixtures, furnishings, equipment and other personal property and repair any damage caused by such removal, at Tenant's sole cost and expense. Any property not removed shall be deemed to have been abandoned by Tenant and may be retained or disposed of by Landlord at Tenant's expense free of any and all claims of Tenant, as Landlord shall desire. All property not removed from the Premises by Tenant may be handled or stored by Landlord at Tenant's expense and Landlord shall not be liable for the value, preservation or safekeeping thereof. At Landlord's option all or part of such property may be conclusively deemed to have been conveyed by Tenant to Landlord as if by bill of sale without payment by Landlord. Tenant hereby waives, to the maximum extent allowable, the benefit of

all Laws now or hereafter in force in the Commonwealth of Massachusetts or elsewhere exempting property from liability for rent or for debt.

ARTICLE 15.

HOLDING OVER

Should Tenant, without Landlord's written consent, hold over after termination of this Lease, Tenant shall become a tenant at sufferance and any such holding over shall not constitute an extension of this Lease. Tenant shall pay Landlord, monthly and in advance, one hundred fifty percent (150%) of the annual Rent that was payable immediately preceding the Expiration Date (without regard to any abatement or reduction of Rent or other alternative rent actually in effect at such time), prorated on a per diem basis, for each day Tenant shall retain possession of the Premises or any part thereof after expiration or earlier termination of this Lease, which percentage shall increase to two hundred percent (200%) after the first (1st) thirty (30) days of such holdover, together with all damages sustained by Landlord on account thereof and all other payments required to be made by Tenant hereunder. The foregoing provisions shall not serve as permission for Tenant to hold-over, nor serve to extend the Term (although Tenant shall remain bound to comply with all provisions of this Lease until Tenant vacates the Premises) and Landlord shall have the right at any time thereafter to enter and possess the Premises and remove all property and persons therefrom or to require Tenant to surrender possession of the Premises as provided in this Lease upon the expiration or earlier termination of the Term. If Tenant fails to surrender the Premises upon the expiration or termination of this Lease, Tenant agrees to indemnify, defend and hold harmless Landlord from all costs, loss, expense or liability, including without limitation, claims made by any succeeding tenant and real estate brokers' claims and attorneys' fees, provided that Tenant shall not be required to indemnify Landlord from losses or damages suffered as a result of or in connection with the loss of (or delay in occupancy or rent payment by, or other increased financial exposure or liability to) a replacement or successor tenant until the sooner of (i) thirty (30) days beyond the expiration or earlier termination of this Lease, or (ii) ten (10) business days after Landlord has given Tenant written notice of such replacement or successor tenant. No acceptance by Landlord of any Rent during or for any period following the expiration or termination of the Lease shall operate or be construed as an extension or renewal of the Lease. Should Tenant remain in the Premises on a month-to-month basis with Landlord's prior and express written approval, such month-to-month tenancy may be cancelled by either party with thirty (30) days' prior written notice or such lesser time period as may be permitted by Law.

ARTICLE 16.

SUBLETTING AND ASSIGNMENT

A. Landlord's Consent. Except as provided herein, Tenant shall not assign its interests hereunder, sublease all or any portion of the Premises (for purposes of this Lease, a license shall be deemed to be a sublease), or list the Premises or any part thereof as available for assignment or sublease with any broker or agent or otherwise advertise, post, communicate or solicit prospective assignees or subtenants through any direct or indirect means, or allow any other person to use or occupy any portion of the Premises, without the prior written consent of Landlord, which shall not be unreasonably withheld, delayed or conditioned, except that Landlord shall not, under any circumstances, be obligated to consent to any assignment or subletting by Tenant (i) to any other tenant of the Building, so long as Landlord then has or will (as of the effective date of Tenant's proposed assignment or subletting) have additional comparable space available in the Building to lease to such other tenant, (ii) by operation of Law (subject to Article 16.B. below) or (iii) to any person who fails to meet any of the other reasonable criteria of Landlord that Tenant was required to meet prior to the execution of this Lease. Without limiting the generality of the foregoing, it shall be reasonable for Landlord to deny consent if:

(1) The financial strength of the proposed assignee, both in terms of net worth and in terms of reasonably anticipated cash flow over the Lease Term, is not reasonably acceptable to Landlord, taking into account the fact that Tenant would still be liable under the terms of this Lease (unless Tenant is released by Landlord as provided herein).

(2) The proposed assignee or subtenant will burden the Premises and/or Building Common Areas to an extent substantially in excess of that of typical office tenants of the Building, whether through disproportionate demand for landlord services or utilities, disproportionate bearing weights on floor areas, disproportionate parking requirements, deterioration of floors or other elements of the Building, or otherwise.

(3) The proposed assignee or subtenant intends to make substantial alterations to the Premises which would, in Landlord's reasonable judgment, result in a material net decrease in the value of the Premises as improved.

(4) The proposed assignee's or subtenant's use of the Premises will not, in Landlord's commercially reasonable judgment, be compatible with the uses of the other tenants in the Building or will be appropriate for a Class A office building.

(5) The use to be made of the Premises by the proposed assignee or subtenant is for other than general or professional business offices and is (A) not generally consistent with the character and nature of all other tenancies in the Office Component, or (B) a use which conflicts with any so-called "exclusive" then in favor of, or for any use which is the same as that stated in any percentage rent lease to, another tenant of the Building, or (C) a use which would be prohibited by any other portion of this Lease (including, but

not limited to, any rules and regulations then in effect).

(6) The proposed assignee or subtenant is either a governmental agency or instrumentality thereof.

(7) Either the proposed assignee or subtenant or any person or entity which controls, is controlled by or is under common control with the proposed assignee or subtenant (A) occupies space in the Building at the time of the request for consent, and Landlord then has or will (as of the effective date of Tenant's proposed assignment or subletting) have additional comparable space available in the Building to lease to such proposed assignee or subtenant, or (B) is negotiating with Landlord or has negotiated with Landlord during the six (6) month period immediately preceding the date of the proposed transfer, to lease space in the Building. For purposes hereof, "control" requires both (a) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person and (b) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person.

(8) The proposed assignee or subtenant (A) has an anticipated use of the Premises involving the generation, storage, use, treatment, or disposal of Hazardous Material in a way or to an extent that is greater than general business office use; or (B) has been required by any prior landlord, lender, or governmental authority to take remedial action in connection with Hazardous Material contaminating a property if the contamination resulted from such transferee's actions or use of the property in question.

With respect to any proposed assignment or subleasing requiring Landlord's consent, Tenant shall submit to Landlord in writing, at least thirty (30) days prior to the effective date of the assignment or sublease, (a) a notice of application to assign or sublease, setting forth the proposed effective date, which shall be not less than thirty (30) or more than one hundred twenty (120) days after the delivery of such notice; (b) the name of the proposed assignee or subtenant; (c) the nature of the proposed assignee's or subtenant's business to be carried on in the Premises; (d) the terms of the proposed sublease or assignment; and (e) a current financial statement of the proposed assignee or subtenant. Tenant shall not submit any such application to Landlord until Tenant has received a bona fide offer from the proposed assignee or subtenant, and Tenant shall furnish Landlord, in addition to the foregoing, with all other information reasonably required by Landlord with respect to such assignment or sublease, assignee or subtenant. Unless the stock in Tenant is publicly traded on a regulated securities exchange, any transfer (or sequence of transfers resulting, in the aggregate, in the transfer) of fifty percent (50%) or more of the beneficial ownership of Tenant shall constitute an assignment for purposes of this Article 16.

B . Transfers Not Requiring Consent. Notwithstanding the foregoing, Landlord's consent shall not be required with respect to any assignment or sublease to (1) an entity which controls Tenant or which controls the entity which controls Tenant (in either case, a "Parent"), or (2) an entity which is controlled by Tenant or a Parent, or (3) an entity which is controlled by an entity which is controlled by Tenant or a Parent, or (4) any entity resulting from a merger or consolidation involving Tenant, or (5) any entity which acquires all or substantially all of Tenant's assets, including, without limitation, Tenant's leasehold interest in and to this Lease (each, a "Permitted Transfer"). For purposes hereof, "control" requires both (a) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person and (b) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. With respect to any Permitted Transfer, the following provisions shall apply:

(a) Tenant shall give Landlord written notice of the assignment or subletting no less than thirty (30) days prior to the effective date thereof (unless restricted from doing so by legal or contractual requirement, in which case such notice shall be given promptly after such transfer),, which notice shall set forth the identity of the proposed assignee or subtenant, the reason(s) why Landlord's consent is not required, and the nature of the proposed assignee's or subtenant's business to be carried on in the Premises.

(b) Except as aforesaid, Tenant shall furnish Landlord (i) no less than thirty (30) days prior to the effective date of the assignment or subletting, with a current financial statement of the proposed assignee or subtenant reasonably acceptable to Landlord, and (ii) within three (3) days following Landlord's demand, with all other information reasonably requested by Landlord with respect to such assignee or subtenant.

Any assignment or subletting to which Landlord's consent is not required and with respect to which the provisions of this Article 16.B. are not complied with shall, at Landlord's option, be void.

C . Procedure. Except for Permitted Transfers, Landlord shall notify Tenant within thirty (30) days from the submission of the aforesaid information as to Landlord's choice, at Landlord's sole discretion, of the following options:

(1) That Landlord consents to a subleasing of the Premises or assignment of the Lease to such replacement tenant provided that Tenant shall remain fully liable for all of its obligations and liabilities under this Lease; or

(2) That upon such replacement tenant's entering into a mutually satisfactory new lease for the Premises with Landlord, then Tenant shall be released from all further obligations and liabilities under this Lease (excepting only any unpaid rentals or any unperformed covenants then past due under this Lease or any guarantee by

Tenant of replacement tenant's obligations); or

(3) That Landlord reasonably declines to consent to such sublease or assignment due to insufficient or unsatisfactory documentation furnished to Landlord to establish Tenant's reputation, financial strength and proposed use of and operations upon Premises; or

(4) That Landlord elects to cancel the Lease and recapture the Premises (in the case of an assignment) or (as to any proposed sublease that either covers all or substantially all of the Premises or covers any portion of the Premises for substantially all of the remaining Term) that Landlord elects to cancel the Lease as to the portion thereof that Tenant had wished to sublease, provided, however, that in either such case, Tenant shall have the right to withdraw its request for Landlord consent to the proposed assignment or sublease in question upon written notice to Landlord delivered within five (5) business days following Tenant's receipt of Landlord's recapture notice, in which case Landlord's recapture notice shall be void. In either such event, and provided that Tenant has not withdrawn its request for consent as provided above, Tenant shall surrender possession of the Premises, or the portion thereof which is the subject of Tenant's request on the date set forth in a notice from Landlord in accordance with the provisions of this Lease relating to the surrender of the Premises. If this Lease shall be canceled as to a portion of the Premises only, the Rent payable by Tenant hereunder shall be abated proportionately according to the ratio that the area of the portion of the Premises surrendered (as computed by Landlord) bears to the area of the Premises immediately prior to such surrender. If Landlord shall cancel this Lease, Landlord may re-let the Premises, or the applicable portion of the Premises, to any other party (including, without limitation, the proposed assignee or subtenant of Tenant), without any liability to Tenant.

D. Net Revenues.

(1) Sublease Revenues. Except in the case of a Permitted Transfer, in the event that Tenant subleases all or any portion of the Premises and the total of all amounts payable to Tenant for any month under any such sublease exceeds the total of all amounts payable to Landlord hereunder for such month for the same space, Tenant shall pay to Landlord one-half (½) of the "Net Revenue," which shall mean such excess actually received by Tenant, but only after Tenant has fully recovered from such excess payments all of Tenant's costs and expenses incurred in connection with such sublease, including without limitation brokerage commissions and legal fees and costs, advertising or marketing costs and the costs of any improvements or alterations (or allowances for improvements or alterations), and any such Net Revenue actually received by Tenant for any month shall be paid to Landlord within five (5) business days thereafter.

(2) Assignment Revenues. Except in the case of a Permitted Transfer, in the event that Tenant assigns this Lease with respect to all or any portion of the Premises (the "assigned premises"), Tenant shall pay to Landlord the Net Revenue actually received by Tenant in connection with such assignment.

E. Continuing Liability; Voidable Transfers. No assignment of this Lease (other than an assignment to Landlord resulting from Landlord's right of recapture), and no subletting of all or any portion of the Premises, shall release Tenant or any guarantor with respect to any post-transfer obligations, unless Landlord agrees otherwise in writing in its absolute discretion and any such assignment or sublease shall, at Landlord's option, be void in the event that Tenant and each such guarantor, if any, does not expressly acknowledge and affirm its continuing liability in form and substance reasonably satisfactory to Landlord. The continuing liability of the assigning Tenant shall be primary, and Landlord shall be entitled to exercise its rights and remedies against any such assignor with respect to any Tenant Default without exhausting its rights and remedies against any successor of such assignor. In the event that it is ever held, notwithstanding the contrary intention of the parties hereto, that any such assignor's continuing liability is that of a guarantor (rather than primary), Tenant hereby waives any and all suretyship rights and defenses to which it would otherwise be entitled in connection with such continuing liability. Notwithstanding the foregoing, in the event that, following any assignment (other than an assignment described in Article 16.B. above), Landlord and such assignee modify this Lease in such a way as to increase Tenant's total obligations hereunder, neither the assigning Tenant nor any guarantor whose guaranty pre-dated such assignment shall be liable for the incremental portion of Tenant's obligations corresponding to such increase. The acceptance of any assignment by an assignee shall automatically constitute the assumption by such assignee of all obligations of Tenant with respect to the assigned premises that accrue following the assignment; provided, however, that any assignment of this Lease shall, at Landlord's option, be void in the event that the assignee does not expressly acknowledge and affirm the effectiveness of the foregoing assumption in form and substance reasonably satisfactory to Landlord. Any assignment or subletting by Tenant to which Landlord's consent is required but not obtained shall, at Landlord's option, be void.

F . Other Provisions Applicable to Transfers . No assignment or subletting shall be deemed to modify any provision of this Lease, with respect to permitted or restricted uses of the Premises or otherwise, unless Landlord then agrees otherwise in writing in its absolute discretion. Tenant shall promptly furnish Landlord with a copy of each executed assignment or sublease, and with copies of any supplements or modifications thereto which may be executed from time to time.

G. [INTENTIONALLY OMITTED]

H . Transfers by Subtenants. The provisions of this Article 16 shall also apply to assignments and subleases by subtenants, sub-subtenants and so on.

I. Assignment of Options. Without limiting the generality of any provision of this Lease which states that any option or other right of Tenant is personal to the original Tenant hereunder or may only be assigned under certain conditions, no option or similar right of Tenant hereunder, including without limitation any option to extend or renew, option to expand, first offer or first refusal right, or first right to lease, may be assigned (except in event of a transfer contemplated by Article 16.B. herein), and any attempt to assign such right shall be null and void.

J. Encumbrance. Tenant shall not assign its interests hereunder as security for any obligation without Landlord's prior written consent, which may be withheld in Landlord's absolute discretion, and any such assignment without such consent shall, at Landlord's option, be void.

K . Transfer Fee. Whether or not Landlord consents to any such transfer, and except with respect to any assignment or sublease described in Article 16.B above, Tenant shall pay to Landlord Landlord's reasonable attorneys' fees incurred in connection with the proposed assignment or sublease.

L. Form of Sublease Consent. Any consent to a sublease by Landlord in accordance with the provisions of this Article 16 shall be provided in the form attached hereto as Exhibit C.

ARTICLE 17.

SUBORDINATION, NON-DISTURBANCE, ATTORNMENT AND MORTGAGEE PROTECTION; LEASE SUBJECT TO PROJECT DOCUMENTS

A . Subordination, Non-Disturbance, Attornment and Mortgagee Protection. This Lease is subject and subordinate to (i) the priority of the lien of any Mortgage now or hereafter placed upon the Building and (ii) all other encumbrances and matters now or hereafter of public record applicable to the Building, including without limitation, any reciprocal easement or operating agreements, ground or underlying leases, covenants, conditions and restrictions, and Tenant shall not act or permit the Premises to be operated in violation thereof (so long as the same do not impair or restrict the use of the Premises for the Permitted Uses contemplated by this Lease).. Landlord shall have the right to cause this Lease to be and become and remain subject and subordinate to any and all ground or underlying leases or Mortgages which may hereafter be executed covering the Premises, the Building or the property or any renewals, modifications, consolidations, replacements or extensions thereof, for the full amount of all advances made or to be made thereunder and without regard to the time or character of such advances, together with interest thereon and subject to all the terms and provisions thereof; provided, however, that as a condition to any such subordination with respect to the Mortgage encumbering the Building as of the date of this Lease, Landlord shall obtain from any Lender or other party in question a written undertaking in favor of Tenant to the effect that such Lender or other party will not disturb Tenant's right of possession or other rights under this Lease if no event of default then exists and otherwise substantially the form attached hereto as Exhibit G, which SNDA Tenant agrees, within ten (10) business days after Tenant's receipt of Landlord's written request therefor, to execute, acknowledge and deliver upon request. With respect to any future Mortgage, Landlord agrees to use commercially reasonable efforts to obtain an SNDA in favor of Tenant, provided, however, that same shall not be a condition to the effectiveness of the subordination of this Lease to such future Mortgage. To the extent not expressly prohibited by Law, Tenant waives the provisions of any Law now or hereafter adopted which may give or purport to give Tenant any right or election to terminate or otherwise adversely affect this Lease or Tenant's obligations hereunder if such foreclosure or power of sale proceedings are initiated, prosecuted or completed.

B. Lease Subject to Project Documents.

(1) This Lease, and Tenant's rights hereunder, are subject and subordinate to any all documents governing the maintenance, operation and use of the Project or the Building, including, without limitation, (i) the Declaration (as defined in Article 29.C.), and any rules or regulations promulgated by or on behalf of the "Developer" or "FPOC" under the Declaration, whether recorded or unrecorded, (ii) Chapter 91 License No. 11904 issued by the Massachusetts Department of Environmental Protection ("DEP") for the Building, recorded with the Suffolk Registry of Deed in Book 42568, Page 73, and Chapter 91 License No. 11907 issued by DEP for all of the public realm areas of the Project, recorded with the Suffolk Registry of Deed in Book 42568, Page 89; (iii) Development Plan for the Fan Pier Development, Planned Development Area #54 approved by the Boston Redevelopment Authority ("BRA") on November 14, 2001, and adopted by the Boston Zoning Commission on February 27, 2002, effective February 28, 2001, as amended by First Amendment to the Development Plan for the Fan Pier Development, Planned Development Area #54 approved by the Boston Redevelopment Authority on December 20, 2007, and adopted by the Boston Zoning Commission on January 30, 2008, effective January 30, 2008, and all agreements with the BRA or the City of Boston relating to the Building or the Project (collectively, and as may be amended or supplemented from time to time, the "Project Documents," and each individually a "Project Document").

(2) [Intentionally Omitted]

(3) [Intentionally Omitted]

(4) The parties acknowledge and agree that all maintenance, repair, replacement, operation and administration of the "Common Areas and Facilities" (as defined in the Project Documents) are under the control of the Developer or FPOC. Further the Developer's or FPOC's election to provide mechanical surveillance or to post security personnel in the Common Areas and Facilities is subject to the Developer's or FPOC's sole discretion. Therefore, and notwithstanding anything to the contrary contained in this Lease, Landlord's sole responsibility with respect to the maintenance, repair, replacement, operation, administration or the provision of surveillance or security in the Common Areas and Facilities, shall be to use commercially reasonable efforts to enforce the obligations of the Developer or FPOC under the Declaration. Tenant hereby releases Landlord from any claim concerning the failure by Developer or FPOC to maintain any portion of the Common Areas and Facilities, other than a failure of Landlord to use commercially reasonable efforts to enforce the Developer or FPOC's obligations under the Project Documents.

ARTICLE 18.

ESTOPPEL CERTIFICATE

Either party shall from time to time, upon written request by the other, execute, acknowledge and deliver to the requesting party (or the lender of the requesting party, as the case may be), within ten (10) business days after receipt of such request, a statement in writing certifying, without limitation: (i) that this Lease is unmodified and in full force and effect (or if there have been modifications, identifying such modifications and certifying that the Lease, as modified, is in full force and effect); (ii) the dates to which Rent and any other charges have been paid; (iii) that to the best knowledge of Tenant, the requesting party is not in default under any provision of this Lease (or if the requesting party is in default, specifying each such default) and that no events or conditions exist which, with the passage of time or notice or both, would constitute a default on the part of the requesting party hereunder; (iv) the address to which notices to the non-requesting party shall be sent; (v) the amount of Tenant's security deposit; and (vi) such other factual matters as the requesting party may reasonably request; it being understood that any such statement so delivered may be relied upon in connection with any lease, mortgage or transfer. No such certificate shall have the effect of amending this Lease, and in the event of any conflict between the terms of this Lease and any such certificate, this Lease shall control.

ARTICLE 19.

DEFAULTS

A . Tenant Defaults: The occurrence of any of the following shall constitute a "default" or "event of default" by Tenant hereunder:

(a) Tenant fails to pay when due any installment or other payment of Rent or any other amount owing to Landlord, and such failure continues for five (5) business days after notice thereof given by or on behalf of Landlord provided, however, that notice relating to Tenant's failure to pay Monthly Base Rent shall only be required two (2) times per any twelve (12) month period and thereafter (during the remainder of such 12-month period) no notice shall be required in connection therewith prior to the same constituting a default; or

(b) Tenant fails to keep in effect any insurance required to be maintained hereunder, and such failure continues for thirty (30) days after notice thereof given by or on behalf of Landlord; or

(c) Tenant or any guarantor hereunder becomes insolvent, makes an assignment for the benefit of creditors, files a voluntary petition in bankruptcy or an involuntary petition in bankruptcy is filed against Tenant which petition is not dismissed within sixty (60) days of its filing; or

(d) Tenant fails to cause to be released any mechanic's liens filed against the Premises, the Building or the Project or any portion thereof within twenty (20) days after the date the same shall have been filed or recorded; or

(e) Tenant fails to observe or perform according to the provisions of Article 17 or 18 within the time periods specified in such Articles; or

(f) A receiver is appointed for Tenant's business or assets and the appointment of such receiver is not vacated within sixty (60) days after such appointment; or

(g) Tenant fails to perform or observe any of the other covenants, conditions or agreements contained herein on Tenant's part to be kept or performed or breaches a representation made hereunder, and such failure shall continue for thirty (30) days after notice thereof from Landlord, or if such default is curable but cure cannot reasonably be effected within such thirty (30) day period, such default shall not be a default hereunder so long as Tenant promptly commences cure within ten (10) days after receipt of such notice and thereafter diligently prosecutes such cure to completion; or

(h) Except for assignments or subleases under Article 16, if the interest of Tenant or any guarantor hereunder shall be offered for sale or sold under execution or other legal process if Tenant makes any transfer, assignment, conveyance, sale, pledge, disposition of all or a substantial portion of Tenant's property.

All notices required to be given under this Article 19.A. shall be in lieu of, and not in addition to any notice requirements imposed by Law now or hereafter in effect.

If Tenant or any guarantor hereunder files a voluntary petition pursuant to the United States Bankruptcy Reform Act of 1978, as the same may be from time to time be amended (the "Bankruptcy Code"), or take the benefit of any insolvency act or be dissolved, or if an involuntary petition or proceeding for dissolution or liquidation is filed against Tenant pursuant to the Bankruptcy Code and said petition is not dismissed within sixty (60) days after such filing, or if a proceeding for the appointment of a trustee or a receiver is commenced for Tenant's business or all or a portion of its assets and the appointment of such receiver is not vacated within sixty (60) days after such appointment, or if it shall make an assignment for the benefit of its creditors, then Landlord shall have all of the rights provided for in the event of nonpayment of the Rent. Tenant hereby stipulates to the lifting of the automatic stay in effect and relief from such stay in the event Tenant files a petition under the Bankruptcy Code, for the purpose of Landlord pursuing its rights and remedies against Tenant and/or a guarantor under this Lease.

If any alleged default on the part of the Landlord hereunder occurs, Tenant shall give written notice to Landlord in the manner herein set forth and shall afford Landlord a reasonable opportunity to cure any such default. In addition, Tenant shall send notice of such default by certified or registered mail, postage prepaid, to the holder of any Mortgage whose address Tenant has been provided in writing, and shall afford such Mortgage holder a reasonable opportunity to cure any alleged default on Landlord's behalf.

Any notice from Landlord to Tenant that claims or alleges a breach or default under this Lease shall state in prominent bold-face type "THIS IS A NOTICE OF DEFAULT UNDER A LEASE OF REAL PROPERTY, AND IMMEDIATE ACTION IS REQUIRED."

ARTICLE 20.

REMEDIES

A. Landlord Remedies. The remedies provided Landlord under this Lease are cumulative. Upon the occurrence of any default by Tenant, and in addition to any and all other rights provided a landlord under law or equity for breach of a lease or tenancy by a tenant, Landlord shall have the right to pursue one or more of the following remedies:

(a) Landlord may serve notice on Tenant that the Term and the estate hereby vested in Tenant and any and all other rights of Tenant hereunder shall cease on the date specified in such notice and on the specified date this Lease shall cease and expire as fully and with the effect as if the Term had expired for passage of time.

(b) Without terminating this Lease in case of a default or if this Lease shall be terminated for default as provided herein, Landlord may re-enter the Premises, remove Tenant, or cause Tenant to be removed from the Premises in such manner as Landlord may deem advisable, with legal process. In the event of re-entry without terminating this Lease, Tenant shall continue to be liable for all Rents and other charges accruing or coming due under this Lease which Rent shall automatically accelerate and become immediately due and payable.

(c) If Landlord, without terminating this Lease, shall re-enter the Premises or if this Lease shall be terminated as provided in Article 20.A.(a) above, then, in either such event:

(i) All Rent due from Tenant to Landlord shall thereupon become due and shall be paid up to the time of re-entry, dispossession or expiration, together with reasonable costs and expenses (including, without limitation, attorneys' fees) of Landlord and without benefit of valuation and appraisement laws which Tenant hereby waives;

(ii) Notwithstanding the foregoing, Landlord shall use commercially reasonable efforts to re-let the Premises after Tenant vacates the Premises after this Lease is terminated on account of a default by Tenant as further provided in Article 20.C. below.

(iii) If Landlord shall have terminated this Lease, Tenant shall also be liable to Landlord for all damages provided for at law and under this Lease resulting from Tenant's breach, including, without limitation, a lump sum equal to the then net present value of the excess (if any) of the aggregate Rents reserved under the terms of this Lease for the balance of the Term together with all other sums payable hereunder as Rent for the balance of the Term, over the fair rental value of the Premises for that period determined as of the date of such termination. For purposes of this Article 20.A.(c)(iii), Tenant shall be deemed to include any guarantor or surety of the Lease.

(d) Landlord may continue this Lease in effect after Tenant's breach and abandonment and recover Rent as it becomes due, if Tenant has the right to sublet or assign, subject only to reasonable limitations.

(e) Whether or not Landlord terminates this Lease, Landlord shall have the right, as Landlord chooses in its absolute discretion, (i) to terminate any or all subleases, licenses, concessions and other agreements entered into by Tenant in connection with its occupancy of the Premises and/or (ii) to maintain any or all such agreements in effect and succeed to Tenant's interests in connection

therewith (in which event Tenant shall cease to have any interest in any such agreement).

(f) Attorneys' Fees.

(i) In any action to enforce the terms of this Lease, including any suit by Landlord for the recovery of Rent or possession of the Premises, the losing party shall reimburse the successful party for its reasonable attorneys' fees incurred in such suit and such attorneys' fees shall be deemed to have accrued prior to the commencement of such action and shall be paid whether or not such action is prosecuted to judgment.

(ii) Should Landlord, without fault on Landlord's part, be made a party to any litigation instituted by Tenant or by any third party against Tenant, or by or against any person holding under or using the Premises by license of Tenant, or for the foreclosure of any lien for labor or material furnished to or for Tenant or any such other person or otherwise arising out of or resulting from any act or transaction of Tenant or of any such other person, Tenant covenants to save and hold Landlord harmless from and against any judgment rendered against Landlord or the Premises or any part thereof and from and against all actual and reasonable costs and expenses, including reasonable attorneys' fees, incurred by Landlord in connection with such litigation.

(iii) When legal services are rendered by an attorney at law who is an employee of a party, attorneys' fees incurred by that party shall be deemed to include an amount based upon the number of hours spent by such employee on such matters multiplied by an appropriate billing rate determined by taking into consideration the same factors, including but not limited by, the importance of the matter, time applied, difficulty and results, as are considered when an attorney not in the employ of a party is engaged to render such service.

(g) In addition to the above, Landlord shall have any and all other rights provided a landlord at law or in equity, including, but not limited to, those remedies provided for by Laws now or hereafter in effect, for breach of a lease or tenancy by a tenant.

(h) TO THE EXTENT PERMITTED BY LAW, EACH OF LANDLORD AND TENANT HEREBY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY CLAIM, ACTION PROCEEDING OR COUNTERCLAIM BY EITHER LANDLORD OR TENANT AGAINST THE OTHER OR ANY MATTER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, AND/OR TENANT'S USE OR OCCUPANCY OR THE PREMISES.

B . Tenant Remedies. Upon the occurrence of any default by Landlord, Tenant shall, except as otherwise expressly provided herein, have all rights and remedies provided hereunder and by law from time to time; provided, however, that Tenant shall in no event have the right to terminate this Lease except as expressly provided herein or as provided by law.

C . Mitigation of Damages. Landlord and Tenant will each exercise commercially reasonable efforts to mitigate the damages caused by the other party's breach of this Lease. Efforts to mitigate damages will not be construed as a waiver of the non-breaching party's right to recover damages. For the purposes of this Article 20.C., marketing of the Premises in a manner similar to the way Landlord markets its other premises shall be deemed to satisfy Landlord's obligation to use such "commercially reasonable efforts." In no event shall Landlord be required (i) to solicit or entertain negotiations with any other prospective tenants for the Premises until Landlord obtains full and complete possession of the Premises including, without limitation, the undisputed right to re-let the Premises free of any claim of Tenant, (ii) to lease the Premises to a tenant whose proposed use, in Landlord's bona fide judgment, would violate any restrictions by which Landlord is bound, (iii) to re-let the Premises before leasing other comparable vacant space in the Building (unless the prospective tenant is directly obtained and presented to Landlord as a result of Tenant's marketing efforts and otherwise satisfies all other requirements of prospective tenants contained in this Lease), (iv) to lease the Premises for a rental less than the current fair market rental then prevailing for similar office space in the Building, or (v) to enter into a lease with any proposed tenant that does not have, in Landlord's reasonable opinion, sufficient financial resources to satisfy a typical office tenant's obligations under an office lease. In no event, however, shall Tenant's liability hereunder be diminished or reduced if or to the extent such reasonable efforts of Landlord to re-let are not successful.

ARTICLE 21.

QUIET ENJOYMENT

Landlord covenants and agrees with Tenant that so long as there exists no uncured default (i.e. beyond notice and cure periods) by Tenant, Tenant may peaceably and quietly enjoy the Premises subject, nevertheless, to the terms and conditions of this Lease, and Tenant's possession will not be disturbed by anyone claiming by, through, or under Landlord.

ARTICLE 22.

ACCORD AND SATISFACTION

No payment by Tenant or receipt by Landlord of an amount less than full payment of Rent then due and payable shall be deemed to be other than on account of Rent then due and payable, nor shall any endorsement or statement on any check or any letter

accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy provided for in this Lease or available at law or in equity. No payment by Landlord or receipt by Tenant of an amount less than the full amount then due and payable shall be deemed to be other than on account of the amount then due and payable, nor shall any endorsement or statement on any check or any letter accompanying any check or payment be deemed an accord and satisfaction, and Tenant may accept such check or payment without prejudice to Tenant's right to recover the balance of such amount.

ARTICLE 23.

SECURITY DEPOSIT

To secure the full and faithful performance by Tenant of all of the covenants, conditions and agreements set forth in this Lease to be performed by it, including, without limitation, the foregoing such covenants, conditions and agreements in this Lease which become applicable upon its termination by re-entry or otherwise, Tenant has deposited with Landlord the sum shown in Article 1 as a "Security Deposit." The Security Deposit shall be subject to the following terms and conditions:

(a) The Security Deposit or any portion thereof may be applied to the curing of any default that may exist and continue beyond the expiration of applicable notice and cure periods, including but not limited to a breach for failure to pay Rent, without prejudice to any other remedy or remedies which Landlord may have on account thereof, and upon such application Tenant shall pay Landlord on demand the amount so applied which shall be added to the Security Deposit so the same will be restored to its original amount.

(b) Should the Premises be conveyed by Landlord, the Security Deposit or any balance thereof shall be turned over to the Landlord's grantee, and when the Security Deposit is actually turned over to such grantee, Tenant hereby releases Landlord from any and all liability with respect to the Security Deposit and its application or return, and Tenant agrees to look solely to such grantee for such application or return.

(c) Unless the Security Deposit is in the form of a Letter of Credit, Landlord may commingle the Security Deposit with other funds, shall not be required to keep the Security Deposit in trust, and shall not be obligated to pay Tenant any interest.

(d) The Security Deposit shall not be considered an advance payment of Rent or a measure of damages for any default by Tenant, nor shall it be a bar or defense to any actions by Landlord against Tenant.

(e) If Tenant shall faithfully perform all of the covenants and agreements contained in this Lease on the part of the Tenant to be performed, and provided there exists no default by Tenant hereunder, the Security Deposit or any then remaining balance thereof, shall be returned to Tenant, without interest, within thirty (30) days after the expiration of the Term, provided that subsequent to the expiration of this Lease, Landlord may retain from the Security Deposit (i) an amount reasonably estimated by Landlord to cover potential Operating Expense reconciliation payments due with respect to the calendar year in which this Lease terminates or expires (such amount so retained shall not, in any event, exceed five percent (5%) of estimated Operating Expense payments due from Tenant for such calendar year through the date of expiration or earlier termination of this Lease and any amounts so retained and not applied to such reconciliation shall be returned to Tenant no later than ninety (90) days after the end of the calendar year in which such termination or expiration occurs (or if sooner, the date on which Landlord delivers such reconciliation), and (ii) any and all amounts permitted by law or this Article 23 (collectively hereinafter referred to as the "Contingent Amount"). In the event Tenant has posted a Letter of Credit (as hereinafter defined) instead of cash, Tenant, at its option, may substitute cash at the expiration of the Term in an amount sufficient to satisfy the Contingent Amount, which amount shall be determined by Landlord, in its reasonable discretion as provided above.

Tenant hereby waives any and all provisions of Laws that limit the types of defaults for which a landlord may claim sums from a security deposit, it being agreed that Landlord, in addition, may claim those sums specified in this Article 23 above and/or those sums reasonably necessary to compensate Landlord for any other loss or damage, foreseeable or unforeseeable, caused by a default by Tenant under this Lease. Tenant further covenants that it will not assign or encumber the money deposited herein as a Security Deposit and that neither Landlord nor its successors or assigns shall be bound by any such assignment, encumbrance, attempted assignment or attempted encumbrance.

(f) The Security Deposit shall be in the form of a letter of credit, which Tenant shall deliver to Landlord (as beneficiary), and a copy to Landlord's attorney, a standby letter of credit ("Letter of Credit"), in form and content reasonably satisfactory to Landlord, simultaneously with Tenant's execution and delivery of this Lease to Landlord. The Letter of Credit shall be, among other things:

(1) subject to International Standby Practices 1998, International Chamber of Commerce Publication No. 590;

(2) irrevocable and unconditional, subject to (1) above;

(3) in the amount of the required Security Deposit;

(4) conditioned for payment solely upon presentation of the Letter of Credit and a sight draft certifying to the issuer of the Letter of Credit the existence of such grounds or circumstances upon which Landlord is permitted to make such draw, and

(5) transferable one or more times by Landlord without the consent of Tenant.

Tenant acknowledges and agrees that it shall pay upon Landlord's demand, as Additional Rent, any and all costs or fees charged in connection with the Letter of Credit that arise due to: (i) Landlord's sale or transfer of all or a portion of the Property on one (1) occasion only, or (ii) the addition, deletion, or modification of any beneficiaries under the Letter of Credit. The Letter of Credit shall be issued by a member of the New York Clearing House Association or a commercial bank or trust company satisfactory to Landlord, having banking offices at which the Letter of Credit may be drawn upon in Boston, Massachusetts or Hartford, Connecticut and a net worth reasonably acceptable to Landlord. Landlord hereby approves TD Bank as an issuing bank. The Letter of Credit shall expire not earlier than twelve (12) months after the date of delivery thereof to Landlord and shall provide that same shall be automatically renewed for successive twelve (12) month periods through a date which is not earlier than sixty (60) days after the expiration date, or any renewal or extension thereof, unless written notice of non-renewal has been given by the issuing bank to Landlord by registered or certified mail, return receipt requested (or by reputable overnight delivery), not less than sixty (60) days prior to the expiration of the current period. If the issuing bank does not renew the Letter of Credit, and if Tenant does not deliver a substitute Letter of Credit or cash in lieu thereof at least thirty (30) days prior to the expiration of the current period, then Landlord shall have the right to draw on the existing Letter of Credit and maintain such funds as a cash security deposit. With respect to draws on the Letter of Credit:

(x) Landlord may use, apply, or retain the proceeds of the Letter of Credit to the same extent that Landlord may use, apply, or retain the cash Security Deposit, as set forth above in this Article 23 or elsewhere in this Lease;

(y) Landlord may draw on the Letter of Credit, in whole or in part, from time to time, at Landlord's election, to the same extent that Landlord may draw on the cash Security Deposit, as set forth above in this Article 23 or elsewhere in this Lease; and

(z) If Landlord partially draws down the Letter of Credit, Tenant shall within ten (10) days after Landlord gives Tenant notice thereof, restore all amounts drawn by Landlord, or substitute cash security instead.

Notwithstanding any of the foregoing to the contrary, provided that, at each such time, there then exists no default of Tenant and this Lease is then in full force and effect, then Tenant shall be entitled to reduce the face amount of a cash Security Deposit (or the Letter of Credit, as the case may be) to: (i) $525,967.76 on the fourth (4th) anniversary of the Rent Commencement Date, and (ii) $394,475.82 on the fifth (5th) anniversary of the Rent Commencement Date, and Landlord shall accept a substitute Letter of Credit for such reduced amounts or an endorsement to the existing Letter of Credit. Tenant hereby agrees to cooperate, at its expense with Landlord to promptly execute and deliver to Landlord any and all modifications, amendments and replacements of the Letter of Credit, as Landlord may reasonably request to carry out the terms and conditions of this Article 23.

In the event the issuer of any Letter of Credit held by Landlord hereunder is insolvent or is placed into receivership or conservatorship by the Federal Deposit Insurance Corporation, or any successor or similar entity, or if a trustee, receiver or liquidator is appointed for the issuer, or if Landlord is unable to effectuate a transfer of the Letter of Credit with the issuer of such letter of credit, then, effective as of the date of such occurrence, said Letter of Credit shall be deemed to not meet the requirements of this Article 23 and Tenant shall, within five (5) business days after receipt of written notice from Landlord, deliver to Landlord a replacement Letter of Credit which otherwise meets the requirements of this Article 23 (and Tenant's failure to do so shall, notwithstanding anything in this Lease to the contrary, constitute an event of default for which there shall be no notice or grace or cure periods being applicable thereto other than the aforesaid five-day period); or, alternatively, Tenant shall, within such five (5)-day period deliver cash to Landlord in the amount required by this Article 23.

ARTICLE 24.

BROKERAGE COMMISSION

Landlord and Tenant represent and warrant to each other that neither has dealt with any broker, finder or agent except for the Broker(s) identified in Article 1. Tenant represents and warrants to Landlord that (except with respect to the Broker(s) identified in Article 1 and with whom Landlord has entered into a separate brokerage agreement) no broker, agent, commission salesperson, or other person has represented Tenant in the negotiations for and procurement of this Lease and of the Premises and that no commissions, fees, or compensation of any kind are due and payable in connection herewith to any broker, agent commission salesperson, or other person. Tenant agrees to indemnify and hold harmless Landlord from and against any and all loss, liabilities, claims, suits, or judgments (including, without limitation, reasonable attorneys' fees and court costs incurred in connection with any such claims, suits, or judgments, or in connection with the enforcement of this indemnity) for any fees, commissions, or compensation of any kind which

arise out of or are in any way connected with any claimed agency relationship not referenced in Article 1. Landlord agrees to indemnify and hold harmless Tenant from and against any and all loss, liabilities, claims, suits, or judgments (including, without limitation, reasonable attorneys' fees and court costs incurred in connection with any such claims, suits, or judgments, or in connection with the enforcement of this indemnity) for any fees, commissions, or compensation of any kind which arise out of or are in any way connected with any claimed agency relationship with Landlord.

ARTICLE 25.

FORCE MAJEURE

Landlord shall be excused for the period of any delay in the performance of any obligation hereunder, except for any delay in the payment of money or any delay in the cure of any default which may be cured by the payment of money, when prevented from so doing by a cause or causes beyond its control, including all labor disputes, civil commotion, war, war-like operations, invasion, rebellion, hostilities, military or usurped power, sabotage, governmental regulations or controls, fire or other casualty, inability to obtain any material, services or financing, or through acts of God (collectively, "Force Majeure"). Tenant shall similarly be excused for delay in the performance of any obligation hereunder; provided:

(a) nothing contained in this Article 25 or elsewhere in this Lease shall be deemed to excuse or permit any delay in the payment of Rent, or any delay in the cure of any default which may be cured by the payment of money; and

(b) no reliance by Tenant upon this Article 25 shall limit or restrict in any way Landlord's right of self-help as provided in this Lease.

ARTICLE 26.

PARKING

(a) Tenant shall be entitled to obtain, and pay for, contracts with the Parking Garage operator for the number of parking access devices set forth in Article 1 permitted use of such number of unreserved parking spaces in the Parking Garage, in areas, if any, as may be designated by Landlord or the Parking Garage operator for occupants of the Building, notwithstanding the number of Tenant's employees, customers or invitees. The parking contracts shall be for unassigned spaces and the monthly rate to be paid by Tenant and its employees shall be the prevailing monthly parking rate charged by the Parking Garage operator, which parking rate may change at any time and from time to time, as determined by such Parking Garage operator. In the event Tenant fails to make any payment of the monthly parking charge within thirty (30) days after receipt of notice from Landlord that the same was not paid when due, then Landlord may revoke those parking contracts as to which payment was not made, and Landlord shall be under no obligation to obtain replacement parking contracts. Tenant shall be responsible for the full amount of any taxes imposed by any governmental authority in connection with the use of the Parking Garage by Tenant. Failure to pay any monthly parking charge shall in no event be grounds for any claim of a default by Tenant under this Lease.

(b) If requested by Landlord, Tenant shall notify Landlord of the license plate number, year, make and model of the automobiles entitled to use the Parking Garage under such contracts and if requested by Landlord, such automobiles shall be identified by electronic or other identification devices provided by Landlord or the Parking Garage operator, and only such designated automobiles shall be permitted to use access control devices provided to monthly contract holders in the Parking Garage. The Parking Garage will be operated in whole or in part as a public parking garage, and at Landlord's sole election, Landlord may make validation stickers available to Tenant for the use of public parking spaces, provided, however, if Landlord makes validation stickers available to any other office tenant in the Building, Landlord shall make such validation stickers available to Tenant. If Landlord has instituted a vehicle identification system or other parking procedure and Tenant's employees, customers or invitees do not comply with any such procedure, then in any of such events, Landlord shall be entitled to, without any liability to Tenant, its employees, customers or invitees, remove any vehicles not complying with Landlord's procedures. Tenant acknowledges and agrees that Landlord may, without incurring any liability to Tenant and without any abatement of Rent under this Lease, from time to time, close-off or restrict access to the Parking Garage for purposes of permitting or facilitating construction, alteration or improvement. Landlord may delegate its responsibilities hereunder to a parking operator or a lessee of the Parking Garage in which case such parking operator or lessee shall have all the rights of control attributed hereby to the Landlord.

(c) Tenant may not assign, transfer, sublease or otherwise alienate its right to use of the Parking Garage, except in connection with a sublease of the Premises or an assignment of this Lease, without Landlord's prior written consent. Tenant's continued right to use the Parking Garage is conditioned upon Tenant abiding by the terms of any parking contracts, and all rules and regulations which are prescribed from time to time for the orderly operation and use of the Parking Garage, Tenant's cooperation in seeing that Tenant's employees and visitors also comply with such rules and regulations, and Tenant not being in default under this Lease.

(d) Tenant acknowledges that the Parking Garage is subject to the provisions of the South Boston Parking Freeze Regulations and to one or more Parking Freeze Permits issued thereunder by the City of Boston Air Pollution Control Commission, which regulations and permits require that twenty percent (20%) of the total parking supply in the Parking Garage be set aside for Off-Peak

use, and not be available weekdays between 7:30 a.m. and 9:30 a.m. Tenant acknowledges that the administration of such requirement may from time to time limit the ability of certain of the monthly parkers to enter the Parking Garage between 7:30 a.m. and 9:30 a.m.

ARTICLE 27.

HAZARDOUS MATERIALS

A . Definition of Hazardous Materials. The term "Hazardous Materials" for purposes hereof shall mean any chemical, substance, materials or waste or component thereof which is at the time in question listed, defined or regulated as a hazardous or toxic chemical, substance, materials or waste or component thereof by any federal, state or local governing or regulatory body having jurisdiction, or which would trigger any employee or community "right-to-know" requirements adopted by any such body, or for which any such body has adopted any requirements for the preparation or distribution of a materials safety data sheet ("MSDS"). The term "Hazardous Material" includes, without limitation, any material, waste or substance which is (i) included within the definitions of "hazardous substances," "hazardous materials," "toxic substances" or "solid waste" in or pursuant to any environmental Law, or subject to regulation under any environmental Law, (ii) listed in the United States Department of Transportation Optional Hazardous Material Table, 49 C.F.R. § 172.101, as to date or hereafter amended, or in the United States Environmental Protection Agency List of Hazardous Substances and Reportable Quantities, 40 C.F.R. Part 302, as to date or hereafter amended, (iii) an explosive, radioactive, asbestos, polychlorinated biphenyl, oil or petroleum product, (iv) designated as a "Hazardous Substance" pursuant to Section 311 of the Federal Water Pollution Control Act (33 U.S.C. § 1317), (v) defined as a "Hazardous Waste" pursuant to Section 1004 of the Federal Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq. (42 U.S.C. § 6903), (vi) defined as a "Hazardous Substance" pursuant to Section 101 of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601 et seq. (42 U.S.C. § 9601), or (vii) any substance deemed to be a "Hazardous Material" by any present or future federal, state or local Law, statute, regulation ordinance, or any judicial or administrative order or judgment thereunder, because it effects the health, industrial hygiene or the environmental or ecological conditions on, under or about the Premises or the Building.

B. No Hazardous Materials. Tenant shall not transport, use, store, maintain, generate, manufacture, handle, dispose, release or discharge any Hazardous Materials. However, the foregoing provisions shall not prohibit the transportation to and from, and use, storage, maintenance and handling within the Premises of Hazardous Materials customarily used in the business or activity expressly permitted to be undertaken in the Premises under Article 6, provided: (a) such Hazardous Materials shall be used and maintained only in such quantities as are reasonably necessary for the Permitted Use of the Premises and the ordinary course of Tenant's business therein, in accordance with applicable Law; (b) such Hazardous Materials shall not be disposed of, released or discharged in the Building, and shall be transported to and from the Premises in compliance with all applicable Laws, and as Landlord shall reasonably require; (c) if any applicable Law or Landlord's trash removal contractor requires that any such Hazardous Materials be disposed of separately from ordinary trash, Tenant shall make arrangements, at Tenant's expense, for such disposal directly with a qualified and licensed disposal company at a lawful disposal site (subject to scheduling and approval by Landlord); and (d) any remaining such Hazardous Materials shall be completely, properly and lawfully removed from the Building upon expiration or earlier termination of this Lease. Any clean up, remediation and removal work shall be subject to Landlord's prior written approval (except in emergencies), and shall include, without limitation, any testing, investigation, and the preparation and implementation of any remedial action plan required by any governmental body having jurisdiction or reasonably required by Landlord. If Landlord or any Lender or governmental body arranges for any tests or studies showing that this Article 27 has been violated by Tenant, Tenant shall pay for the costs of such tests.

C . Notices To Landlord. Tenant shall promptly notify Landlord of: (i) any enforcement, cleanup or other regulatory action taken or threatened in writing by any governmental or regulatory authority against Tenant with respect to the presence of any Hazardous Materials on the Premises or the migration thereof from the Premises to other property; (ii) any demands or claims made or threatened in writing by any party against Tenant relating to any loss or injury resulting from any Hazardous Materials on the Premises; (iii) any release, discharge or non-routine, improper or unlawful disposal or transportation of any Hazardous Materials on or from the Premises or in violation of this Article 27 of which Tenant obtains knowledge; and (iv) any matters where Tenant is required by Law to give a notice to any governmental or regulatory authority respecting any Hazardous Materials on the Premises. Landlord shall have the right (but not the obligation) to join and participate, at its expense, as a party, in any legal proceedings or actions affecting the Premises initiated in connection with any environmental, health or safety Law. At such times as Landlord may reasonably request, if Tenant is using the Premises for other than business or professional offices, Tenant shall provide Landlord with a written list, certified to be true and complete, identifying any Hazardous Materials then used, stored or maintained upon the Premises, the use and approximate quantity of each such material, a copy of any MSDS issued by the manufacturer therefor and such other information as Landlord may reasonably require or as may be required by Law. The foregoing requirement shall not apply to certain Hazardous Materials customarily found in offices in first-class office buildings in the Boston market and otherwise permitted by applicable Law, such as, by way of example and not limitation, toner for copiers, ink for printers and customary cleaning products.

D. Indemnification. If any Hazardous Materials are released, discharged or disposed of by Tenant or any other occupant of the Premises, or their employees, agents, invitees or contractors, on or about the Building in violation of the foregoing provisions, Tenant shall immediately, properly and in compliance with applicable Laws clean up, remediate and remove the Hazardous Materials from the Building and any other affected property and clean or replace any affected personal property (whether or not owned by Landlord), at Tenant's expense (without limiting Landlord's other remedies therefor). Tenant shall further be required to indemnify, hold harmless

and defend (by counsel reasonably acceptable to Landlord) Landlord, and it attorneys and agents from and against any and all claims, demands, liabilities, losses, damages, penalties, forfeitures, judgments or expenses (including attorneys' fees) or death or injury to any person or damage to any property whatsoever, arising directly or indirectly arising out of or attributable to: (i) a violation of the provisions of this Article 27 by Tenant, Tenant's occupants, employees, contractors or agents; (ii) the presence in, on, under or about the Premises or discharge in or from the Premises of any Hazardous Materials placed in, under or about the Premises by Tenant or at Tenant's direction, excluding any tenant improvement work done by Landlord; (iii) Tenant's use, analysis, storage, transportation, disposal, release, threatened release, discharge or generation of Hazardous Materials to, in, on, under, about or from the Premises; or (iv) Tenant's failure to comply with any Hazardous Materials Law applicable hereunder to Tenant. Any clean up, remediation and removal work shall be subject to Landlord's prior written approval (except in emergencies), and shall include, without limitation, any testing, investigation, and the preparation and implementation of any remedial action plan required by any governmental body having jurisdiction or reasonably required by Landlord. Notwithstanding any provision of this Lease to the contrary, Tenant shall in no event have any liability (by way of indemnification or otherwise) for removal or remediation of any Hazardous Materials from the Premises or the Property to the extent that such Hazardous Materials (A) existed in, on or under the Premises or the Property, as the case may be, on the Commencement Date, or (B) were placed or released in, on or under the Premises other than by the act or omission of Tenant or its agents, employees, or contractors or anyone claiming by, through or under Tenant.

Landlord represents and warrants to Tenant that, as of the Commencement Date, the Premises will be free of unlawful levels or concentrations of any Hazardous Materials. Landlord will indemnify, defend (by counsel reasonably acceptable to Tenant), protect, and hold Tenant and each of Tenant's employees, agents, attorneys, successors and assigns, free and harmless from and against any and all claims, liabilities, penalties, forfeitures, losses or expenses (including attorney's fees) or death of or injury to any person or damage to any property whatsoever, arising from or caused in whole or in part, directly or indirectly, by:

(a) the presence in, on, under or about the Premises or the Building or discharge in or from the Premises or the Building of any Hazardous Materials placed, in, on, under or about the Premises or the Building by Landlord or at Landlord's direction; or

(b) Landlord's use, analysis, storage, transportation, disposal, release, threatened release, discharge or generation of Hazardous Materials to, in, on, under, about or from the Premises or the Building; or

(c) Landlord's failure to comply with any Hazardous Materials Law.

The obligations of each party pursuant to this Article 27 include, without limitation, and whether foreseeable or unforeseeable, all costs of any required or necessary repair, cleanup or detoxification or decontamination of the Premises or the Building, and the preparation and implementation of any closure, remedial action or other required plans in connection therewith, and survives the expiration or earlier termination of the term of the Lease.

ARTICLE 28.

ADDITIONAL RIGHTS RESERVED BY LANDLORD

In addition to any other rights provided for herein, Landlord reserves the following rights, exercisable without liability to Tenant for damage or injury to property, person or business and without effecting an eviction, constructive or actual, or disturbance of Tenant's use or possession or giving rise to any claim:

(a) To name the Building and to change the name or street address of the Building;

(b) To install and maintain all signs and exterior lighting on the exterior and interior of the Building and Project;

(c) To designate all sources furnishing sign painting or lettering for use in the Building;

(d) [Intentionally Omitted];

(e) To have pass keys to the Premises and all doors therein, excluding Tenant's vaults and safes;

(f) On reasonable prior notice to Tenant, and at reasonable times, to exhibit the Premises to any prospective purchaser, Lender, mortgagee, or assignee of any mortgage on the Building or the land on which the Building is located and to others having an interest therein at any time during the Term, and to prospective tenants during the last twelve (12) months of the Term;

(g) To take any and all measures, including entering the Premises for the purpose of making inspections, repairs, alterations, additions and improvements to the Premises or to the Building (including for the purpose of checking, calibrating, adjusting and balancing controls and other parts of the Building Systems), as may be necessary or desirable for the operation, improvement, safety, protection or preservation of the Premises, the Building or the Project including, but not limited to, the temporary closure of roads or sidewalks, or in order to comply with all Laws, or as may otherwise be permitted or required by this Lease; provided, however, that during the progress of any work on the Premises or at the Building, Landlord will attempt not to inconvenience Tenant, but shall not be

liable for inconvenience, annoyance, disturbance, loss of business, or other damage to Tenant by reason of performing any work or by bringing materials, supplies, tools or equipment in the Building or Premises during the performance of any work, and so long as Tenant continues to have reasonable use of the Premises, the obligations of Tenant under this Lease shall not thereby be affected in any manner whatsoever;

(h) To relocate various facilities within the Building and/or the Building Common Areas if Landlord shall determine such relocation to be in the best interest of the development and operation of the Building, provided that such relocation shall not materially restrict the reasonable and safe access to or use of the Premises. In the course of any such action, Landlord shall use all reasonable efforts not to interfere with Tenant's business operations in the Premises or its access to the Premises and other areas that Tenant is entitled to use; and

(i) To install vending machines of all kinds in common areas of the Building and to receive all of the revenue derived therefrom.

ARTICLE 29.

DEFINED TERMS

A. "Building" shall collectively refer to (i) the office and retail Building named in Article 1 of which the Premises are a part (including all modifications, additions and alterations made to the Building during the Term of this Lease), (ii) the real property on which the same is located (which real property constitutes Parcel "F" of the Project), and (iii) all plazas, Building Common Areas and any other areas located on said real property and designated by Landlord for use by all tenants in the Building.

B. "Building Common Areas" shall mean and include all areas, facilities, equipment, directories and signs of the Building (exclusive of the Premises and areas leased to other tenants) made available and designated by Landlord for the common and joint use and benefit of Landlord, Tenant and other tenants and occupants of the Building including, but not limited to, lobbies, public washrooms, hallways, sidewalks, parking areas, landscaped areas and service entrances. Building Common Areas may further include such areas in the Project or in adjoining properties under reciprocal easement agreements, operating agreements or other such agreements now or hereafter in effect and which are available to Landlord, Tenant and Tenant's employees and invitees. Landlord reserves the right in its sole discretion and from time to time, to construct, maintain, operate, repair, close, limit, take out of service, alter, change, and modify all or any part of the Building Common Areas. "Building Systems" shall mean all systems serving the Building, including, without limitation, the mechanical, electrical, HVAC and plumbing systems of the Building.

C. "Declaration" shall mean that certain Declaration of Covenants, Easements and Restrictions by and between Fan Pier Development LLC, a Delaware limited liability company, and Fan Pier Owners Corporation, a Massachusetts corporation, dated January 31, 2008 and recorded on February 4, 2008 in Book 43059 at Page 1 of the Suffolk County Registry of Deeds, as the same may be amended from time to time.

D. "Default Rate" shall mean twelve percent (12%) per annum, or the highest rate permitted by applicable law, whichever shall be less. If the application of the Default Rate causes any provision of this Lease to be usurious or unenforceable, the Default Rate shall automatically be reduced to the highest rate allowed by law so as to prevent such result.

E. "FPOC Expenses" shall mean Landlord's "Percentage Share" of "CAM Charges" (as those terms defined in the Declaration), and shall include, without limitation, the categories of costs and expenses set forth in the pro forma budget of FPOC Expenses attached hereto as Exhibit H. Tenant hereby acknowledges that it has reviewed and approved the categories of FPOC Expenses set forth on said Exhibit H.

F. "Hazardous Materials" shall have the meaning set forth in Article 27.

G. "Landlord" and "Tenant" shall be applicable to one (1) or more parties as the case may be, and the singular shall include the plural, and the neuter shall include the masculine and feminine; and if there is more than one (1), the obligations thereof shall be joint and several. For purposes of any provisions indemnifying or limiting the liability of either party, the term "Landlord" or "Tenant," as the case may be, shall include the indemnitee's then partners, beneficiaries, trustees, officers, directors, employees, shareholders, principals, successors and assigns.

H. "Law" or "Laws" (or, sometimes, "law" or "laws") shall mean all federal, state, county and local governmental and municipal laws, statutes, ordinances, rules, regulations, codes, decrees, orders and other such requirements, applicable equitable remedies and decisions by courts in cases where such decisions are binding precedents in the Commonwealth of Massachusetts, and decisions of federal courts applying the Laws of the Commonwealth of Massachusetts.

I. "Lease" shall mean this lease executed between Tenant and Landlord, including any extensions, amendments or modifications and any Exhibits attached hereto.

J. "Lease Year" shall mean each consecutive twelve (12) month period thereof during the Term, with the first (1 st) Lease Year

commencing on the Rent Commencement Date; provided, however, that (a) if the Rent Commencement Date falls on a day other than the first (1st) day of a calendar month, the first (1st) Lease Year shall end on the last day of the calendar month within which the first (1st) anniversary of the Rent Commencement Date falls, and the second (2nd) and each succeeding Lease Year shall commence on the first (1st) day of the next calendar month, and (b) the last Lease Year shall end on the Expiration Date. Each full month during a Lease Year shall be referred to herein as a "Lease Month." In the event that the Commencement Date falls on a day other than the first (1st) day of a calendar month, the first (1st) Lease Month shall be deemed to end on the last day of the first (1st) full calendar month following the calendar month within which the Commencement Date falls.

K. "Lender" shall mean the holder of a Mortgage at the time in question, and where such Mortgage is a ground lease, such term shall refer to the ground lessee.

L. "Mortgage" shall mean all mortgages, deeds of trust, ground leases and other such encumbrances now or hereafter placed upon the Building or any part thereof with the written consent of Landlord, and all renewals, modifications, consolidations, replacements or extensions thereof, and all indebtedness now or hereafter secured thereby and all interest thereon.

M. "Office Component" shall collectively refer to the office space located on the second (2nd) through eighteenth (18th) above-ground levels of the Building, measuring approximately 470,949 rentable square feet, of which the Premises are a part. Landlord reserves the right, in its sole discretion, to add all or any part of the second (2nd) floor premises of the Building to the Retail Component (and, thereafter, to re-add said premises back to the Office Component) at any time and from time to time. In any such event, the square footage of the Office Component shall be revised to reflect the reallocation of premises.

N. "Operating Expenses" shall mean all operating expenses of any kind or nature which are necessary, ordinary or customarily incurred in connection with the operation, maintenance, ownership or repair of the Building, all as determined by Landlord, as well as Landlord's "Percentage Share" of "CAM Charges" (as defined in the Declaration), FPOC Expenses, and any periodic assessments, both regular and special, for which Landlord is or becomes responsible under the Project Documents.

Operating Expenses shall include, but not be limited to:

1.1 costs of supplies, including, but not limited to, the cost of relamping all standard lighting as the same may be required from time to time;

1.2 costs incurred in connection with obtaining and providing energy for the Building, including, but not limited to, costs of propane, butane, natural gas, steam, electricity, solar energy and fuel oils, coal or any other energy sources, including any taxes thereon;

1.3 costs of water and sanitary and storm drainage services;

1.4 costs of janitorial and security services;

1.5 costs of general maintenance and repairs, including costs under HVAC, the intrabuilding network cable and other mechanical maintenance contracts and maintenance, repairs and replacement of equipment and tools;

1.6 costs of maintenance and replacement of landscaping;

1.7 insurance premiums, including fire and all-risk coverage, together with loss of rent endorsements, the part of any claim required to be paid under the commercially reasonable deductible portion of any insurance policies carried by Landlord (where Landlord is unable to obtain insurance without such deductible from a major insurance carrier at reasonable rates), public liability insurance and any other insurance carried by Landlord (all such insurance shall be in such amounts as may be set forth in this Lease or, if greater, required by any holder of a Mortgage or (if greater) as Landlord may reasonably determine);

1.8 labor costs, including wages and other payments, costs to Landlord of worker's compensation and disability insurance, payroll taxes, employment taxes, general welfare benefits, pension payments, medical and surgical benefits, fringe benefits up to the level of Building Manager, and all legal fees and other costs or expenses incurred in resolving any labor dispute;

1.9 commercially reasonable professional property management fees, not to exceed three percent (3%) of the gross receipts of the Building;

1.10 legal, accounting, inspection, and other consultation fees (including, without limitation, fees charged by consultants retained by Landlord for services that are designed to produce a reduction in Operating Expenses or to reasonably improve the operation, maintenance or state of repair of the Building) incurred in the ordinary course or in connection with making the computations required hereunder or in any audit of operations; and

1.11 the costs of capital improvements or structural repairs or replacements in each case to the extent necessary to conform to changes first having effect subsequent to the date of this Lease, in any applicable Laws, ordinances, rules, regulations or

orders of any governmental or quasi-governmental authority having jurisdiction over the Building (herein "Required Capital Improvements") or the costs incurred by Landlord to install a new or replacement capital item for the purpose of reducing Operating Expenses (herein "Cost Savings Improvements") provided that Landlord reasonably and in good faith concludes that a savings will result. The expenditures for Required Capital Improvements and Cost Savings Improvements shall be amortized over the useful life of such capital improvement or structural repair or replacement (as determined by Landlord). All costs so amortized shall bear interest on the amortized balance at the rate of nine percent (9%) per annum or such higher rate as may have actually been paid by Landlord on funds borrowed for the purpose of constructing these capital improvements.

In making any computations contemplated hereby, Landlord shall also be permitted to make such adjustments and modifications to the provisions of this paragraph and Article 4 as shall be reasonable and necessary to achieve the intention of the parties hereto.

The following items shall be excluded from Operating Expenses, provided that such exclusions shall not apply to items of cost and expense included within FPOC Expenses: (aa) interest on and amortization of debts (other than expressly provided in Section 1.11 above); (bb) brokerage commissions (whether for sale, leasing or financing), and advertising expenses for procuring new tenants; (cc) financing and refinancing costs; (dd) Taxes; (ee) leasehold improvements made exclusively for one or more particular tenant(s) (which do not benefit or are not made available to the Tenant); (ff) the cost of any item included in Operating Expenses under this Article 29.N. to the extent that Landlord is actually reimbursed by a warranty, guaranty, service contract, an insurance company, a condemnor, or a tenant (except as a reimbursement of Operating Expenses) or any other party; (gg) ground rent, or any other rent payments under any superior lease; (hh) expenses incurred in the sale, refinancing, syndication, transfer, or other disposition of any portion of the Building, or any interest therein; (ii) legal fees and court costs relating to acquisition, financing, refinancing, syndication or sale of the Building, or any interest therein, or related to disputes with other tenants or other occupants of the Building, or associated with the preparation, negotiation or enforcement of any leases; (jj) administrative salaries, benefits and other compensation of Landlord's or its agents' employees above the grade of Building Manager; (kk) costs of additional or extra services furnished to other tenants for which Landlord is actually separately reimbursed; (ll) depreciation and amortization of Landlord's acquisition and development cost of the Building and the Project; and (mm) the cost of any work performed or service provided to the extent the fees charged or other compensation received would result in a duplicative recovery by the Landlord; (nn) wages, salaries or other compensation paid for clerks or attendant in concessions, kiosks, information centers or stores or establishments operated by Landlord or any affiliate of Landlord; and (oo) any costs representing an amount paid to an entity related to Landlord which is in excess of the amount which would have been paid absent such relationship.

O. "Parking Garage" shall collectively mean (i) the three (3) level subterranean parking garage located below the Building and (ii) such other parking garages or parking areas as may be constructed from time to time in connection with the development of the Project and subsequently made available to Landlord and Tenant under reciprocal easement agreements, operating agreements or other such agreements now or hereafter in effect.

P. "Project" shall mean the entire mixed-use development known as "Fan Pier," of which the Building is a part. The Project shall initially consist of nine (9) lettered parcels of land ("A" through "F" and "H" through "J"), the buildings and other improvements now or hereafter constructed thereon, and any and all common areas and facilities, accessory parking areas, access roadways, sidewalks, landscaped open areas, and maritime facilities now or hereafter constructed in connection with the development of the aforesaid parcels.

Q. "Rent" shall have the meaning specified therefor in Article 3.

R. "Retail Component" shall collectively mean the retail space located on the first (1st) above-ground level of the Building, measuring approximately 18,588 of gross leasable area. Landlord reserves the right, in its sole discretion, to add all or any part of the second (2nd) floor premises of the Building to the Retail Component (and, thereafter, to re-add said premises back to the Office Component) at any time and from time to time. In any such event, the square footage of the Retail Component shall be revised to reflect the reallocation of premises.

S. "Tax" or "Taxes" shall mean:

1.1 all real property taxes and assessments levied against the Building by any governmental or quasi-governmental authority. To the extent not included in Operating Expenses, the foregoing shall include all federal, state, county, or local governmental, special district, improvement district, municipal or other political subdivision taxes, fees, levies, assessments, charges or other impositions of every kind and nature, whether general, special, ordinary or extraordinary, respecting the Building, including without limitation, real estate taxes, general and special assessments, interest on any special assessments paid in installments, transit taxes, taxes based upon the receipt of rent, personal property taxes imposed upon the fixtures, machinery, equipment, apparatus, appurtenances, furniture and other personal property owned by Landlord and used in connection with the Building which Landlord shall pay during any calendar year, any portion of which occurs during the Term (without regard to any different fiscal year used by such government or municipal authority except as provided below), provided, however, that any taxes which shall be levied on the rentals of the Building shall be determined as if the Building were Landlord's only property, and provided further that in no event shall the term "taxes or assessment," as used herein, include any net federal or state income taxes levied or assessed on Landlord, unless such taxes are a

specific substitute for real property taxes, or any corporate or franchise taxes, inheritance, gift or transfer taxes. Such term shall, however, include gross taxes on rentals. Expenses incurred by Landlord for tax consultants and in contesting the amount or validity of any such taxes or assessments shall be included in such computations.

1.2 to the extent the same are not included in Operating Expenses, all "assessments," including so-called special assessments, license tax, business license tax, levy, charge, penalty or tax imposed by any authority having the direct power to tax, including any city, county, state or federal government, or any school, agricultural, lighting, water, drainage, or other improvement or special district thereof, against the Premises or the Building or any legal or equitable interest of Landlord therein. For the purposes of this Lease, any special assessments shall be deemed payable in such number of installments as is permitted by law, whether or not actually so paid. If the Building is not fully built-out for occupancy by tenants or is otherwise not leased or assessed at full market value during the Base Year for Taxes or during any particular Comparison Year, then the Taxes for the Base Year or the particular Comparison Year will be adjusted to reflect the undiscounted fair market value of the Building as shown on the City of Boston Tax Assessor's field card for the Building as of the Rent Commencement Date. If the method of taxation of real estate prevailing to the time of execution hereof shall be, or has been altered, so as to cause the whole or any part of the taxes now, hereafter or theretofore levied, assessed or imposed on real estate to be levied, assessed or imposed on Landlord, wholly or partially, as a capital levy or otherwise, or on or measured by the rents received therefrom, then such new or altered taxes attributable to the Building shall be included within the term real estate taxes, except that the same shall not include any enhancement of said tax attributable to other income of Landlord. All of the items set forth in the preceding clauses S.1.1 and S.1.2 are collectively referred to as the "Tax" or "Taxes".

All other capitalized terms shall have the definition set forth in the Lease.

ARTICLE 30.

MISCELLANEOUS PROVISIONS

A. RULES AND REGULATIONS.

Tenant shall comply with all of the rules and regulations promulgated by Landlord from time to time for the Building. A copy of the current rules and regulations is attached hereto as Exhibit D. Landlord shall not be liable to Tenant for violation of any such rules and regulations, or for the breach of any covenant or condition in any lease by any other tenant in the Building. A waiver by Landlord of any rule or regulation for any other tenant shall not constitute nor be deemed a waiver of that rule or regulation for Tenant. Landlord shall not apply and enforce any Rules or Regulations in a discriminatory manner. In the case of any conflict between this Lease and any rule or regulation, this Lease shall control.

B. EXECUTION OF LEASE.

If Tenant or Landlord is a corporation, partnership or limited liability company, each individual executing this Lease on behalf of said entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on behalf of said entity in accordance with: (i) if such party is a corporation, a duly adopted resolution of the Board of Directors of said corporation or in accordance with the by-laws of said corporation; (ii) if such party is a partnership, the terms of the partnership agreement; and (iii) if such party is a limited liability company, the terms of its operating agreement, and that this Lease is binding upon said entity in accordance with its terms.

C. NOTICES.

All notices under this Lease shall be in writing and will be deemed sufficiently given for all purposes if, to Tenant, by delivery to Tenant at the Premises during the hours the Building is open for business or by certified mail, return receipt requested or by overnight delivery service (with one acknowledged receipt), to Tenant at the address set forth below, and if to Landlord, by certified mail, return receipt requested or by overnight delivery service (with one acknowledged receipt), at the addresses set forth below, or at such other address from time to time established by Landlord. Any notice from Landlord to Tenant that claims or alleges a breach or default under this Lease shall state in prominent bold-face type "THIS IS A NOTICE OF DEFAULT UNDER A LEASE OF REAL PROPERTY, AND IMMEDIATE ACTION IS REQUIRED."

Landlord: at the address set forth in Article 1

with a copy to: the Building Manager at the address set forth in Article 1

and a copy to: c/o The Fallon Company, LLC
One Marina Park Drive
Boston, Massachusetts 02210

Tenant: at the address set forth in Article 1

with a copy to: Langer & McLaughlin, LLP
535 Boylston Street
Boston, Massachusetts 02116
Attn: Stephen T. Langer

D. TRANSFERS.

The term "Landlord" appearing herein shall mean only the owner of the Building from time to time and, upon a sale or transfer of its interest in the Building, the then landlord and transferring party shall have no further obligations or liabilities for matters accruing after the date of transfer of that interest, provided (and only to the extent) that the transferee or successor to Landlord has assumed such liabilities and obligations. Tenant, upon receipt of written notice of such sale or transfer, agrees to attorn to the transferee and shall look solely to the successor owner and transferee of the Building, as the lessor under this Lease, for performance of Landlord's obligations arising hereunder to the extent so assumed. Tenant shall, within ten (10) business days after request, execute such further instruments or assurances (in form and substance reasonably acceptable to Tenant and such transferee) as such transferee may reasonably deem necessary to evidence or confirm such attornment.

E. [INTENTIONALLY OMITTED].

F. TENANT FINANCIAL STATEMENTS.

Upon the written request of Landlord, and to the extent that the same are not otherwise publicly available, Tenant shall submit financial statements for its most recent financial reporting period and for the prior Lease Year. Landlord shall make such request no more than twice during any Lease Year, unless such request is in connection with an uncured event of default hereunder or any prospective sale, financing or refinancing of the Building, in which event there shall be no such limitation. All such financial statements shall be certified as true and correct in all material respects by the responsible officer or partner of Tenant and if Tenant is then in default hereunder (beyond all applicable notice and grace periods), the financial statements shall be certified by an independent certified public accountant.

G. RELATIONSHIP OF THE PARTIES.

Nothing contained in this Lease shall be construed by the parties hereto, or by any third party, as constituting the parties as principal and agent, partners or joint venturers, nor shall anything herein render either party (other than a guarantor) liable for the debts and obligations of any other party, it being understood and agreed that the only relationship between Landlord and Tenant is that of Landlord and Tenant.

H. ENTIRE AGREEMENT; MERGER; SEVERABILITY.

This Lease and any Exhibits or Addenda hereto, embody the entire agreement and understanding between the parties respecting the Lease and the Premises and supersedes all prior negotiations, agreements and understandings between the parties, all of which are merged herein. No provision of this Lease may be modified, waived or discharged except by an instrument in writing signed by the party against which enforcement of such modification, waiver or discharge is sought. Any provision of this Lease which shall prove to be invalid, void or illegal shall in no way affect, impact, impair or invalidate any other provision hereof and such other provisions shall remain in full force and effect.

I. NO REPRESENTATION BY LANDLORD.

Neither Landlord nor any agent of Landlord has made any representations, warranties, or promises with respect to the Premises or the Building except as expressly set forth herein.

J. LIMITATION OF LIABILITY.

Notwithstanding anything in this Lease to the contrary, any remedy of Tenant for the collection of a judgment (or other judicial process) requiring the payment of money by Landlord in the event of any default by Landlord hereunder or any claim, cause of action or obligation, contractual, statutory or otherwise by Tenant against Landlord concerning, arising out of or relating to any matter relating to this Lease and all of the covenants and conditions or any obligations, contractual, statutory, or otherwise set forth herein, shall be limited solely and exclusively to an amount which is equal to the interest of Landlord in and to the Building. Any judgments rendered against Landlord shall be satisfied solely out of the rents, issues and profits of the Building and the proceeds of sale of Landlord's interest in the Building. No other property or assets of Landlord, or any member, officer, director, shareholder, partner, trustee, agent, servant or employee of Landlord (the "Representatives") shall be subject to levy, execution or other enforcement procedure for the satisfaction of Tenant's remedies under or with respect to this Lease, Landlord's obligations to Tenant, whether contractual, statutory or otherwise, the relationship of Landlord and Tenant hereunder, or Tenant's use or occupancy of the Building. Tenant further understands that any liability, duty or obligation of Landlord to Tenant, shall automatically cease and terminate as of the date that Landlord or any of Landlord's Representatives no longer have any right, title or interest in or to the Building, to the extent that the successor to Landlord has assumed the obligations of Landlord under this Lease as provided above.. The provisions hereof shall

inure to Landlord's successors and assigns including any Lender. The foregoing provisions are not intended to relieve Landlord from the performance of any of Landlord's obligations under this Lease, but only to limit the personal liability of Landlord in case of recovery of a judgment against Landlord; nor shall the foregoing be deemed to limit Tenant's rights to obtain injunctive relief or specific performance or other remedy which may be accorded Tenant by law or under this Lease. If Tenant claims or asserts that Landlord has violated or failed to perform a covenant under the Lease, then except as may otherwise be expressly provided in this Lease, Tenant's sole remedy shall be an action for specific performance, declaratory judgment or injunction and in no event shall Tenant be entitled to any money damages in any action or by way of set off, defense or counterclaim and Tenant hereby specifically waives the right to any money damages or other remedies for any such violation or failure. Neither Tenant's officers, directors, trustees, shareholders, agents or employees, nor their respective partners, heirs, successors and assigns, shall ever have any personal liability for the obligations of Tenant hereunder, and Landlord hereby expressly waives and releases such personal liability on behalf of itself and all persons claiming by, through or under Landlord.

K. NOTICE OF LEASE.

Tenant agrees that it will not record this Lease; however, each party hereto agrees, concurrently with the execution of this Lease, to execute a so-called notice of lease in recordable form and complying with applicable Law and reasonably satisfactory to Landlord's and Tenant's respective attorneys. In no event shall such document set forth the rent or other charges payable by Tenant under this Lease; and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease, and is not intended to vary the terms and conditions of this Lease.

L. NO WAIVERS.

Failure of Landlord or Tenant to insist upon strict compliance by the other party of any condition or provision of this Lease shall not be deemed a waiver by the first party of that condition. No waiver by Landlord or Tenant of any provision of this Lease shall be deemed to be a waiver of any other provision hereof or of any subsequent breach by the other party of the same or any other provision. No provision of this Lease may be waived by Landlord or Tenant, except by an instrument in writing executed by Landlord or Tenant, as applicable, and except as otherwise expressly provided in this Lease. Landlord's or Tenant's consent to or approval of any act by the other party requiring the first party's consent or approval shall not be deemed to render unnecessary the obtaining of such first party's consent to or approval of any subsequent act of the other party, whether or not similar to the act so consented to or approved. No act or thing done by Landlord or a Landlord agent during the Term of this Lease shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept such surrender shall be valid unless in writing and signed by Landlord. Similarly, this Lease cannot be amended except by a writing signed by Landlord and Tenant. Any payment by one party to another hereunder or receipt by a party of an amount less than the total amount then due hereunder shall be deemed to be in partial payment only thereof and not a waiver of the balance due or an accord and satisfaction, notwithstanding any statement or endorsement to the contrary on any check or any other instrument delivered concurrently therewith or in reference thereto. Accordingly, a party may accept any such amount and negotiate any such check without prejudice to such party's right to recover all balances due and owing and to pursue its other rights against the other party under this Lease, regardless of whether the first party makes any notation on such instrument of payment or otherwise notifies the other party that such acceptance or negotiation is without prejudice to the first party's rights.

M. SUCCESSORS AND ASSIGNS.

The conditions, covenants and agreements contained herein shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and assigns.

N. GOVERNING LAW; INDEPENDENT COVENANTS; WAIVER.

This Lease shall be governed by the law of the Commonwealth of Massachusetts. No conflicts of law rules of any state or country (including, without limitation, the conflicts of law rules of the Commonwealth of Massachusetts) shall be applied to result in the application of any substantive or procedural laws of any state or country other than the Commonwealth of Massachusetts. All controversies, claims, actions or causes of action arising between the parties hereto and/or their respective successors and assigns, shall be brought, heard and adjudicated by the courts of the Commonwealth of Massachusetts, with venue in the County of Suffolk. Each of the parties hereto hereby consents to personal jurisdiction by the courts of the Commonwealth of Massachusetts in connection with any such controversy, claim, action or cause of action, and each of the parties hereto consents to service of process by any means authorized by the law of the Commonwealth of Massachusetts and consent to the enforcement of any judgment so obtained in the courts of the Commonwealth of Massachusetts on the same terms and conditions as if such controversy, claim, action or cause of action had been originally heard and adjudicated to a final judgment in such courts. Each of the parties hereto further acknowledges that the laws and courts of the Commonwealth of Massachusetts were freely and voluntarily chosen to govern this Lease and to adjudicate any claims or disputes hereunder.

Tenant waives all rights (i) to any abatement, suspension, deferment, reduction or deduction of or from Rent, and (ii) to quit, terminate or surrender this Lease or the Premises or any part thereof, except, in either case, as expressly provided in this Lease. Tenant hereby acknowledges and agrees that the obligations of Tenant hereunder shall be separate and independent covenants and agreements, that Rent shall continue to be payable in all events and that the obligations of Tenant hereunder shall continue unaffected, unless the requirement to pay or perform the same shall have been terminated pursuant to an express provision of this Lease. Landlord

and Tenant each acknowledges and agrees that the independent nature of the obligations of Tenant hereunder represents fair, reasonable and accepted commercial practice with respect to the type of property subject to this Lease, and that this agreement is the product of free and informed negotiation during which both Landlord and Tenant were represented by counsel skilled in negotiating and drafting commercial leases in Massachusetts, and that the acknowledgements and agreements contained herein are made with full knowledge of the holding in Wesson v. Leone Enterprises, Inc., 437 Mass. 708 (2002). Such acknowledgements, agreements and waivers by Tenant are a material inducement to Landlord entering into this Lease.

O. EXHIBITS.

All exhibits attached to this Lease are a part hereof and are incorporated herein by reference and all provisions of such exhibits shall constitute agreements, promises and covenants of this Lease.

P. CAPTIONS.

The captions and headings used in this Lease are for convenience only and in no way define or limit the scope, interpretation or content of this Lease.

Q. COUNTERPARTS.

This Lease may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

R. TIME OF ESSENCE.

Each covenant herein is a condition and time is of the essence with respect to the performance of every provision of this Lease.

S. SURVIVAL OF OBLIGATIONS.

Any obligations of Tenant occurring prior to the expiration or earlier termination of this Lease shall survive such expiration or earlier termination.

T. CONFIDENTIALITY.

Tenant acknowledges that the material financial terms of this Lease and any related documents are confidential information. Tenant shall use commercially reasonable efforts to keep such confidential information strictly confidential and shall not disclose such confidential information to any person or entity other than Tenant's financial, legal and space planning consultants and any proposed subtenants or assignees.

U. **NO OPTION.**

THE SUBMISSION OF THIS LEASE BY LANDLORD, ITS AGENT OR REPRESENTATIVE FOR EXAMINATION OR EXECUTION BY TENANT DOES NOT CONSTITUTE AN OPTION OR OFFER TO LEASE THE PREMISES UPON THE TERMS AND CONDITIONS CONTAINED HEREIN OR A RESERVATION OF THE PREMISES IN FAVOR OF TENANT, IT BEING INTENDED HEREBY THAT THIS LEASE SHALL ONLY BECOME EFFECTIVE UPON THE EXECUTION HEREOF BY LANDLORD AND DELIVERY OF A FULLY EXECUTED LEASE TO TENANT.

V. USE OF BUILDING NAME; IMPROVEMENTS.

Tenant shall not be allowed to use the name, picture or representation of the Building, or words to that effect, or any logo or trademark associated with the Project, in connection with any business carried on in the Premises or otherwise (except that Tenant may use the name of the Building as Tenant's address) without the prior written consent of Landlord. In the event that Landlord undertakes any additional improvements on the property on which the Building is located including, but not limited to, new construction or renovation or additions to the existing improvements, Landlord shall not be liable to Tenant for any noise, dust, vibration or interference with access to the Premises or disruption in Tenant's business caused thereby.

W. RIGHT OF LANDLORD TO PERFORM.

All covenants and agreements to be performed by Tenant under any of the terms of this Lease shall be performed by Tenant at Tenant's sole cost and expense and without any abatement of Rent. If Tenant shall fail to pay any sum of money, other than Rent, required to be paid by it hereunder or shall fail to perform any other act on its part to be performed hereunder, and such failure shall continue beyond any applicable notice and cure period set forth in this Lease, Landlord may, but shall not be obligated to, without waiving or releasing Tenant from any obligations of Tenant, make any such payment or perform any such other act on Tenant's part to be made or performed as is in this Lease provided. All sums so paid by Landlord and all reasonable incidental costs, together with interest thereon at the Default Rate from the date of such payment by Landlord, shall be payable to Landlord on demand and Tenant

covenants to pay any such sums, and Landlord shall have (in addition to any other right or remedy of Landlord) the same rights and remedies in the event of the nonpayment thereof by Tenant as in the case of default by Tenant in the payment of the Rent.

X. ACCESS, CHANGES IN BUILDING, FACILITIES, NAME.

(i) Every part of the Building except the inside surfaces of all walls, windows and doors bounding the Premises (including exterior building walls, core corridor walls and doors and any core corridor entrance), and any space in or adjacent to the Premises used for shafts, stacks, pipes, conduits, fan rooms, ducts, electric or other utilities, sinks or other building facilities, and the use thereof, as well as access thereto through the Premises for the purposes of operation, maintenance, decoration and repair, are reserved to Landlord, provided that Tenant shall have reasonable, non-exclusive access through the risers, shafts and conduits serving the Premises to other portions of the Building (including the roof and mechanical floors) serving the Premises, and to utility connections at common connection points for the installation, repair and maintenance, of electronic, fiber, phone and data cabling, connections, and equipment for such cabling, conduits, transmitters, receivers, and other office, computer, communications and word and data processing cable, equipment and facilities, subject to Landlord's right to require any vendor, contractor or service provider of Tenant to execute Landlord's then commercially reasonable form of license agreement or access agreement permitting such vendor, contractor or service provider access to such portions of the Building for purposes of installing the applicable cabling, wiring and/or equipment.

(ii) Tenant shall permit Landlord to install, use and maintain pipes, ducts and conduits within the walls, columns and ceilings of the Premises, provided that the same shall not interfere with Tenant's then-existing installations, interfere with Tenant's use and operation of the Premises for the Permitted Use or create any violation of the conditions of Tenant's operating licenses, or reduce the usable floor area by more than a de minimis amount or change the interior configuration of the Premises by more than a de minimis amount.

(iii) Landlord reserves the right, without incurring any liability to Tenant therefor, to make such changes in or to the Building and the fixtures and equipment thereof, as well as in or to the street entrances, halls, passages, elevators, stairways and other improvements thereof, as it may deem necessary or desirable.

(iv) Landlord may adopt any name for the Building and Landlord reserves the right to change the name or address of the Building at any time.

Y. IDENTIFICATION OF TENANT.

(1) If Tenant constitutes more than one person or entity, (A) each of them shall be jointly and severally liable for the keeping, observing and performing of all of the terms, covenants, conditions and provisions of this Lease to be kept, observed and performed by Tenant, (B) the term "Tenant" as used in this Lease shall mean and include each of them jointly and severally, and (C) the act of or notice from, or notice or refund to, or the signature of, any one or more of them, with respect to the tenancy of this Lease, including, but not limited to, any renewal, extension, expiration, termination or modification, of this Lease, shall be binding upon each and all of the persons or entities executing this Lease as Tenant with the same force and effect as if each and all of them had so acted or so given or received such notice or refund or so signed.

(2) If Tenant is a general partnership (or is comprised of two or more persons, individually and as co-partners of a general partnership) or if Tenant's interest in this Lease shall be assigned to a general partnership (or to two or more persons, individually and as co-partners of a general partnership) pursuant to Article 16 hereof (any such partnership and such persons hereinafter referred to in this Article 30.Y. as "Partnership Tenant"), the following provisions of this Lease shall apply to such Partnership Tenant:

(A) The liability of each of the parties comprising Partnership Tenant shall be joint and several.

(B) Each of the parties comprising Partnership Tenant hereby consents in advance to, and agrees to be bound by, any written instrument which may hereafter be executed, changing, modifying or discharging this Lease, in whole or in part, or surrendering all or any part of the Premises to the Landlord, and by notices, demands, requests or other communication which may hereafter be given, by the individual or individuals authorized to execute this Lease on behalf of Partnership Tenant under Article 30.B. above.

(C) Any bills, statements, notices, demands, requests or other communications given or rendered to Partnership Tenant or to any of the parties comprising Partnership Tenant shall be deemed given or rendered to Partnership Tenant and to all such parties and shall be binding upon Partnership Tenant and all such parties.

(D) If Partnership Tenant admits new partners, all of such new partners shall, by their admission to Partnership Tenant, be deemed to have assumed performance of all of the terms, covenants and conditions of this Lease on Tenant's part to be observed and performed.

(E) Partnership Tenant shall give prompt notice to Landlord of the admission of any such new partners, and, upon demand of Landlord, shall cause each such new partner to execute and deliver to Landlord an agreement in form satisfactory to

Landlord, wherein each such new partner shall assume performance of all of the terms, covenants and conditions of this Lease on Partnership Tenant's part to be observed and performed (but neither Landlord's failure to request any such agreement nor the failure of any such new partner to execute or deliver any such agreement to Landlord shall terminate the provisions of clause (d) of this Article 30.Y.(2) or relieve any such new partner of its obligations thereunder).

Z. ANTI-TERRORISM REPRESENTATION. MAKE MUTUAL

(1) Each party certifies to the other that:

(a) It is not acting, directly or indirectly, for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department as a terrorist, "Specially Designated National and Blocked Person," or other banned or blocked person, entity, nation, or transaction pursuant to any law, order, rule, or regulation that is enforced or administered by the Office of Foreign Assets Control; and

(b) It is not engaged in this transaction, directly or indirectly on behalf of, or instigating or facilitating this transaction, directly or indirectly on behalf of, any such person, group, entity, or nation.

(2) Each party hereby agrees to defend, indemnify, and hold harmless the other from and against any and all claims, damages, losses, risks, liabilities, and expenses (including attorney's fees and costs) arising from or related to any breach of the foregoing certification by the first party.

AA. ERISA/UBIT.

(1) Tenant will not use the assets of an employee benefit plan as defined in Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA") and covered under Title I, Part 4 of ERISA or Section 4975 of the Internal Revenue Code of 1986, as amended, in the performance, discharge or satisfaction of any of its obligations under this Lease such that it would constitute a "prohibited transaction" under ERISA. Notwithstanding any provision of the Lease to the contrary, Tenant shall not assign the Lease or sublease all or any portion of the Premises unless (i) such assignee or subtenant delivers to Landlord a certification (in form and content satisfactory to Landlord) with respect to the status of such assignee or subtenant (and any guarantor of such assignee's or subtenant's obligations) as a party in interest and a disqualified person, as provided above; and (ii) such assignee or subtenant undertakes not to take any action that would cause the Lease to constitute a non-exempt prohibited transaction under ERISA.

(2) Notwithstanding any provision of the Lease to the contrary, Tenant shall not (i) sublease all or any portion of the premises under a sublease in which the rent is based upon the net income or net profits of any person or (ii) enter into any other transaction with respect to the Lease or the Premises such that the revenues to be received by Landlord from time to time in connection with the Lease would, as a result of such transaction, be subject to Unrelated Business Income Tax under Section 511 through 514 of the Internal Revenue Code of 1986, as amended.

(3) Tenant agrees that it shall incorporate these requirements in any sublease of the Premises.

ARTICLE 31.

RIGHT OF FIRST OFFER

A. Provided that this Lease is in full force and effect and that no default (continuing uncured beyond the expiration of applicable notice and cure periods) shall exist under this Lease both at the time of Tenant's exercise of the ROFO (as hereinafter defined) and on the date of entry into the agreement incorporating the Offered Space (as hereinafter defined), Tenant shall have a one (1)-time right (except as otherwise provided in Article 31.C. below) (the "ROFO"), at the expiration of the term of the first lease entered into with a bona fide third party tenant in respect of the ROFO Space (as hereinafter defined) (the parties acknowledging and agreeing that, as of the date of this Lease, the ROFO space is not leased to any other tenant and thus is not yet "available" to Tenant under this Article 31), to lease all or any portion of the thirteenth (13th) floor of the Building (the "ROFO Space") on the first (1st) occasion that such ROFO Space "becomes available." For purposes of this Article 31, the ROFO Space shall be deemed to "become available" if and only if Landlord, following the date of this Lease, has first leased the ROFO Space to a bona fide third party tenant and such third party's lease or other occupancy agreement with respect to the ROFO Space subsequently expires or is otherwise terminated.

B. Notwithstanding anything set forth in this Article 31 to the contrary, the ROFO Space shall not be deemed to "become available" if the ROFO Space is:

(i) Assigned or subleased by the then current tenant of the ROFO Space (following Landlord's initial leasing of the ROFO Space as provided above) as to which Tenant was afforded notice as provided herein; or

(ii) Re-leased by such then current tenant of the ROFO Space by renewal, extension, or renegotiation (whether or not an express renewal option is afforded to such tenant under the terms of its lease); or

(iii) Not leased to a tenant as of the date of this Lease (until that space is leased, and then subsequently "becomes available," as provided above); or

(iv) Subject to an existing (as of the date of this Lease) right of first offer, right of first refusal or other expansion right of another tenant in the Building, the parties acknowledging and agreeing that, as of the date of this Lease, only Fish & Richardson P.C. has a superior right of first offer with respect to the ROFO Space; or

(v) Subject to a holdover by the then current tenant of the ROFO Space.

C. Subject to the foregoing, the first time during the Term that Landlord proposes to offer for lease all or any portion of the ROFO Space which Landlord anticipates will "become available," Landlord shall furnish to Tenant a notice (the "First Offer Proposal") containing the material terms of the proposed lease in respect of the applicable portions of the available ROFO Space (the "Offered Space"), including (i) a floor plan of the Offered Space, (ii) annual base rent for the Offered Space, (iii) the proposed effective date of the lease for the Offered Space, and (iv) any other material terms which Landlord shall deem appropriate. Tenant shall have the option, exercisable by notice delivered to Landlord within ten (10) days after Tenant's receipt or refusal of receipt of Landlord's First Offer Proposal, TIME BEING OF THE ESSENCE, to lease the Offered Space upon such terms and conditions as are contained in the First Offer Proposal. If Tenant timely delivers to Landlord written notice of Tenant's exercise of the ROFO for the Offered Space, then, within ten (10) business days thereafter, the parties shall enter into a commercially reasonable amendment to this Lease incorporating the Offered Space as part of the Premises on the terms and conditions contained in the First Offer Proposal and for the then remaining term of this Lease (provided, however, that at least three (3) full years would remain on the Term following the effective date of Tenant's lease of the Offered Space, whether in the ordinary course or a result of Tenant's exercise of a then available extension option in accordance with the terms and conditions of this Lease). If Tenant declines or fails to timely exercise the ROFO with respect to the Offered Space, Landlord shall thereafter be free, for a period of one hundred eighty (180) days after the expiration of the ten (10) day ROFO exercise period referenced above, to lease the Offered Space (and any other portion of the ROFO Space, if applicable) without regard to the restrictions contained in this Article 31 and on such terms and conditions as Landlord may decide in its sole discretion, so long as each material term (as hereinafter defined) of such third party lease is no more than ten percent (10%) more favorable to such third party tenant than each corresponding material term set forth in the applicable First Offer Proposal (on a line item basis). The following shall constitute "material terms" under this paragraph: (1) base rent, (2) term (including extension, renewal, expansion and early termination rights), (3) free rent (inside the term), (4) operating expenses and (5) tenant improvement allowance. If no such third party lease for the Offered Space shall be concluded within said one hundred eighty (180) day period, then the provisions of this paragraph shall again be applicable to the Offered Space.

D. The ROFO is personal to Tenant and shall become null and void upon the occurrence of an assignment of the Lease or subletting of all or any portion of the Premises in accordance with the terms of this Lease, except in connection with a Permitted Transfer.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the parties have duly executed this Lease with the Exhibits attached hereto, as of the day and year first written above.

LANDLORD:

FALLON CORNERSTONE ONE MPD LLC,
a Delaware limited liability company

By: MASSACUSETTS MUTUAL LIFE INSURANCE COMPANY,
a Massachusetts corporation,
its Member

By: CORNERSTONE REAL ESTATE ADVISERS LLC,
a Delaware limited liability company,
its Authorized Agent

By: /s/ Linda C. Houston____
Name: Linda C. Houston
Title: Senior Vice President

TENANT:

KERYX BIOPHARMACEUTICALS, INC.,
a Delaware corporation

By: /s/ Gregory P. Madison
Name: Gregory P. Madison
Title: President & COO

Exhibit A

Space/Floor Plan Showing Premises

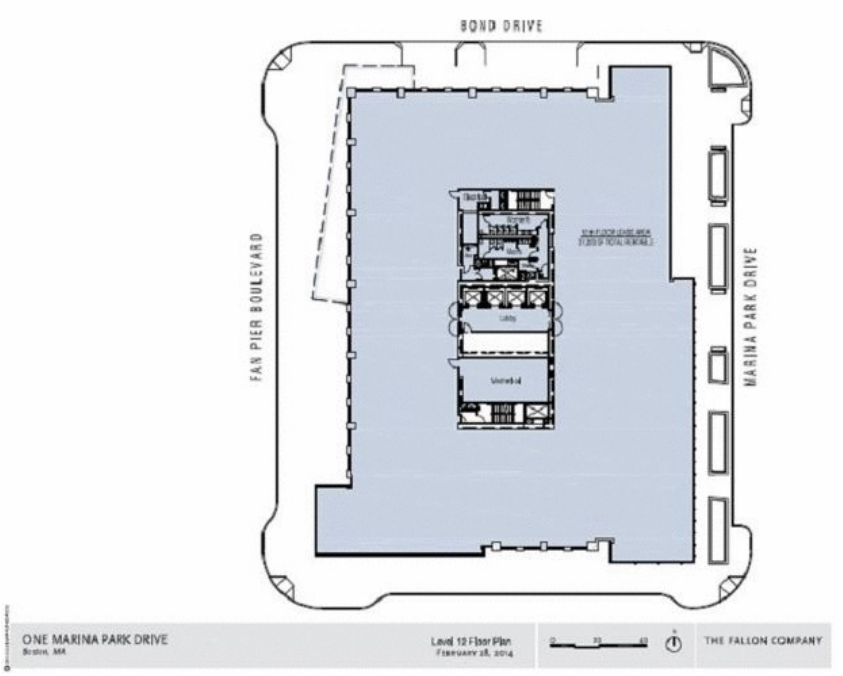


Exhibit B

Tenant's Work Exhibit

1. (a) Tenant shall, at Tenant's expense, submit to Landlord final and complete dimensioned and detailed plans and drawings of partition layouts (including openings), ceiling and lighting layouts, colors, mechanical and electrical circuitry plans and any and all other information as may be reasonably necessary to complete the construction of the Premises in accordance with this Exhibit B (such plans are collectively referred to herein as "Tenant's Plans"). The partition layout, and ceiling and lighting layout plans shall be 1'0" = 1/8" scale. Tenant shall submit Tenant's Plans and any other plans required by this Exhibit B to Landlord in form, quality and quantity acceptable for the purposes of filing for a building permit with the Inspectional Services Department of the City of Boston ("ISD"), and such plans shall be signed and sealed by an architect licensed in the Commonwealth of Massachusetts.

(b) Landlord shall not unreasonably withhold, delay or condition its approval of Tenant's Plans. Landlord shall approve Tenant's Plans as soon as reasonably possible or designate by notice to Tenant the specific changes required to be made to Tenant's Plans, which Tenant shall make within three (3) business days of receipt. This procedure shall be repeated until Tenant's Plans are finally approved by Landlord.

(c) Any architect or designer acting for or on behalf of Tenant shall be deemed an agent of and authorized to bind Tenant in all respects.

(d) All plans, drawings and specifications with respect to the Premises required to be submitted by Tenant to Landlord shall comply with and conform to the Building plans filed with the ISD, Building standard specifications (the receipt of which Tenant hereby acknowledges) and with all the rules, regulations and/or other requirements of any governmental department having jurisdiction over the construction of the Building and/or Premises. Tenant shall prepare drawings in accordance with pre-existing conditions and field measurements.

(e) Landlord's review of Tenant's Plans is solely to protect the interests of Landlord in the Building and the Premises, and Landlord shall be neither the guarantor of, nor responsible for, the correctness or accuracy of Tenant's Plans, or the compliance of Tenant's Plans with applicable requirements of any governmental authority. Landlord's review and approval of any submissions shall not be deemed to be an approval of the adequacy for any particular purpose or system capacity or the cost of the Tenant Improvements.

(f) Tenant shall reimburse Landlord for all actual, out-of-pocket costs incurred by Landlord in connection with having third parties review all submissions, plans and specifications submitted to Landlord for its review and approval pursuant to this Exhibit B, subject to the Allowance; provided that Tenant shall in no event be required to reimburse Landlord more than $2,500 on account of such review costs (and no costs reimbursed hereunder shall be duplicative of costs reimbursed under the Lease).

2. (a) Tenant shall, at its expense (except for the Allowance), in accordance with the terms and conditions of this Exhibit B, be responsible for the construction of all improvements and alterations necessary to prepare the Premises to conform with Tenant's Plans (the "Tenant Improvements"). The term "Substantial Completion" shall mean when Tenant has obtained a temporary or final certificate of occupancy from ISD with respect to the Premises as improved in accordance with the terms and conditions of this Exhibit B. After completion of Tenant's Plans, Tenant shall submit Tenant's Plans to the appropriate governmental body for plan checking and a building permit. Tenant shall deliver a copy of the building permit to Landlord prior to the commencement of construction of the Tenant Improvements. Tenant shall not make any material changes to Tenant's Plans once finally approved by Landlord without Landlord's consent.

(b) Tenant shall select a contractor (the "Contractor"), subject to the approval of Landlord, which approval will not be unreasonably withheld and shall be granted or denied within 15 calendar days of request for such approval. With its request for approval of the Contractor, Tenant shall furnish to Landlord such information concerning the proposed Contractor's background and experience as Landlord may reasonably require. A price for a construction contract based on Tenant's Plans shall be mutually agreed upon by Tenant and the Contractor. Tenant shall enter into an agreement with the Contractor to build the Tenant Improvements, at Tenant's sole cost, except for the Allowance.

The construction contract will provide for progress payments, no more frequently than once per calendar month, in minimum increments of $25,000.00, and each progress payment will be funded as follows: Landlord will fund the percentage of each progress payment equal to a fraction expressed as a percentage, the numerator of which is the Allowance and the denominator of which is the total cost of the Tenant Improvements; and Tenant will fund the remainder. Ten percent (10%) of each progress payment shall be retained by Landlord until Tenant delivers, or causes to be delivered, to Landlord a certificate of occupancy or certificate of completion, in form and substance reasonably satisfactory to Landlord, with respect to the Premises together with final and unconditional waivers of mechanic's liens concerning the work for all labor and services performed and all material furnished in connection with the work, signed by the Contractor and all subcontractors, suppliers, and laborers involved in the work. Notwithstanding anything contained herein or in the Lease to the contrary, Landlord shall have no obligation to disburse any portion of the Allowance during any period of time that Tenant is in default of its obligations under the Lease (continuing uncured following receipt of notice thereof from Landlord) or upon or following termination of the Lease.

(c) If the cost of the design and construction of the Tenant Improvements is less than the Allowance, the difference shall be retained by Landlord. In the event that Tenant requests any changes to Tenant's Plans, Landlord shall not unreasonably withhold, delay or condition its consent to any such changes, provided the changes do not adversely affect the Building's structure, systems, equipment or appearance.

(d) The Allowance will be applied to the design and construction of the Tenant Improvements and for no other purpose. The "Allowance" shall be an amount equal to the product of (i) the area of the Premises in rentable square feet and (ii) $70.00. All costs attributable to the Tenant Improvements in excess of the Allowance shall be paid for by Tenant.

3. (a) Before beginning the Tenant Improvements, Tenant shall pay for and deliver to Landlord satisfactory evidence of the insurance coverage(s) required to be maintained by Tenant under Article 8 of the Lease. Landlord and the Contractor shall be named as additional insureds in such liability policies or certificates of insurance and the same shall remain in effect during the period of the performance of the Tenant Improvements.

(b) All the Tenant Improvements shall be in accordance with the Project Documents and the rules and regulations of any governmental department or bureau having jurisdiction thereover and shall not conflict with, or be in violation or cause any violation of, Landlord's basic Building plans and/or the construction of the Building, and all the Tenant Improvements shall be completed free of all liens and encumbrances. All permits which may be required by Tenant for the Tenant Improvements shall be

procured and paid for by Tenant or, if Landlord shall deem the same advisable, Landlord may procure such permits and Tenant shall pay for the same. No plans and/or specifications required to be filed by Tenant pursuant to any work contemplated to be performed by it within the Premises shall be filed or submitted to any governmental authority having jurisdiction thereover without first having obtained Landlord's approval of same.

(c) Upon completion of the Tenant Improvements, Tenant will remove all debris and excess materials from the Building and the Premises.

(d) Without limiting the applicability of Article 5.E. of the Lease, the labor employed by Tenant or the Contractor shall always be harmonious and compatible with the labor employed by Landlord or any contractors or sub-contractors of Landlord. Should such labor be incompatible with such Landlord's labor as shall be determined by the sole judgment of Landlord, to be exercised in good faith, Landlord may require Tenant to withdraw from the Premises until the completion of the Building and/or Premises by Landlord.

(e) In the event Tenant or the Contractor shall enter upon the Premises or any other part of the Building, as may be permitted by Landlord, Tenant shall indemnify and save Landlord free and harmless from and against any and all claims arising from or out of any entry thereon or the performance of the Tenant Improvements and from and against any and all claims arising from or claimed to arise from any act or neglect of Tenant or Tenant's representatives or from any failure to act, or for any other reason whatsoever arising out of said entry or such work.

(f) Tenant Improvements which Landlord reasonably determines are specialized to Tenant's use and occupancy of the Premises, including, without limitation, wiring and cabling, shall, at the election of Landlord (which election shall be made in writing at the time of Landlord's approval of Tenant's Plan hereunder), either (1) be removed by Tenant at its expense before the expiration or earlier termination of the term of the Lease or (2) remain upon the Premises and be surrendered therewith without disturbance, molestation or injury upon the expiration or earlier termination of the Lease. If Landlord requires the removal of all or part of the specialized Tenant Improvements, Tenant, at its expense, shall repair any damage to the Premises or the Building caused by such removal. If Tenant fails to remove any specialized Tenant Improvements upon Landlord's request, then Landlord may (but shall not be obligated to) remove the same and the cost of such removal and repair of any damage caused by the same, together with any and all damages which Landlord may suffer and sustain by reason of the failure of Tenant to remove the same, shall be charged to Tenant and paid upon demand.

4. In no event shall Tenant be eligible to receive or entitled to any credit for any portion of the Allowance not used by Tenant by July 31, 2016. Tenant shall be responsible for the maintenance, repair and replacement of all Tenant Improvements unless the same is necessitated by the negligent acts of Landlord.

5. Tenant hereby authorizes Timothy Betjemann as Tenant's representative to act on its behalf and represent its interests with respect to all matters which pertain to the construction of Tenant Improvements, and to make decisions binding upon Tenant with respect to such matters. Landlord hereby authorizes Richard Martini to be Landlord's representative in connection with construction of the Tenant Improvements. Tenant hereby expressly recognizes and agrees that no other person claiming to act on behalf of the Landlord is authorized to do so, and any costs, expenses liabilities or obligations incurred or paid by Tenant in reliance on the discretion of any such other person shall be Tenant's sole responsibility.

6. In the event of a conflict between the terms and provisions of the Lease and the terms and provisions of this Exhibit B, the terms and provisions of this Exhibit B shall control.

Exhibit B-1

Tenant's Conceptual Space Plan

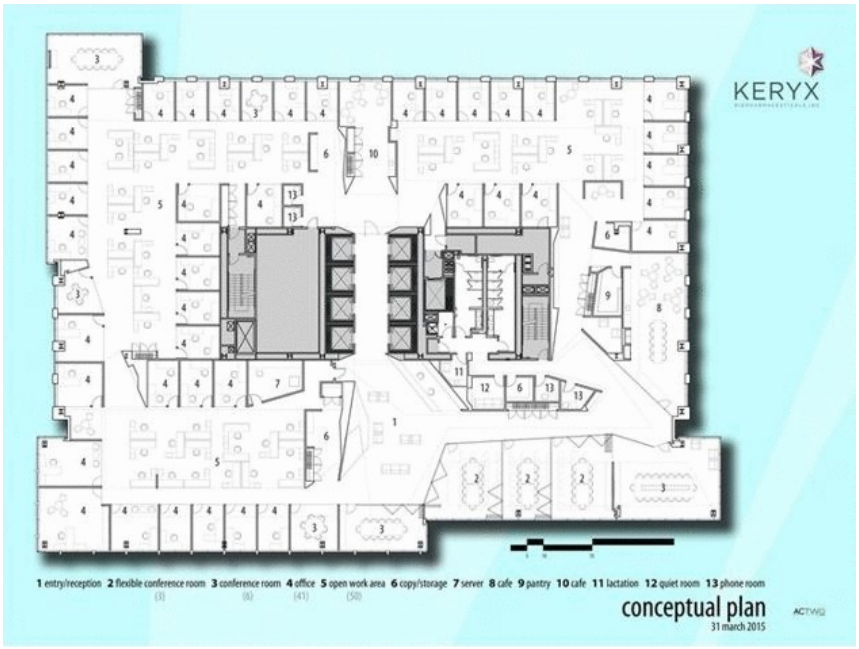


Exhibit C

Form of Sublease Consent

Pursuant to Article 16 of that certain Office Lease dated as of _____, 2015 (as amended, the "Lease"), by and between **FALLON CORNERSTONE ONE MPD LLC**, a Delaware limited liability company, as "Landlord," and **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation, as "Tenant," demising certain office space in the building located at One Marina Park Drive, Boston, Massachusetts 02210, Landlord hereby consents to that certain Sublease by and between Tenant, as sublessor, and _____, a _____, as sublessee (the "Sublease"), a copy of which Sublease is attached hereto as Exhibit A, provided that, notwithstanding anything contained in the Sublease to the contrary, this consent shall in no way be deemed to (i) modify or amend any of the terms of the Lease, (ii) expand or alter in any way Landlord's obligations or Tenant's rights thereunder, (iii) serve as a consent of Landlord to any request other than the consent set forth above, (iv) waive any rights or remedies Landlord may have under the Lease or (v) constitute a release of Tenant of any of its obligations under the Lease. Without limiting the generality of the foregoing, Landlord shall not be bound by any of the terms or provisions contained in the Sublease and any provision in the Sublease that purports to impose any obligation upon Landlord that is greater than its obligation under the Lease or reduce the obligation of Tenant shall be of no force or effect as to Landlord.

FALLON CORNERSTONE ONE MPD LLC,
a Delaware limited liability company

By: MASSACHUSETTS MUTUAL LIFE INSURANCE COMPANY,
a Massachusetts corporation,
its Member

By: CORNERSTONE REAL ESTATE ADVISERS LLC,
a Delaware limited liability company,
its Authorized Agent

By: _____
Name: Linda C. Houston
Title: Senior Vice President

Exhibit D

Building's Rules and Regulations

and Janitorial Specifications

The following rules and regulations shall apply, where applicable, to the Premises, the Building, the property on which the Project is located, the Parking Garage and the appurtenances.

1. Sidewalks, doorways, vestibules, halls, stairways and other similar areas shall not be obstructed by Tenant or used by Tenant for any purpose other than ingress and egress to and from the Premises. No rubbish, litter, trash, or material shall be placed, emptied, or thrown in those areas. At no time shall Tenant permit Tenant's employees to loiter in Building Common Areas or elsewhere about the Building or the property on which the Project is located.

2. Plumbing fixtures and appliances shall be used only for the purposes for which designed, and no sweepings, rubbish, rags or other unsuitable material shall be thrown or placed in the fixtures or appliances. Damage resulting to fixtures or appliances by Tenant, its agents, employees or invitees, shall be paid for by Tenant, and Landlord shall not be responsible for the damage.

3. Landlord shall designate and approve standard window coverings for the Premises and to establish rules to assure that the Building presents a uniform exterior appearance. Tenant shall not place objects against glass partitions, doors or windows which would be unsightly from the Building corridor or from the exterior of the Building. Tenant shall ensure, to the extent reasonably practicable, that window coverings are closed on windows in the Premises while they are exposed to the direct rays of the sun.

4. No signs, advertisements or notices shall be painted or affixed to windows, doors or other parts of the Building, except those of such color, size, style and in such places as are first approved in writing by Landlord. All tenant identification and suite numbers at the entrance to the Premises shall be installed by Landlord, at Tenant's cost and expense, using the standard graphics for the Building. Except in connection with the hanging of lightweight pictures and wall decorations, no nails, hooks or screws shall be inserted into any part of the Premises or Building except by the Building maintenance personnel.

5. Landlord will provide and maintain in the main lobby of the Building an alphabetical directory board and/or other directory device listing tenants, and no other directory shall be permitted unless previously consented to by Landlord in writing.

6. Tenant shall not place any additional or different lock(s) on any door in the Premises or Building without Landlord's prior written consent and Landlord shall have the right to retain at all times and to use keys to all locks within and into the Premises. A reasonable number of keys to the locks on the entry doors in the Premises shall be furnished by Landlord to Tenant at Tenant's cost, and Tenant shall not make any duplicate keys. All keys shall be returned to Landlord at the expiration or early termination of this Lease.

7. All contractors, contractor's representatives and installation technicians performing work in the Building shall be subject to Landlord's prior approval and shall be required to comply with Landlord's standard rules, regulations, policies and procedures, which may be revised from time to time.

8. Tenant shall not use the Premises so as to cause any increase above normal insurance premiums on the Building.

9. No space in the Building shall be used for manufacturing, or for the sale of merchandise of any kind at auction, or for storage thereof preliminary to such sale.

10. Landlord may from time to time adopt appropriate systems and procedures for the security or safety of the Building, any persons occupying, using, or entering the Building, or any equipment, finishings, or contents of the Building, and Tenant will comply with Landlord's reasonable requirements relative to such systems and procedures. Notwithstanding anything to the contrary contained in the Lease, Tenant is solely responsible for the security of the Premises.

11. Movement in or out of the Building of furniture or office equipment, or dispatch or receipt by Tenant of merchandise or materials requiring the use of elevators, stairways, lobby areas or loading dock areas, shall be restricted to hours designated by Landlord. Tenant shall not make deliveries to or from the Premises in a manner that might interfere with the use by any other tenant of its premises or of the Building Common Areas, any pedestrian use, or any use which is inconsistent with good business practice. Tenant shall obtain Landlord's prior approval by providing a detailed listing of the activity. If approved by Landlord, the activity shall be under the supervision of Landlord and expense of tenant must be performed in the manner required by Landlord. Tenant shall assume all risk for damage to articles moved and injury to any persons resulting from the activity. If equipment, property, or personnel of Landlord or of any other party is damaged or injured as a result of or in connection with the activity, Tenant shall be solely liable for any resulting damage or loss. Landlord reserves the right to inspect all freight to be brought into the building and exclude from the building all freight which violates any of the rules or regulations or provisions of Tenant's lease.

12. The elevator designated for freight by Landlord will be available for use by all tenants in the Building during the hours and pursuant to such procedures as Landlord may determine from time to time. The persons employed to move Tenant's equipment, material, furniture, or other property in or out of the Building must be acceptable to Landlord and a certificate of insurance must be provided to Landlord naming Landlord and Landlord's Property Manager as additional insured. All moving operations will be conducted at such times and in such a manner as Landlord will direct, and all moving will take place during non-Business Hours unless Landlord agrees in writing otherwise.

13. Landlord shall have the right to approve the weight, size, or location of heavy equipment or articles in and about the Premises. Damage to the Building by the installation, maintenance, operation, existence or removal of Tenant's Property shall be repaired at Tenant's sole expense.

14. All floor slab and beam penetrations must be reviewed and approved by Landlord's structural engineer prior to construction and will be performed by Landlord at Tenant's expense. All openings through structurally-supported concrete slabs will be corebored, sleeved, grouted, sealed and made waterproof. Sleeves, except for water closets, will extend at least two inches (2") above the finished floor.

15. Tenant shall not commit or permit any act or practice which may tend to injure the Building nor permit its equipment to be a nuisance to other tenants, nor keep merchandise on or obstruct the common areas, sidewalks or other areas outside the Premises, nor conduct or permit any fire, bankruptcy, auction or going out of business sales, nor erect, retain or display any sign, light, lettering, inscription, symbol or mark which is not approved by Landlord, nor install any antennae, fixture, or improvement outside the Premises, nor permit any loudspeaker, radio, television broadcast to be heard outside the Premises, nor sell or display merchandise outside the Premises.

16. Tenant shall not install, operate or maintain in the Premises or in any other area of the Building, electrical equipment that would overload the electrical system beyond its capacity for proper, efficient and safe operation as determined solely by Landlord. Tenant shall not furnish cooling or heating to the Premises, including, without limitation, the use of electronic or gas heating devices, without Landlord's prior written consent. Tenant shall not use more than its proportionate share of telephone lines and other telecommunication facilities available to service the Building.

17. Tenant shall not waste electricity or water in the Building premises and shall cooperate fully with Landlord to assure the most effective operation of the Building heating and air conditioning systems.

18. Corridor doors, when not in use, shall be kept closed.

19. No cooking will be done or permitted by Tenant within the Premises.

20. Tenant shall not: (1) make or permit any improper, objectionable or unpleasant noises or odors in the Building, or otherwise interfere in any way with other tenants or persons having business with them; (2) solicit business or distribute, or cause to be distributed, in any portion of the Building, handbills, promotional materials or other advertising; or (3) conduct or permit other activities in the Building that might, in Landlord's sole opinion, constitute a nuisance.

21. No flammable, explosive or dangerous fluids or substances shall be used or kept by Tenant in the Premises, Building or about the property on which the Building is located. Tenant shall not, without Landlord's prior written consent, use, store, install, spill, remove, release or dispose of, within or about the Premises or any other portion of the property on which the Building is located, any asbestos-containing materials or any solid, liquid or gaseous material now or subsequently considered toxic or hazardous under the provisions of 42 U.S.C. Section 9601 et seq. or any other applicable environmental Law which may now or later be in effect. Tenant shall comply with all Laws pertaining to and governing the use of these materials by Tenant, and shall remain solely liable for the costs of abatement and removal. Tenant shall cooperate with Landlord in minimizing loss and risk thereof from fire and associated perils. No live or artificial holiday trees or wreaths are permitted. Artificial trees and wreaths may be permitted by Landlord if any lighting thereon is approved by landlord and turned off at the end of the day.

22. Tenant shall not use or occupy the Premises in any manner or for any purpose, which might injure the reputation or impair the present or future value of the Premises or the Building. Tenant shall not use, or permit any part of the Premises to be used, for lodging, sleeping or for any illegal purpose.

23. Tenant shall not take any action which would violate Landlord's labor contracts or which would cause a work stoppage, picketing, labor disruption or dispute, or interfere with Landlord's or any other tenant's or occupant's business or with the rights and privileges of any person lawfully in the Building ("Labor Disruption"). Tenant shall take the actions necessary to resolve the Labor Disruption, and shall have pickets removed and, at the request of Landlord, immediately terminate any work in the Premises that gave rise to the Labor Disruption, until Landlord gives its written consent for the work to resume. Tenant shall have no claim for damages against Landlord or any of the Landlord Related Parties, nor shall the Commencement Date of the Term be extended as a result of the above actions.

24. Tenant shall not operate or permit to be operated a coin or token operated vending machine or similar device (including, without limitation, telephones, lockers, toilets, scales, amusement devices and machines for sale of beverages, foods, candy, cigarettes and other goods), except for machines for the exclusive use of Tenant's employees, and then only if the operation does not violate the lease of any other tenant in the Building.

25. No bicycles, vehicles, or animals (except guide dogs for the disabled) of any kind shall be brought into or kept in the Premises. Interior and exterior bicycle racks provided by the Landlord are for non-motorized vehicles only.

26. Landlord shall have the right to prohibit the use of the name of the Building or any other publicity by Tenant that in Landlord's sole opinion may impair the reputation of the Building or its desirability. Upon written notice from Landlord, Tenant shall refrain from and discontinue such publicity immediately.

27. Tenant shall not canvass, solicit or peddle in or about the Building or the property on which the Building is located.

28. The Landlord has designated the Building as a non-smoking building. Tenant acknowledges that the Building has been designated a non-smoking building. At no time shall Tenant permit its agents, employees, contractors, guests or invitees to smoke in the Building or directly outside the Building.

29. The work of cleaning personnel shall not be hindered by Tenant after 5:30 p.m., and cleaning work may be done at any time when the offices are vacant. Windows, doors and fixtures may be cleaned at any time. Tenant shall provide adequate waste and rubbish receptacles to prevent unreasonable hardship to the cleaning service.

30. Other Tenants; Changes in Use. Landlord reserves the absolute right to effect other tenancies in the Building as Landlord shall determine in the exercise of its sole business judgment. Tenant does not rely on the fact, nor does Landlord represent: (1) that as of or after the Commencement Date any specific tenant, or occupant, or the number of tenants, or occupants, shall occupy any space in the Building, (2) hours or days that such other tenants shall or may be open for business, or gross sales which may be achieved by Tenant or any other tenants in the Building, or (3) that any portion or portions of the Building shall be used for any specific purpose. A vacation or abandonment of premises or cessation of operations by any other tenant(s) in the Building or any change in the use of any portion or portions of the Building shall not in any way release Tenant from its obligations under this Lease.

31. Tenant shall not engage or pay any employees of the building without approval from the Landlord.

32. Landlord reserves the right at any time to rescind, alter or waive any rule or regulation at any time prescribed for the Building and to impose additional reasonable rules and regulations when in its judgment deems it necessary, desirable or proper for its best interest and for the best interest of the tenants and no alteration or waiver of any rule or regulation in favor of one tenant shall operate as an alteration or waiver in favor of any other tenant, provided such rules and regulations do not diminish Tenant's rights under the Lease, and provided that Landlord shall not discriminate in the enforcement of the Rules and Regulations. Landlord shall not be responsible to any tenant for the nonobservance or violation by any other tenant however resulting of any rules or regulations at any time prescribed for the Building.

33. No smoking is permitted in the building by tenant, employees, its agents, contractors, guests or invitees.

JANITORIAL SPECIFICATIONS

I. Interior Tenant Areas

Nightly Monday through Friday, excluding holidays

1. Dust mop all stone, ceramic tile, terrazzo and other type of un-waxed flooring.

2. Dust mop all vinyl, asphalt, rubber and similar types of flooring. Remove gum and other substances, spot mop if necessary.

3. Vacuum all carpeted areas.

4. Dust mop all private and public stairways and vacuum if carpeted.

5. Hand dust and wipe clean all horizontal surfaces including furniture, file cabinets, fixtures, and windowsills, using chemically treated dust cloth.

6. Remove fingerprints from all painted surfaces near light switches, entrance doors, drinking fountains, etc.

7. Remove all gum and foreign matter on sight.

8. Empty and clean all waste receptacles and remove waste materials to compactors. Replace liners as necessary.

9. Damp wash interiors of all waste disposal receptacles and wash as necessary.

10. Clean and sanitize all water fountains, and water coolers with a disinfectant solution. Wash all sinks and the floors adjacent to them on a nightly basis.

11. Spot mop floors for spills, etc.

12. Clean all low ledges, shelves, bookcases, chair rails, trim, pictures, charts etc. within reach.

13. Clean mirrors, metal work, glass tabletops.

14. Upon completion of work, all slop sinks are to be thoroughly cleaned and all cleaning equipment and supplies stored neatly in locations designated by the Management of the building.

15. All cleaning operations shall be scheduled so that a minimum of lights are to be left on at any time. Upon completion of cleaning all lights are to be turned off. All entrance doors are to be kept locked during the cleaning operation.

16. Spot clean both sides of tenant entry glass doors.

17. Spot clean desk tops and counter tops.

18. Pick up all recyclable material and take to appropriate place.

Weekly

1. Hand dust all door louvers and other ventilating louvers within reach.

2. Dust all baseboards.

3. In high traffic areas, damp mop if necessary and apply spray-buffing solution in a fine mist and buff with a synthetic pad.

4. Damp mop all non-carpeted and public stairways.

5. Wipe clean all bright work.

6. Dust all chair rails.

7. Dust walls up to normal reach.

Monthly

1. Hose vacuum underneath all furniture.

2. Dust all vertical surfaces such as walls, furniture, partitions and surfaces not reached in nightly cleaning.

3. Dust exterior of lighting fixtures.

Quarterly

1. Dust all exterior window blinds

2. Dust and/or clean all diffusers

Other

1. Cleaning of computer rooms will be responsibility of individual tenants.

2. Coffee stations and dishware are responsibility of the tenant.

II. Public Corridors, Stairwells (Emergency Egress), Service Areas

Nightly

1. Vacuum and spot clean carpeting.
2. Sweep and mop public concrete floors.
3. Sweep and mop public stairwells and landings.
4. Clean baseboards of scuffs and marks.
5. Clean all directories, signage kiosks, wall signage and electric kiosks.
6. Clean corridor glass and metal work.
7. Spot clean walls, ceilings, lights, etc.
8. Clean telephones and telephone booth areas.
9. Dust all handrails.
10. Dust to hand height all horizontal surfaces of equipment ledge, sill, shelves, radiators, frames, partitions, handrails, etc.
11. Clean exterior surfaces of all trash containers and planters.
12. Keep slop sinks, closets, supply rooms and other janitorial areas in a clean orderly condition.
13. Keep electrical and telephone closets clean and free of storage.

Weekly

1. Clean all door vents.
2. Dust all vertical surfaces within reach.
3. Sweep emergency egress stairs and landings.

Monthly

1. Wash all corridor glass and metal completely including atriums.
2. Shampoo heavily traveled carpeted areas.

Quarterly

1. Clean handrails, wall mounted equipment casings, landings, walls, kick plates in emergency egresses.
2. Shampoo and extract all carpeting.
3. Damp clean inside reflectors of high hat lighting fixtures.

III. Restrooms

Building Operating Hours

Day porters and matrons will be assigned to perform the following:

1. Empty trash containers and insert new liners.

2. Sweep and spot wash floors as necessary.

3. Spot clean sinks and mirrors. Clean and spot polish shelves and metal dispensers. Check for Graffiti and spot clean if necessary.

4. Ensure cleanliness of urinals and toilets.

5. Refill all dispenser units as needed.

Non-Operating Hours

1. Damp wash, sanitize (using disinfectant solution) and polish all fixtures including toilet bowls, urinals and wash basins.

2. Sweep and wash floors with approved germicidal solution.

3. Wash and polish mirrors, powder shelves, dispensers, hand dryers, bright work including flushometers, piping and toilet seat hinges.

4. Clean and sanitize both sides of toilet seats.

5. Empty all containers and disposal units and insert new liners.

6. Wash and sanitize interiors and exteriors of all containers prior to inserting new liners.

7. Empty, clean and sanitize all sanitary napkin disposal units.

8. Dust and spot wash where necessary partitions, tile walls, dispensers, ceiling lights, switches and receptacles.

9. Refill all dispensers to normal limits including sanitary supplies, soap, tissue, towels, etc.

10. Remove all rubbish and transport to compactor.

11. Dust ceiling door vents and doorframes.

Periodic

Monthly

1. Machine scrub all tile floors, hand brush corners and hand brush toilet edges with approved germicidal detergent solution.

2. Wash completely all partitions, tile walls and enamel surfaces.

IV. Window Cleaning

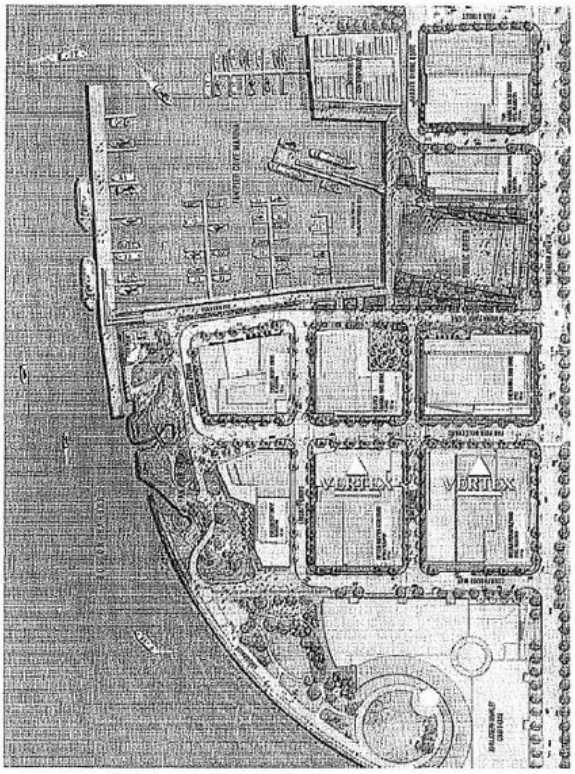
Periodic

1. Windows will be washed and cleaned a minimum of two times per year.

Exhibit E

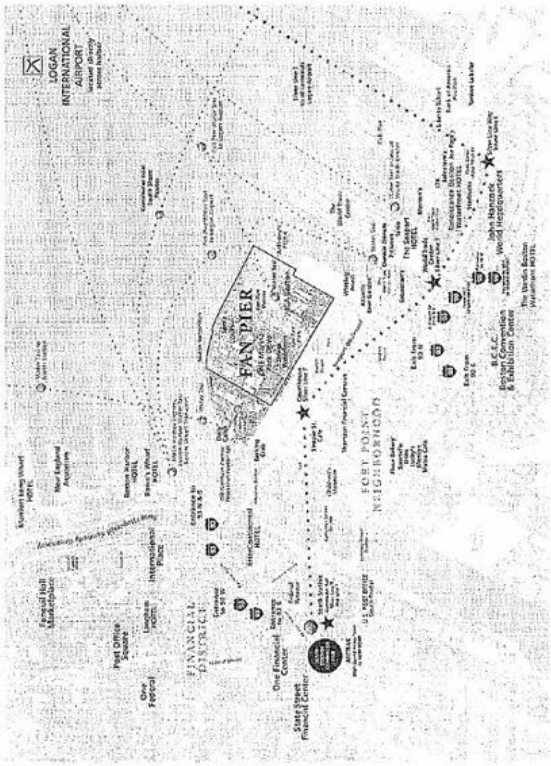
Description of Base Building Condition

FAN PIER:
CONCEPTUAL MASTER PLAN



FAN PIER:

TRANSPORTATION MAP



ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
SITEWORK			
Perimeter sidewalks, street curbs, street trees, and site furniture.	X		
Adjacent Fan Pier Park with large lawn, landscaping, and seating.	X		
BUILDING ENVELOPE			
Core and shell building has received LEED-Gold Certification	X		
Façade of insulated glass curtain wall, precast architectural concrete and natural stone.	X		
Windows and curtain wall is made up of 1" insulated dual pane tinted low E glass units glazed into high performance, thermally broken frames for maximum energy efficiency. The window wall consists of full height floor to ceiling glass with an 11" sill provided for tenant electric / telecom services and outlets at the exterior wall.	X		
Punched windows have a horizontal mullion at 34-½" maximizing view above desk height. Curtain wall elements are mullion-free from sill to ceiling. Vertical mullions and columns / pilasters typically are spaced on a 5' module. Within the typical 9' floor to ceiling office zone, on a typical upper floor there is approximately 70% glass / 30% solid wall at the exterior facade.	X		
Architecturally integrated mechanical penthouse and screened roof area with space for tenant equipment subject to Landlord approval.	X		
Modifications to façade, penthouse or screen wall system necessary to accommodate tenant requirements, provided that any such modifications must be approved by the Landlord.			X
ROOFING			
TPO thermoplastic roofing system with walking pads to all base building equipment	X		
Modifications to roofing system to accommodate tenant equipment and tenant required roof penetrations and walking pads to tenant equipment.			X

ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
STRUCTURE			
Steel framing with braced frames and composite steel and concrete floors fireproofed as required by code.	X		
Concrete floor slabs on metal deck with a live load capacity of 100 psf on the typical office floor, 150 psf in mechanical spaces.	X		
Structural upgrades, openings, modifications or other changes to the Base Building to accommodate specific tenant requirements, subject to Landlord approval.		X	
45 to 57 feet of column free space (core to glass) on typical office floors.	X		
BASE BUILDING COMMON AREAS			
Two story entrance lobby with finishes that include stone flooring, wood accent walls, venetian plaster and drywall ceilings with appropriate accent lighting. Lobby has direct interior access to Strega Waterfront as well as Cafe di Marina.	X		
Parking garage elevator lobby off first floor main lobby with 2 elevators and direct stair access to parking garage. Garage lobby finishes compliment main entrance lobby finishes.	X		
Main electrical service rooms, main telephone / data room, water and gas service rooms and fire pump room.	X		
Finished interior loading area with two truck bays and one trash bay.	X		
Common recycling room adjacent to loading dock.	X		
Base building mail room. All deliveries / pickups (FedEx, UPS, USPS etc.) to be accommodated.	X		
Toilet rooms at each floor with granite vanity with undermount sinks, contemporary fixtures, stainless steel partitions, tile floors and wet walls.	X		
Janitor closets, telephone and electric closets and egress stairways serving each floor.	X		
Accessible shower and changing room on each tenant floor.	X		

ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
BASE BUILDING COMMON AREAS (CONT.)			
Construction and finish of common corridor and elevator lobby on multi-tenant floors.	X		
GWB walls with one coat of primer at core walls at single tenant floors ready for tenant finish.	X		
Tenant entrances off common areas.		X	
Modifications to common areas provided that any such modifications must be approved by Landlord.			X
TENANT AREAS			
Insulation, vapor barrier and metal studs or curtainwall at exterior wall ready for tenant wiring / infrastructure and wall finish.	X		
Interior drywall and finish at exterior wall.		X	
Partitions, ceilings, floorings, painting, other finishes, doors, millwork, and all other office build out within tenant Premises.		X	
Building Standard window blinds at all windows.	X		
ELEVATORS			
8 high speed passenger elevators (700 FPM) with a 3,500 pound capacity. Low-rise bank serves floors 1 through 10. High-rise bank serves floors 1, 10 through 18 (transfer floor at 10).	X		
One service / freight elevator with a speed of 500 FPM and a 4,000 pound capacity serving floors 1 through 18.	X		
Two Passenger elevators with service directly from main lobby to underground parking levels B1, B2, B3.	X		

ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
HVAC			
Rooftop fresh air unit with factory fabricated package type variable air volume air conditioning units utilizing condenser water / dual compressor and free cooling section on each floor. Total cooling capacity of approx. 80 tons (65 tons for general air conditioning and 15 tons for supplemental tenant cooling).	X		
Medium pressure supply duct loop on each floor available for tenant tie-in.	X		
Hot water loop on each floor available for tenant tie-in to VAV boxes with hot water coils. Hot water for heating is supplied from high efficiency gas fired boilers located in the building's mechanical penthouse.	X		
Supply and return air distribution within tenant spaces from Landlord supplied medium pressure supply air loop including ducts, VAV boxes, fan powered units, reheat coils, piping from Landlord supplied hot water loop, diffusers, registers, grilles and controls.		X	
Ductwork, VAV boxes, fan powered units, hot water piping, reheat coils, diffusers, registers, grills and controls for first floor main lobby and core areas including toilet / shower room exhaust system.	X		
The on floor HVAC load (including electric hot water heaters and on-floor packaged AC units) is 98kW/floor or 3.9w/sf based on 25,000SF/fl. HVAC loads are fed from a separately metered switchboard and separate busway riser from the tenant busway.	X		
General exhaust riser with capped connection and constant volume box at each level.	X		
Central computerized temperature control / energy management system to optimize building operation*	X		
Temperature controls within tenant space and link to base building energy management system		X	

ONE MARINA PARK DRIVE:

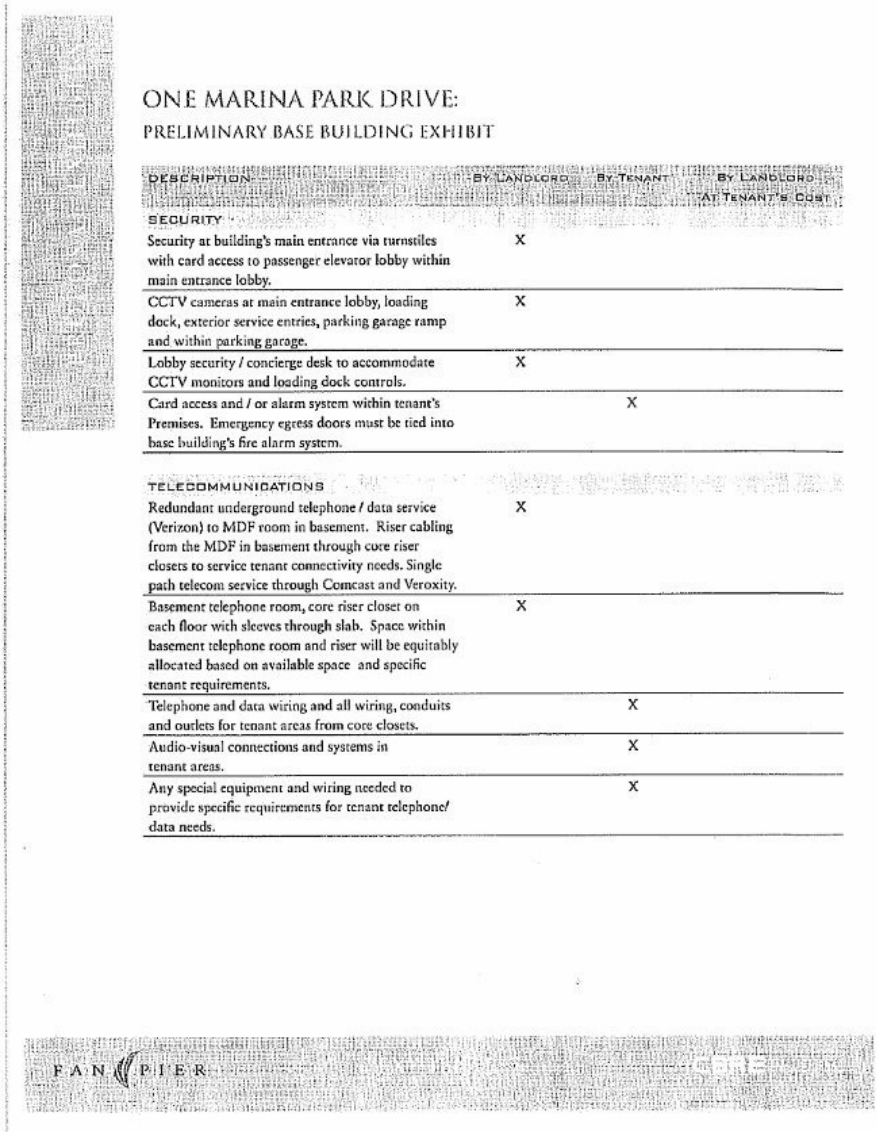
PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
PLUMBING			
Building water service from municipal water system with backflow preventer and pressure augmented by pressure boosting equipment.	X		
Waste and vent risers on each floor available for tenant tie-in.	X		
Water riser with capped and valved connections on each floor available for tenant tie-in.	X		
Plumbing, including production and distribution of hot water, to core, restroom and shower room.	X		
Distribution of domestic water from Landlord provided riser and production of hot water for tenant use.		X	
Natural gas system to supply base building heating system. Building gas service sized to allow for future restaurants, cafeteria, and generators.	X		
FIRE PROTECTION			
Sprinkler service entrance to building including fire department connection, and standpipe in each stair.	X		
Fire pump and related controls.	X		
Core and first floor main lobby sprinkler heads and piping.	X		
Primary sprinkler loop on each floor.	X		
All run outs, upturned heads, and related equipment within shell space of the building as required to obtain a building occupancy permit.	X		
Modifications to sprinkler piping and layout to suit tenant build-out.		X	
Fire extinguishers and cabinets in core areas and main entrance lobby.	X		
Fire extinguishers and cabinets in tenant areas.		X	
Base building expandable addressable fire alarm system that meets all high rise code requirements.	X		
Detection and annunciation devices in core areas and main entrance lobby.	X		
Detection and annunciation devices and wiring as required to tie into base building system.		X	

ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
ELECTRICAL			
Each tenant floor has capacity of 7.75 watts/sf for tenant lighting and power (1.25 watts/sf for lighting and 6.5 watts/sf for receptacles and miscellaneous power).	X		
Primary electric service to the building is at 13.8kV from NSTAR. NSTAR primary transformer vault is located at Parking Garage Level B2. The 13.8kV primary is stepped down at this location, to the building voltage, 480/277V 3phase 4wire primary service.	X		
480/277V Busway Duct riser through two building core electric rooms on each floor. One Busway serves floors 2 - 9 and the second Busway serves 10 -18.	X		
The main electric room has two 4000A., 480/277V, 3ph, 4w, switchboards serving the building. One 4000A., 480/277V switchboard serves tenant floors 2 -18, on floor tenant lighting, receptacles and miscellaneous office equipment. The second 4000A., 277/480V. switchboard serves the building house loads and on floor HVAC units at floors 2 - 18.	X		
Service from bus duct to point of use including metering / check metering. Tenant fit up of panels transformers, receptacles and lighting in tenant areas.		X	
Life safety emergency generator and transfer switch to provide stand-by power for code-required egress lighting, fire alarm system, elevator (one at a time) and fire pump. The base building emergency generator run time is approximately 20 hrs.	X		
Backup generator for tenant requirements including transfer switch, gas piping or diesel storage tanks and permits, controls and associated base building modifications as required.		X	
Emergency and egress lighting in core areas and main entrance lobby.	X		
Emergency egress lighting and exit lighting in tenant areas, linked to base building life safety emergency generator pannel.		X	



ONE MARINA PARK DRIVE:

PRELIMINARY BASE BUILDING EXHIBIT

DESCRIPTION	BY LANDLORD	BY TENANT	BY LANDLORD AT TENANT'S COST
SECURITY			
Security at building's main entrance via turnstiles with card access to passenger elevator lobby within main entrance lobby.	X		
CCTV cameras at main entrance lobby, loading dock, exterior service entries, parking garage ramp and within parking garage.	X		
Lobby security / concierge desk to accommodate CCTV monitors and loading dock controls.	X		
Card access and / or alarm system within tenant's Premises. Emergency egress doors must be tied into base building's fire alarm system.		X	
TELECOMMUNICATIONS			
Redundant underground telephone / data service (Verizon) to MDF room in basement. Riser cabling from the MDF in basement through core riser closets to service tenant connectivity needs. Single path telecom service through Comcast and Veroxity.	X		
Basement telephone room, core riser closet on each floor with sleeves through slab. Space within basement telephone room and riser will be equitably allocated based on available space and specific tenant requirements.	X		
Telephone and data wiring and all wiring, conduits and outlets for tenant areas from core closets.		X	
Audio-visual connections and systems in tenant areas.		X	
Any special equipment and wiring needed to provide specific requirements for tenant telephone/ data needs.		X	

FAN PIER

Exhibit F

Option to Extend Term

(a) Tenant shall have and is hereby granted the option to extend the Term of the Lease of the entire Premises (the "Extension Option") for one (1) additional period of five (5) years (the "Extension Period"), provided that: (i) Tenant gives written notice to Landlord of Tenant's election of interest to exercise the Extension Option no later than fifteen (15) months prior to the Expiration Date ("Tenant's Notice to Extend"); and (ii) no event of default exists and is continuing uncured (following notice to Tenant) at the time of the exercise of the Extension Option, or arises subsequent thereto and is not cured prior to what otherwise would have been the commencement of the Extension Period.

(b) All terms and conditions of this Lease, including without limitation all provisions governing the payment of Additional Rent, shall remain in full force and effect during the Extension Period, except that the Base Rent payable during the Extension Period shall be the then-current fair market rental rate for comparable office space in Boston at the time of the exercise of the option granted herein, taking into consideration all relevant factors (the "Current Market Rental Rate"), but in no event less than the fully-escalated Base Rent and Escalation Increases in effect for the last Lease Year of the Term, and the Base Year shall be the calendar year in which the Extension Period commences.

(c) Landlord shall notify Tenant of Landlord's proposed Base Rent for the Extension Period within thirty (30) days after Landlord's receipt of Tenant's Notice to Extend. Promptly after Landlord gives Tenant Landlord's proposal for Current Market Rental Rate with respect to the Extension Period, Landlord and Tenant shall commence negotiations to agree upon the Current Market Rental Rate. If Landlord and Tenant are unable to reach agreement on the Current Market Rental Rate within thirty (30) days after the date on which Landlord gives Tenant Landlord's proposal for Current Market Rental Rate, then the Current Market Rental Rate shall be determined as provided below.

(d) If Landlord and Tenant are unable to agree on the Current Market Rental Rate within said thirty (30) day period, then within five (5) days thereafter, Landlord and Tenant shall each simultaneously submit to the other in a sealed envelope its good faith estimate of the Current Market Rental Rate. If the higher of such estimates is not more than one hundred five percent (105%) of the lower of such estimates, then the Current Market Rental Rate shall be the average of the two (2) estimates. If the matter is not resolved by the exchange of estimates or averaging, then Current Market Rental Rate shall be determined as hereinafter provided.

(e) Within seven (7) days after the exchange of estimates, the parties shall select, as an arbitrator, a mutually acceptable commercial real estate broker licensed in the Commonwealth of Massachusetts as a real estate broker specializing in the field of commercial office leasing in the downtown Boston rental market, having no less than ten (10) years' experience in such field (an "Approved Broker"). If the parties cannot agree on such person, then within a second (2nd) period of seven (7) days, each shall select an Approved Broker and within a third (3rd) period of seven (7) days, the two (2) appointed persons shall select a third (3rd) Approved Broker and the third (3rd) person shall be the arbitrator. If one (1) party shall fail to make such appointment within said second seven (7) day period, then the person chosen by the other party shall be the sole arbitrator. Once the arbitrator has been selected as provided for above, then, as soon thereafter as practicable, but in any case within fourteen (14) days after his or her appointment, the arbitrator shall determine the Current Market Rental Rate by selecting either the Landlord's estimate of Current Market Rental Rate or the Tenant's estimate of Current Market Rental Rate. There shall be no discovery or similar proceedings and the arbitrator shall have no power or authority to make any independent determination. The arbitrator's decision as to which estimate of Current Market Rental Rate shall be the Current Market Rental Rate for the Extension Period shall be rendered in writing to both Landlord and Tenant and shall be final and binding upon them and shall be the Base Rent for the Extension Period. The costs of the arbitrator will be equally divided between Landlord and Tenant. Any fees of any counsel engaged by Landlord or Tenant, however, shall be borne by the party that retained such counsel.

(f) The parties shall execute an amendment modifying this Lease to set forth the Base Rent for the Premises during the Extension Period within ten (10) business days following the parties' agreement or, in the alternative, within ten (10) business days following the arbitrator's determination, of the Base Rent for the Extension Period, but the failure to do so shall have no effect on Tenant's otherwise valid and timely exercise of the Extension Option.

Exhibit G

Form of SNDA

SUBORDINATION, NON-DISTURBANCE AND ATTORNMENT AGREEMENT

THIS SUBORDINATION, NON-DISTURBANCE AND ATTORNMENT AGREEMENT (this " **Agreement**") is made by and between TEACHERS INSURANCE AND ANNUITY ASSOCIATION OF AMERICA, a New York corporation with offices at 730 Third Avenue, New York, New York 10017 ("**Lender**") and _____, a [an] [individual] name of state [corporation] [limited liability company] [general partnership] [limited partnership] [d/b/a/ _____] with its principal place of business at _____ ("**Tenant**").

RECITALS:

A. Lender has made or is about to make a loan (together with all advances and increases, the "**Loan**") to FALLON CORNERSTONE ONE MPD LLC, a Delaware limited liability company ("**Borrower**").

B. Borrower, as landlord, and Tenant have entered into a lease dated _____ as amended by amendments dated _____ (the "**Lease**") which leased to Tenant Suite No. _____ (the "Leased Space"), consisting of _____ rentable square feet on the _____ (_____) floor of the office building located on the Property (defined below).

C. The Loan is or will be secured by the [Open-End] Mortgage, Assignment of Leases and Rents, Fixture Filing Statement and Security Agreement recorded or to be recorded in the official records of the County of Suffolk, Commonwealth of Massachusetts (together with all advances, increases, amendments or consolidations, the "**Mortgage**") and the Assignment of Leases and Rents recorded or to be recorded in such official records (together with all amendments or consolidations, the "**Assignment**"), assigning to Lender the Lease and all rent, additional rent and other sums payable by Tenant under the Lease (the "**Rent**").

D. The Mortgage encumbers the real property, improvements and fixtures located at One Marina Park Drive in the City of Boston, County of Suffolk, Commonwealth of Massachusetts, commonly known as Fan Pier, and described on Exhibit "A" (the "**Property**").

IN CONSIDERATION of the mutual agreements contained in this Agreement, Lender and Tenant agree as follows:

1. The Lease and all of Tenant's rights under the Lease are and will remain subject and subordinate to the lien of the

Mortgage and all of Lender's rights under the Mortgage and Tenant will not subordinate the Lease to any other lien against the Property without Lender's prior consent.

2. This Agreement constitutes notice to Tenant of the Mortgage and the Assignment and, upon receipt of notice from Lender, Tenant will pay the Rent as and when due under the Lease to Lender and the payments will be credited against the Rent due under the Lease. Tenant shall have no obligation to inquire as to the propriety of any such notice from Lender, or to see to the application of any payment made by Tenant to or at the direction of Lender.

3. Tenant does not have any right or option to purchase any portion of or interest in the Property.

4. Tenant and Lender agree that if Lender exercises its remedies under the Mortgage or the Assignment and if Tenant is not then in default beyond any applicable grace and cure periods under the Lease:

(a) Lender will not name Tenant as a party to any judicial or non-judicial foreclosure or other proceeding to enforce the Mortgage unless joinder is required under applicable law but in such case Lender will not seek affirmative relief against Tenant, the Lease will not be terminated and Tenant's possession of the Leased Space will not be disturbed;

(b) If Lender or any other entity (a "**Successor Landlord**") acquires the Property through foreclosure, by other proceeding to enforce the Mortgage or by deed-in-lieu of foreclosure (a "**Foreclosure**"), Tenant's possession of the Leased Space will not be disturbed and the Lease will continue in full force and effect between Successor Landlord and Tenant; and

(c) If, notwithstanding the foregoing, the Lease is terminated as a result of a Foreclosure, a lease between Successor Landlord and Tenant will be deemed created, with no further instrument required, on the same terms as the Lease except that the term of the replacement lease will be the then unexpired term of the Lease. Successor Landlord and Tenant will execute a replacement lease at the request of either.

5. Upon Foreclosure, Tenant will recognize and attorn to Successor Landlord as the landlord under the Lease for the balance of the term. Tenant's attornment will be self-operative with no further instrument required to effectuate the attornment except that at Successor Landlord's request, Tenant will execute instruments reasonably satisfactory to Successor Landlord confirming the attornment.

6. Successor Landlord will not be:

(a) liable for any act or omission of any prior landlord under the Lease occurring before the date of the Foreclosure except for obligations of a continuing nature imposed on the landlord under the Lease;

(b) required to credit Tenant with any Rent paid more than one month in advance or for any security deposit unless such Rent or security deposit has been received by Successor Landlord;

(c) bound by any amendment, renewal or extension of the Lease that is inconsistent with the terms of the Lease or is not in writing and signed both by Tenant and landlord;

(d) bound by any reduction of the Rent unless the reduction is pursuant to the terms of the Lease or is in connection with an extension or renewal of the Lease at prevailing market terms or was made with Lender's prior consent;

(e) bound by any reduction of the term of the Lease or any termination, cancellation or surrender of the Lease unless the reduction, termination, cancellation or surrender is pursuant to the terms of the Lease or occurred during the last six (6) months of the term or was made with Lender's prior consent;

(f) bound by any amendment, renewal or extension of the Lease entered into without Lender's prior consent if the Leased Space represents fifty percent (50%) or more of the net rentable area of the building in which the Leased Space is located;

(g) INTENTIONALLY OMITTED;

(h) subject to any credits, offsets, claims, counterclaims or defenses that Tenant may have that arose prior to the date of the Foreclosure or liable for any damages Tenant may suffer as a result of any misrepresentation, breach of warranty or any act of or failure to act by any party other than Successor Landlord;

(i) bound by any obligation to make improvements to the Property, including the Leased Space, to make any payment or give any credit or allowance to Tenant provided for in the Lease or to pay any leasing commissions arising in connection with the execution of the Lease, except that Successor Landlord will be bound to comply with the maintenance and repair and casualty and condemnation restoration provisions included in the Lease; or

(j) liable for obligations under the Lease with respect to any off-site property or facilities for the use of Tenant (such as off-site leased space or parking) unless Successor Landlord acquires in the Foreclosure the right, title or interest to the off-site property.

7. Lender will have the right, but not the obligation, to cure any default by Borrower, as landlord, under the Lease. Tenant will notify Lender of any default that would entitle Tenant to terminate the Lease or abate the Rent and any notice of termination or abatement will not be effective unless Tenant has so notified Lender of the default and Lender has had a thirty (30)-day cure period (or such longer period as may be necessary if the default is not susceptible to cure despite diligent efforts within thirty (30) days) commencing on the latest to occur of the date on which (i) the cure period under the Lease expires; (ii) Lender receives the notice required by this paragraph; and (iii) Successor Landlord obtains possession of the Property if the default is not susceptible to cure without possession.

8. All notices, requests or consents required or permitted to be given under this Agreement must be in writing and sent by certified mail, return receipt requested or by nationally recognized overnight delivery service providing evidence of the date of delivery, with all charges prepaid, addressed to the appropriate party at the address set forth above.

9. Any claim by Tenant against Successor Landlord under the Lease or this Agreement will be satisfied solely out of Successor Landlord's interest in the Property and Tenant will not seek recovery against or out of any other assets of Successor Landlord. Successor Landlord will have no liability or responsibility for any obligations under the Lease that arise subsequent to any transfer of the Property by Successor Landlord.

10. This Agreement is governed by and will be construed in accordance with the laws of the state or commonwealth in which the Property is located.

11. Lender and Tenant waive trial by jury in any proceeding brought by, or counterclaim asserted by, Lender or Tenant relating to this Agreement.

12. If there is a conflict between the terms of the Lease and this Agreement, the terms of this Agreement will prevail as between Successor Landlord and Tenant.

13. This Agreement binds and inures to the benefit of Lender and Tenant and their respective successors, assigns, heirs, administrators, executors, agents and representatives.

14. This Agreement contains the entire agreement between Lender and Tenant with respect to the subject matter of this Agreement, may be executed in counterparts that together constitute a single document and may be amended only by a writing signed by Lender and Tenant.

IN WITNESS WHEREOF, Lender and Tenant have executed and delivered this Agreement as of _____, 20___.

LENDER:

TEACHERS INSURANCE AND ANNUITY
ASSOCIATION OF AMERICA,
a New York corporation

By: _____
Name: _____
Title: _____

TENANT:

_____,
a _____

By: _____
Name: _____
Title: _____

ACKNOWLEDGMENT

State of _____

County of _____

On this the ____ day of _____, 20__ before me, the undersigned officer, personally appeared _____ who acknowledged himself to be the _____I of _____, a corporation, and that he, as such _____ being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by himself as _____.

In witness whereof I hereunto set my hand and official seal.

_____

_____

Title of Officer

ACKNOWLEDGMENT

State of _____

County of _____

On this the ____ day of _____, 20__ before me, the undersigned officer, personally appeared _____ who acknowledged himself to be the _____I of _____, a corporation, and that he, as such _____ being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by himself as _____.

In witness whereof I hereunto set my hand and official seal.

_____

_____

Title of Officer

EXHIBIT A

Property Description

Exhibit H

Pro Forma Budget of FPOC Expenses

FPOC Common Area Maintenance Costs

Summary

Administration	Administration			
Salaries and Wages		$	226,200	
Office and Storage Rent		$	58,030	
Supplies		$	93,000	
Management Fee	Management Fee	$	175,000	
Audit Fee		$	15,000	This is not required under FPOC Documents
Repairs and Maintenance	R&M			
Salaries and Wages		$	187,475	
Supplies		$	172,000	
Landscaping	Landscaping			Based on high-quality 26 acre suburban office park
Landscaping		$	252,500	
Snow Management		$	210,000	This is a "wild card" - removal costs are high
Cleaning	Cleaning			
Cleaning Contract		$	109,701	Two 24-hour Public Bathrooms, Ferry Terminal, and 7-day Parkwide Maintenance
Cleaning Supplies		$	25,000	
Security	Security	$	252,252	3 Security Officers on the overnight
Dues	Dues	$	45,000	
Utilities	Utilities	$	107,000	
Insurance		$	100,000	Need to Check on this
Transportation	Transportation	$	300,000	
Public Events	Public Events	$	235,000	Based on 40+ Events
Taxes		$	-	
Capital	Capital			
Capital Reserves for Replacement		$	230,000	
Start - Up Expense Depreciation		$	43,143	
TOTAL		$	2,836,301	

PSF Costs

	Area	Civic / Cultural Area			Building Share		2008 psf		2009 psf		2010 psf
	These might not be the accurate area numbers								4% Growth		
Building A	497,420		17.0%	$	482,006	$	0.97	$	1.01	$	1.05
Building B	430,536		14.7%	$	417,195	$	0.97	$	1.01	$	1.05
Building C	241,395		8.2%	$	233,915	$	0.97	$	1.01	$	1.05
Building D	238,227	14,760	8.1%	$	230,845	$	0.97	$	1.01	$	1.05
Building E	302,105		10.3%	$	292,744	$	0.97	$	1.01	$	1.05
Building F	487,984		16.7%	$	472,863	$	0.97	$	1.01	$	1.05
Building H	221,392	26,240	7.6%	$	214,532	$	0.97	$	1.01	$	1.05
Building I	507,942		17.4%	$	492,202	$	0.97	$	1.01	$	1.05
Building J		66,000	0%								
Total	2,927,001	107,000	100.0%	$	2,836,301	$	0.97				

FPOC Management Fee Expense

	Expense Budget	Management Fee
Fixed Fee		$ 175,000

FPOC Administrative Expenses

Salaries	FPOC Allocation	Base Salary	Bonus Potential	Benefits @ 30%	Total Compensation	FPOC Cost	Subtotal
Property Manager	50%	$ 98,000	$ 15,000	$ 29,400	$ 142,400	$ 71,200	
Accounting / Reporting	50%	$ 70,000	$ 10,000	$ 21,000	$ 101,000	$ 50,500	
Administrative Support	20%	$ 50,000		$ 15,000	$ 65,000	$ 13,000	
Dock Master	50%	$ 75,000	$ 8,000	$ 22,500	$ 105,500	$ 52,750	
Director of Event Programming	50%	$ 55,000	$ 6,000	$ 16,500	$ 77,500	$ 38,750	
							$ 226,200

Office Rent	Area s.f.	S. F. Cost	Annual Cost	FPOC Cost	Subtotal
Property Manager	50% 180	$ 70	$ 12,600	$ 6,300	
Accounting / Reporting	50% 160	$ 70	$ 11,200	$ 5,600	
Administrative Support	50% 100	$ 70	$ 7,000	$ 3,500	
Dock Master	50% 120	$ 70	$ 8,400	$ 4,200	
Director of Event Programming	50% 120	$ 70	$ 8,400	$ 4,200	
Engineering Manager	30% 160	$ 70	$ 11,200	$ 3,360	
Conference Room	30% 250	$ 70	$ 17,500	$ 5,250	
Kitchen	30% 120	$ 70	$ 8,400	$ 2,520	
Common Area	30% 300	$ 70	$ 21,000	$ 6,300	
Storage Space - Equipment and Supplies	80% 600	$ 35	$ 21,000	16800	
					$ 58,030

FPOC Supplies			
Office Supplies / Rentals	50%	$ 25,000	
Telephones	50%	$ 20,000	
IT Connection / License Fees	50%	$ 45,000	
Training	50%	$ 3,000	
			$ 93,000

Audit Fees		
	$ 15,000	
		$ 15,000

FPOC Repair and Maintenance Expenses

Salaries	FPOC Allocation	Base Salary	Bonus Potential / Overtime	Benefits @ 30%	Total Compensation	FOPC Cost	Subtotal
Engineering Manager	25%	$ 96,000	$ 15,000	$ 28,800	$ 139,800	$ 34,950	
Chief Engineer	25%	$ 90,000	$ 12,000	$ 27,000	$ 129,000	$ 32,250	
Senior Engineer	25%	$ 75,000	$ 10,000	$ 22,500	$ 107,500	$ 26,875	
Engineer	50%	$ 58,000	$ 5,000	$ 17,400	$ 80,400	$ 40,200	
Engineer	50%	$ 58,000	$ 5,000	$ 17,400	$ 80,400	$ 40,200	
Administrative Support	20%	$ 50,000		$ 15,000	$ 65,000	$ 13,000	
							$ 187,475

Supplies							
Electrical Supplies	100%	$ 50,000				$ 50,000	
Plumbing Supplies	100%	$ 50,000				$ 50,000	
Generator Supplies	100%	$ 20,000				$ 20,000	
Hand Tools	100%	$ 10,000				$ 10,000	
Vehicle Maintenance	100%	$ 10,000				$ 10,000	
Equipment Maintenance	100%	$ 10,000				$ 10,000	
Hardware	100%	$ 10,000				$ 10,000	
Uniforms	100%	$ 12,000				$ 12,000	
							$ 172,000

FPOC Landscape Maintenance Cost

	FPOC Allocation						
Landscaping Contract	100%	$ 150,000				$ 150,000	
Tree/Shrub Maintenance	100%	$ 45,000				$ 45,000	
Irrigation System	100%	$ 10,000				$ 10,000	
Annual Rotations	100%	$ 35,000				$ 35,000	
Street Sweeping	100%	$ 7,500				$ 7,500	
Lawn/Plant Fertilization	100%	$ 5,000				$ 5,000	
							$ 252,500
	FPOC Allocation						
Snow Removal Contract	100%	$ 125,000				$ 125,000	
Snow Disposal	100%	$ 85,000				$ 85,000	
							$ 210,000

FPOC Cleaning Expenses

Hours	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total	
Cleaner 1	8	8	8	8	8	8	8	56	
Cleaner 2	3	3	3	3	3	3	3	21	77
Day Porter 1	8	8	8	8	8	8	8	56	
Day Porter 2	3	3	3	3	3	3	3	21	77

	Hours Quantity	Rate	Frequency	Total Cost	FPOC allocation	Annual FPOC Cost	
Contract Cleaning	77	$18	52	$ 72,072	70%	$ 50,450.40	
Day Porters	77	$18	52	$ 72,072	70%	$ 50,450.40	
Glass Cleaning	10	$25	4	$ 1,000	100%	$ 1,000.00	
Trash Removal	1	$150	52	$ 7,800	100%	$ 7,800.00	
							$ 109,701

Cleaning Supplies	**$ 25,000**

FPOC Dues and Subscriptions Expense

Save the Harbor Save the Bay	$ 10,000	
The Boston Harbor Association	$ 10,000	
Friends of Fort Point Channel	$ 10,000	
Seaport Transportation Management Association	$ 10,000	
BOMA	$ 5,000	
		$ 45,000

FOPC Security Costs

Security Contract Services	Hours Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total Hours
Security Officer 1	8	8	8	8	8	8	8	56
Security Officer 2	8	8	8	8	8	8	8	56
Security Officer 3	8	8	8	8	8	8	8	56
Security Officer 4	8	8	8	8	8	8	8	56
Security Supervisor	3	3	3	3	3	3	3	21
								245

	Hours Quantity	Rate	Frequency	Total Cost	FPOC allocation	Annual FPOC Cost	Total
Security Officers	245	$22	52	$ 280,280	90%	$ 252,252	
							$ 252,252

FPOC Transportation Expenses

Water Transportation Subsidy	$ 150,000	
Surface Transportation Subsidy	$ 150,000	
		$ 300,000

FPOC Utilities Costs

Electricity		
Site Lighting	$ 30,000	
Water Transportation Dock	$ 3,500	
Floating Wave Attenuator	$ 3,500	
Public Bathrooms	$ 10,000	
Water	$ 50,000	
Sewer	$ 10,000	
		$ 107,000

FPOC Capital Start-up Costs and FPOC Reserve for Replacement

Start-up Costs		FPOC Allocation	Cost	FPOC Costs	Estimated Life	Annual Depreciation	
Sidewalk and Roadway Sweeper	1	50%	$ 40,000	$ 20,000	7	$ 2,857	
Bobcat and Attachments	1	80%	$ 25,000	$ 20,000	7	$ 2,857	
Cricket Transportation Vehicle	1	100%	$ 25,000	$ 25,000	7	$ 3,571	
Holiday Decorations	1	100%	$ 35,000	$ 35,000	7	$ 5,000	
Pick-up Truck	1	80%	$ 20,000	$ 16,000	7	$ 2,286	
Mobile Stage/AV/Lighting	1	100%	$ 150,000	$ 150,000	7	$ 21,429	
Maintenance Cart	2	80%	$ 10,000	$ 16,000	7	$ 2,286	
Small Tools	1	100%	$ 20,000	$ 20,000	7	$ 2,857	
			$ 325,000	$ 302,000			$ 43,143

Reserve for Capital Replacement		FPOC Allocation	Cost	FPOC Costs	Annual Reserve
Road Maintenance / Repairs	1	100%	$ 85,000	$ 85,000	
Sidewalk Maintenance / Repairs	1	100%	$ 85,000	$ 85,000	
Street Furniture Replacement	1	100%	$ 25,000	$ 25,000	
Interior Capital Repalcement	1	100%	$ 25,000	$ 25,000	
Shade Structure on WTD	1	100%	$ 10,000	$ 10,000	
					$ 230,000

FPOC Public Events Programming Expenses

Public Events	Quantity	Cost		
Movies	10	$2,500	$ 25,000	
Concerts	10	$5,000	$ 50,000	
Ballroom/Swing Dancing	10	$5,000	$ 50,000	
Family Events	10	$5,000	$ 50,000	
Holiday Decorations	1	$35,000	$ 35,000	
Other	1	$25,000	$ 25,000	
				$ 235,000

Exhibit I

Memorandum Outlining Landlord's Sustainable Design Strategies

ONE MARINA PARK DRIVE:

SUSTAINABLE DESIGN STRATEGIES

LEED (Leadership in Energy and Environmental Design) is a tool to help design teams and owners define project goals, identify green design strategies, measure and monitor progress and documents success. The LEED rating system provides criteria for credits earned for addressing specific environmental impacts of building design, construction operations and maintenance in five key areas – sustainable site development, water savings, energy efficiency, material selection and indoor air quality. ONE Marina Park Drive has attained a Gold rating from the US Green Building Council.

Some of the key "Green" features of ONE Marina Park Drive that helped it achieve the Gold rating include the following:

- ONE Marina Park Drive's heating / ventilation / air conditioning system is designed to reduce energy consumption by 10 – 15% compared to the already stringent requirements of the Massachusetts State Energy Code.
- ONE Marina Park Drive uses innovative, water efficient plumbing fixtures that will reduce water use by over 30%.
- To increase indoor air quality, ONE Marina Park Drive uses sophisticated ventilation control systems that will deliver, when needed, filtered outdoor fresh air to the occupied spaces at least 30% above standard. In addition, indoor air contaminants are reduced through the use of low-emitting paints, coatings, adhesives, sealants, and composite wood products and carpets.
- At least 10 % of the material used to construct ONE Marina Park Drive was recycled material.
- A construction waste management plan has been developed that will divert from the waste stream and recycles at least 50% of construction debris.
- At least 50% of the wood-based materials in the project is certified to have been grown, harvested and produced in a sustainable manner.
- To reduce the burden on transportation infrastructure and fuel consumption associated with transportation, at least 10% of the materials used to construct ONE Marina Park Drive were extracted, processed and manufactured within 500 miles of the project site.
- To accommodate bicycle commuters, bicycle racks are provided in the underground parking garage and a shower and changing room is provided on every office floor.
- To encourage the use of low-emitting and fuel efficient vehicles at least 5% of the parking spaces within the underground parking garage are reserved for preferred parking for hybrid and fuel efficient vehicles.
- To encourage carpooling and reduce the number of single occupant vehicle trips to the site, at least 3% of the parking spaces within the underground parking garage will be reserved for preferred parking for carpools and vanpools.
- Over 52% of Fan Pier will be publicly-accessible open space. New park space will be created along the entire length of the waterfront as well as on the former parking lot adjacent to ONE Marina Park Drive. Park space is designed to promote storm water infiltration and reduce runoff. Plant species have been selected and the irrigation system has been designed to reduce the amount of water required for irrigation.
- As part of the development of the marina, the Fan Pier Cove bottom will be re-contoured, improving the marine habitat within the cove. Also, granite blocks will be will be removed from the harbor bottom adjacent to the sea wall to enhance the marine habitat for native fish species.

FAN PIER

Exhibit J

OTIS

ONE MARINA PARK DRIVE

Office Building at the Fan Pier, Boston, Massachusetts

OFFICE TENANT
INTERIOR STANDARDS

ELKUS | MANFREDI
ARCHITECTS

1. OVERVIEW : OUTLINE OF SYSTEMS AND TENANT PROVISIONS

1.1 Code
1.2 Structural
1.3 Architectural, Building Materials, Interior Finishes
1.4 Mechanical
1.5 Electrical
1.6 Plumbing
1.7 Fire Protection
1.8 Tel / Data
1.9 Security

2. KEY PLANS AND BUILDING INTERFACE DETAILS

2.1 Infrastructure Key Plans

A. EXHIBIT 1- Garage Level B-1 Plan
B. EXHIBIT 2- Level 1, Ground Floor
C. EXHIBIT 3- Level 2 Core
D. EXHIBIT 4- Typical Floor Cores, Levels 3-18
E. EXHIBIT 5- Penthouse / Roof Plan
F. EXHIBIT 6- Typical Floor Section

2.2 Details at Office Levels 2-18

A. EXHIBIT -7 Column Enclosure at Curtainwall
B. EXHIBIT -8 Column Enclosure at Curtainwall; corner condition
C. EXHIBIT -9 Interior Wall / Curtainwall Condition
D. EXHIBIT -10 Head and sill detail, Bay Window, Floor 2
E. EXHIBIT -11 Head and sill detail, Ribbon Window, Floor 3
F. EXHIBIT -12 Head and sill detail, typical punched opening, Floors 4-18
G. EXHIBIT -13 Head and sill detail, typical curtainwall condition, Floors 2-18

2.3 Elevator Lobbies

A. EXHIBIT -14 Elevator Lobby – Single Tenant Floor Plan
B. EXHIBIT -15 Elevator Lobby – Single Tenant Lobby Elevation
C. EXHIBIT -16 Elevator Lobby – Multi Tenant Floor Plan
D. EXHIBIT -17 Elevator Lobby – Multi Tenant RCP
E. EXHIBIT -18 Elevator Lobby – Multi Tenant Lobby Elevation

3. SUSTAINABILITY (LEED)

One Marina Park Drive, the first class A office tower at Fan Pier, is an 18 story building, approximately 525,000 square feet, designed to accommodate 2 floors of "streetscape" retail and 16 levels of office space. Additionally, the building includes 3 levels of underground parking.

The first class building lobby, two stories in height with glass exterior walls, will command spectacular views of the waterfront park and marina; finishes to include natural stones and woods. The lobby provides direct access to approximately 375 self-park parking spaces located in a 3 level underground parking garage directly beneath the building. It will also provide amenities and services such as 24 hour security, concierge and access to restaurants and café's.

The office tenant floors, 16 floors at approximately 29,000 sq. ft. each, provide over 465,000 square feet of gross area. The floor plate size along with a 55' column free span between the building core and exterior wall provides office tenants design flexibility for both open and closed office configurations.

1. OVERVIEW : OUTLINE OF SYSTEMS AND TENANT PROVISIONS

1.1 CODE

Construction Type

Type 2A, protected, non combustible construction as specified in 780 CMR Table 602

Occupancy Types

One Marina Park Drive is designed for the following non-separated mixed-uses as per 780 CMR §313.1.1:

Use Group Classification	Uses*
Use Group A-3, Assembly	Conference/Meeting Rooms, Restaurants
Use Group B, Business	Offices
Use Group F-2 / F-2	Mechanical Equipment Rooms
Use Group M, Mercantile	Retail Shops
Use Group S-1 / S-2, Storage	Storage Rooms
Use Group S-2, Storage	Passenger Vehicle Parking Garage

1.2 STRUCTURAL

The structure is designed to accommodate a floor live load 100 lbs. (including partitions).

The structure consists of a concentrically braced core supporting a composite steel and concrete floor, with substantially column free floors from core to perimeter wall. Floor to floor heights are 18'-0" at floor 1, 16'-8" at floor 2 (to accommodate retail tenants), and 12'-6" at the typical office floors. Typical floor ceiling height, floors 3-18, is 9'-0" measured from the core floor.

Minimum floor leveling requirements will be ¼" over 10'.

The structure can be locally reinforced to accommodate the use of high density filing systems or other special loading requirements on a case-by-case basis. Work must be reviewed and approved by Landlord's structural engineer prior to construction and will be at Tenant's expense.

All floor slab and beam penetrations must be reviewed and approved by Landlord's structural engineer prior to construction and will be at Tenant's expense. All openings through structurally-supported concrete slabs will be fire safed, sleeved, grouted, sealed and made waterproof. Sleeves, except for water closets, will extend at least two inches (2") above the finished floor.

1.3 ARCHITECTURAL

Curtainwall: High performance, thermally broken frames based on Kawneer 1600 or equal, designed and engineered in accordance to Massachusetts State Building Code

Glazing: 1" insulating unit, tinted low E,

Base Building Lobby: Security / concierge desk, direct access to parking and abutting retail, direct access to back of house space (loading, recycling, mail) entries at Northern and Marina Park Drive

Enclosed Loading docks: Accommodations have been made for (2) 35' trailers as well as a waste dumpster sized for both retail and office use. Hydraulic dock levelers and dock bumpers are provided at each dock. The loading area has direct and secure access to the dedicated service elevator.

A recycling room has been provided for tenant use adjacent to the loading / and trash area. Recycling to be managed by owner.

Base building mail room is located at the first floor service area adjacent to the secured building elevator lobby. All deliveries / pick ups (FedEX, UPS, USPS, etc.) to be accommodated.

Elevators

Office Passenger Elevators:

(4) passenger elevators, 3500# capacity @ 700 fpm, serving floors 1-10

(4) passenger elevators, 3500# capacity @ 700 fpm, serving floors 1, 10-18

Dedicated Service Elevator:
(1) service elevator, 4500# capacity @ 500 fpm, serving floors 1-18
Service elevator has direct access to enclosed loading dock

Garage Elevators:
(2) garage passenger elevators, 2500# capacity @ 350 fpm serving floors 1 and B1-B3

All elevator cab interior finishes by owner. Elevator call buttons and hall lanterns are satin stainless steel. Elevator doors are satin stainless steel (floors 1-2) and painted steel (floors 3-18)

Signage:
For all typical office tenants, identity signage which faces a public corridor or lobby, or is visible from the exterior shall be approved by the Landlord.

Signage provided by owner:
Exterior:
1.Exterior building main entrance signage-address identity
2.Loading dock door signage
3.Service entry information signage

Interior:
1.Interior common rooms identity signage
2.Floor level identity signage (inside and outside of stairwell door)
3.Elevator information (lobby) signage
4.Interior code required core/shell signage

Door and Hardware

Tenant Doors:
Entry doors at single tenant floors and multi-tenant corridors to be approved by owner. Framed glass, herculite, and wood doors acceptable

Base Building Core Doors (by owner):
Service doors: Hollow metal doors primed, hollow metal frames primed
Floor Elevator Lobby Vestibules: Solid wood doors (on hold opens) primed, hollow metal frames primed
Bathrooms, shower room, janitor closet: Solid wood door painted, hollow metal frame painted

Closers:
All Tenant door closers shall be installed on the Tenant side.

Door hardware:
Care should be taken to coordinate the hardware finish with all other adjacent finishes. Tenant hardware shall match base building hardware standard in common/public areas; satin stainless steel.

All tenant locks on doors to premises must be part of the Landlord's master key system to assure fire department access to all areas. The Landlord's master key system is a SMALL FORMAT INTERCHANGABLE CORE (SFIC) with 6-pins.

Hollow metal doors and frames:
Provide welded, mitered frame construction at locations facing Building Common Corridors. Knock-down frames are permitted within Tenant space.

Ceiling Finish :

Building Perimeter (at windows): It is the owner's goal to maintain a consistent appearance from the exterior. White acoustical ceiling tiles (2x2), or white drywall soffits at 9'-0" A.F.F.are acceptable

Office Floor Elevator Lobbies (single tenant): To be designed by tenant, approved by owner

Multi-tenant corridors: Owner provided drywall ceiling at elevator lobby and ACT at corridors

Building core (service rooms, toilet rooms): Provided by owner.

Paint / Wall Standards:

Office Floor Elevator Lobbies (single tenant) To be designed by tenant, approved by owner

Multi-tenant corridors: painted / maintained by owner

Building core (service rooms, toilet rooms): painted / maintained by owner

Column Enclosures:

Building Perimeter (at windows): a consistent appearance from the exterior is desired; column enclosures (by tenant) to be of drywall construction, (square, tight to column) and painted a neutral color.

Perimeter Window Sills:

Building Perimeter (at windows): All window sills are at approximately 8" to 11" AFF to allow for elec. and tel/data at the perimeter (by tenant). Window sill framing by owner and finish by tenant.

Window Blinds:

Exterior windows, floors 2-18: Owner to supply building standard blinds for installation by tenant. Special blind conditions (black out shades at conference rooms, etc) are by the tenant and to be approved by owner

1.4 MECHANICAL / HVAC

The HVAC systems will be capable of maintaining indoor conditions no higher than 78°, 50% RH when outdoor conditions are no higher than 91°F DB and 74°F WB, and no lower than 72°F DB when the

outdoor conditions are no lower than 9°F DB. No provision for humidification is provided in the base building system. Tenant may install humidification if required for tenant's specific needs.

Outdoor air will be introduced to the building at a minimum rate of 20 cfm per person, assuming one person per 150 square feet of gross usable floor area.

Internal heat gain will be calculated on the basis of sustained peak loading conditions of one person per 150 square feet of gross usable floor area and a combined lighting and power load of 5.0 watts per gross usable square foot area

Heated supply air temperature will be 95°F to 110°F. Cooled supply air temperature will be 55°F to 58°F.

Total cooling capacity per floor is 80 tons (65 tons for general air conditioning and 15 tons for supplemental cooling).

Perimeter zones typically 15 feet deep by maximum 40 feet length or as dictated by perimeter offices. Interior zones maximum 2000 square feet area. The Titus TBDI-10, 4 foot split throw linear diffuser was used as the basis of design for a perimeter linear diffuser.,

Gas-fired hot water heating system: Building hot water is circulated throughout the public areas via variable speed pumps. Hot water loop on each office floor is available for tenant tie-in. Hot water supply temperature shall be +/-180°F. Heating for typical office tower floor shall be via fan boxes with hot water heating coils. The HWS/R piping loop is provided under base building, the tie in connections to (FP VAV boxes) are under tenant fitout. Tenant to provide isolation valves and balancing shutoff valves at each piece of equipment.

A central automatic temperature control system consisting of direct digital controls (DDC) and appurtenances is provided for tenant use by base building owner. Connections of fan powered boxes, pumps and associated systems, and the tie into the owner's central control system is by tenant.

A General exhaust duct riser with 14 inch X 12 inch capped connections and constant volume box, has been provided at each level by owner.

Sound attenuation has been provided by owner at the the following locations:

- All Mechanical Equipment Room ductwork is externally insulated
- Attenuation sound traps and insulation are located at all locations where ductwork exits the MER
- All Medium Pressure ductwork is fully insulated (external) throughout

Provisions for on-floor supplemental (24/7) cooling via capped and valved condenser water connections sized for 15 tons per floor is provided by landlord. If the tenant chooses to utilize this excess capacity, the tenant will be responsible for the cost of condenser water at the prevailing rate. The consumption will be determined by a water meter installed on the condenser water line by the Tenant.

Tenant shall not furnish cooling or heating to the Premises, including, without limitation, the use of electronic or gas heating devices, without Landlord's prior written consent.

1.5 ELECTRICAL

Electrical power distribution system will be at 480/277 volts, 3 phase, 4-wire fed from two unit substations stepping down utility 13.8kV service to 480/277V. Dry type transformers will be utilized to step down 480V. to 208/120V. power for respective equipment. Distribution system will supply power as follows:

480 volts, 3 phase to all mechanical, plumbing, and fire protection equipment motors ½ horsepower and larger and electric heating equipment 3kW and larger.

277 volts, single phase to all fluorescent and H.I.D. lamp type luminaires.

120 volts, single phase to all incandescent luminaires.

120 volts, single phase to all general convenience receptacle outlets.

120 volts, single phase; 208 volts, single phase and/or 208 volts, 3 phase to equipment utilizing direct connections or receptacles, as determined by requirements of specific equipment.

Tenant floors 2 - 18 are served via two busways that rise vertically through the buildings core electric rooms:

- One busway serves floors 2 - 9 and the other serves floors 10 -18. The plug-in busways serve on floor tenant lighting, receptacles and miscellaneous office equipment. Each tenant floor has capacity of 7.8 watts/SF for tenant lighting, receptacles and miscellaneous office equipment. This is roughly 40 amps for lighting at 277/480V(1.25w/sf) and 450 amps (6.5w/sf) for receptacles and miscellaneous power at 120/208V.
- The tenant is responsible for the plug-in disconnect on the busway at each floor and distribution beyond that point. (panels and transformers).

Tenant shall not install, operate or maintain in the Premises or in any other area of the Building, electrical equipment that would overload the electrical system beyond its capacity for proper, efficient and safe operation as determined solely by Landlord.

Metering will be accomplished as follows:

- Service to the building is primary metered at the NSTAR primary meter room.
- *Separate Meters:* Tenant space shall be separately metered for electrical consumption which shall include, but not be limited to, lights, plugs and power (including, without limitation, power for the fans for VAV boxes). Tenant shall install said meter(s), at its expense, and shall pay the utility company directly for its actual consumption as measured by the meter(s).

The emergency electrical power system will consist of:

- Diesel powered emergency generator sized to meet the power demands of base building emergency and standby equipment. Generator will be located in the rooftop mechanical penthouse.

- An emergency power distribution system will supply power to the following: luminaries illuminating egress passages and stairs, exit signs, elevators (one-at-a-time basis), fire alarm system, fire pump, stairwell smoke supply and exhaust fans, security equipment, garage exhaust fans, cooling tower pan heaters, generator fuel oil pumps, circulating pumps, ATC equipment, building management equipment.

- Automatic transfer switches will transfer the building distribution system to the emergency power system. Transfer switches will be provided for emergency distribution system, elevators and standby loads.

- Tenant is responsible for back-up generation, if required by tenant, including transfer switch, fuel distribution to generator, controls, associated base building modifications and permits as required.

1.6 PLUMBING

- Domestic water system will be supplied by metered service from a public water main, with operating pressure provided above code standard, 40 psi. Electric domestic water heaters serving 3 to 4 floors with a recirculation system will be provided for toilet room hot water.

- Natural gas system to supply base building heating system. Building gas service is sized to allow for future restaurants, future generators, and future tenant cooking loads.

- The building will have one (1) water cooler per floor, specified for lead-free fabrication, compliant with ADA accessibility guidelines (Hi-lo fountain).

1.7 FIRE PROTECTION

The Base Building provides distribution piping and sprinkler heads for common areas such as mechanical rooms, toilets, etc. and general coverage (15' x 10' grid) with upturned heads in Tenant areas. Each floor's loop will be individually valved off the riser and can be drained.

1.8 TELEPHONE / DATA

Main Data Room- Redundant underground telephone and data service is provided to the MDF Room at Garage level B-1. Provisions have also been made for connectivity to all future Fan Pier buildings; conduits by owner.

Tenant Riser- Sleeves by owner, tel data feeds by tenant and service provider
A total of (3) 4" sleves provided at each tenant floor in tele/data rooms, levels 2-18

Tenant shall not use more than its proportionate share of telephone lines and other telecommunication facilities available to service the Building.

1.9 SECURITY

Lobby - 24/7 Security desk, passenger elevator lobby secured by turnstiles, cameras throughout lobby

Elevators – Card readers in all (8) passenger elevators serving floors 1-18

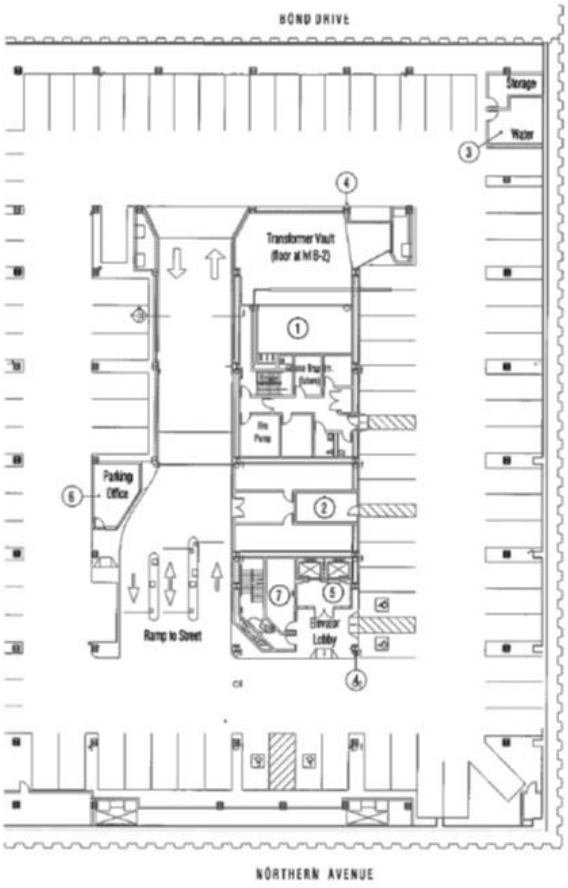
Back of House Spaces- Card readers provided by owner at all corridor doors and exterior loading dock. Cameras are also located throughout the loading dock area

Stairwell doors will accommodate tenant card readers; Circuitry, card reader, and any hardware modifications to be provided by tenant and approved by owner

2. KEY PLANS AND BUILDING INTERFACE DETAILS

NOTES:

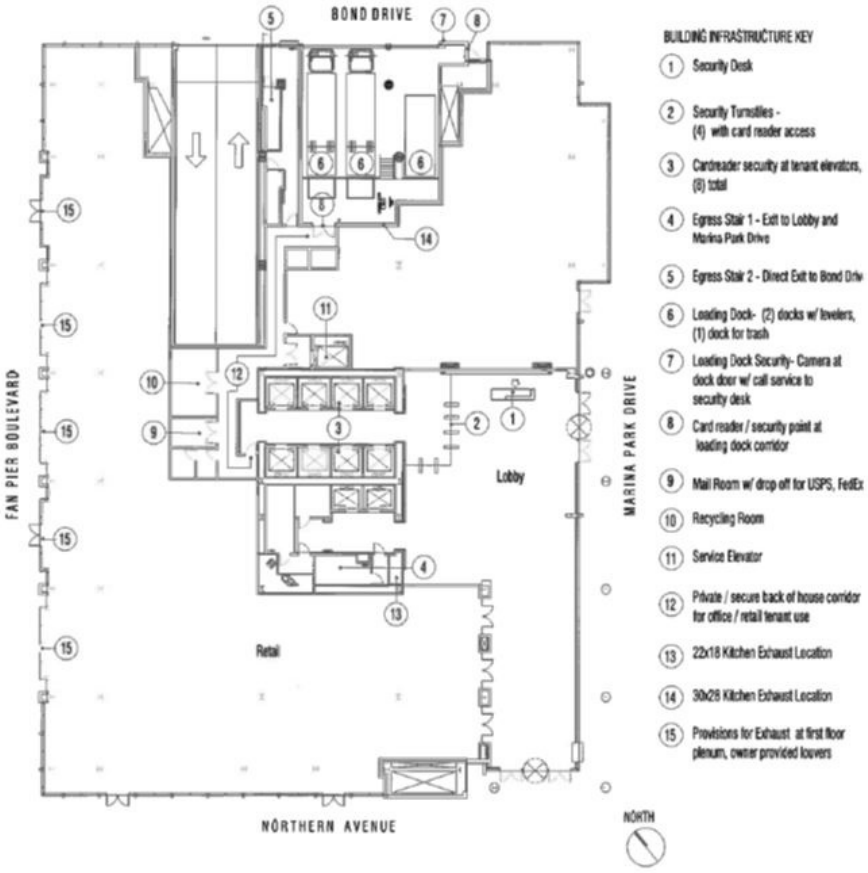
- All utility points and connections shown diagrammatically; refer to record drawings for exact dimensions
- All architectural details at the interface of the base building exterior wall and the tenant interior fit-out must be approved by the Owner. Careful attention should be given to maintaining a consistent appearance of the interior from the exterior.



BUILDING INFRASTRUCTURE KEY

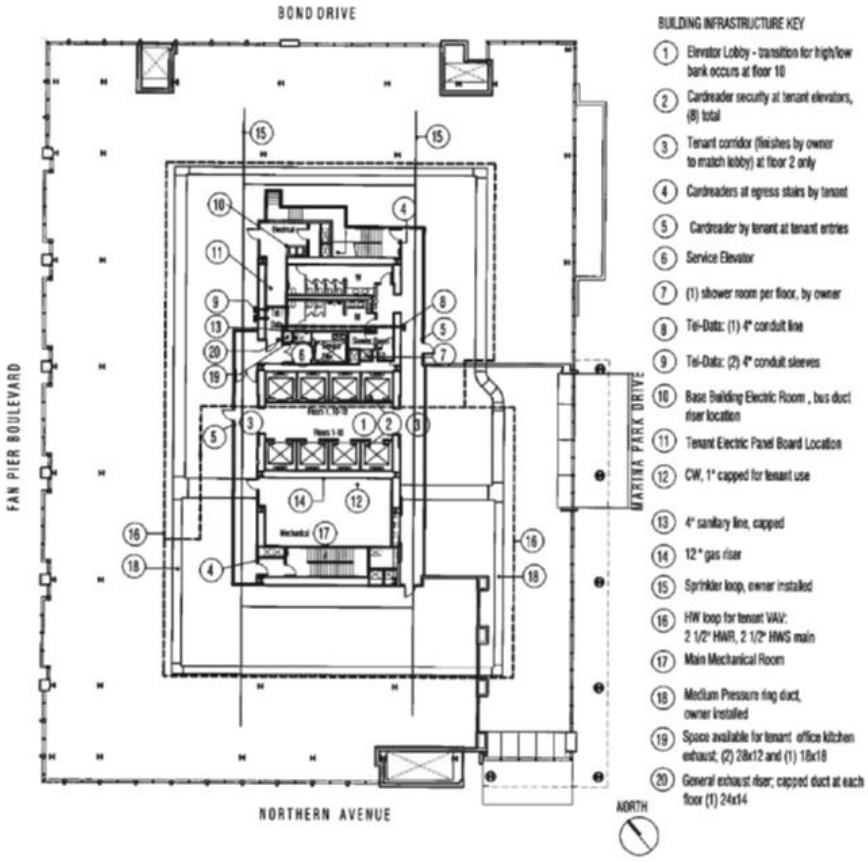
1. Main Electric Room, Access at B-2 Level 13.8 KV service distributed as 480/277V, 3 phase, 4 wire fed
2. Main Tel / Data Room
   - Primary feed from Marina Park Drive
   -Secondary Feed from Northern Ave
   -Provisions for connectivity to Parcels A and E
3. Main Water Meter Room
4. Security Call Box Locations , all floors
5. Elevators to building lobby only, monitored by security desk
6. Parking Service Office w/ Attendant
7. Building Engineering Office

GARAGE LEVEL B-1 INFRASTRUCTURE KEY PLAN
EXHIBIT 1



LEVEL 1 INFRASTRUCTURE KEY PLAN
EXHIBIT 2

ELKUS | MANFREDI ARCHITECTS

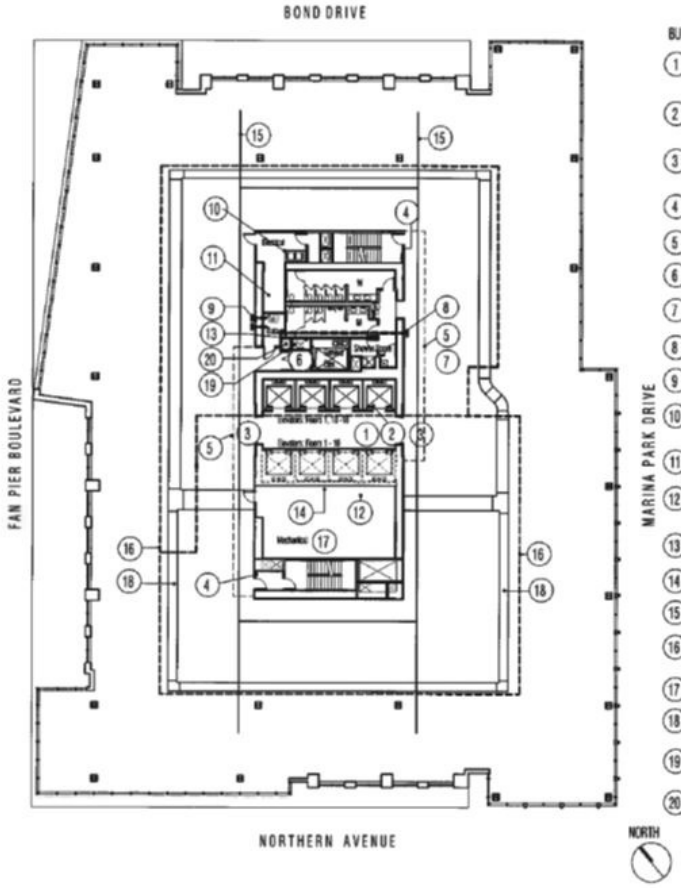


BUILDING INFRASTRUCTURE KEY

1. Elevator Lobby - transition for high/low bank occurs at floor 10
2. Cardreader security at tenant elevators, (8) total
3. Tenant corridor (finishes by owner to match lobby) at floor 2 only
4. Cardreaders at egress stairs by tenant
5. Cardreader by tenant at tenant entries
6. Service Elevator
7. (1) shower room per floor, by owner
8. Tel-Data: (1) 4" conduit line
9. Tel-Data: (2) 4" conduit sleeves
10. Base Building Electric Room , bus duct riser location
11. Tenant Electric Panel Board Location
12. CW, 1" capped for tenant use
13. 4" sanitary line, capped
14. 12" gas riser
15. Sprinkler loop, owner installed
16. HW loop for tenant VAV: 2 1/2" HWR, 2 1/2" HWS main
17. Main Mechanical Room
18. Medium Pressure ring duct, owner installed
19. Space available for tenant office kitchen exhaust; (2) 28x12 and (1) 18x18
20. General exhaust riser; capped duct at each floor (1) 24x14

LEVEL 2 INFRASTRUCTURE KEY PLAN
EXHIBIT 3

ELKUS | MANFREDI ARCHITECTS

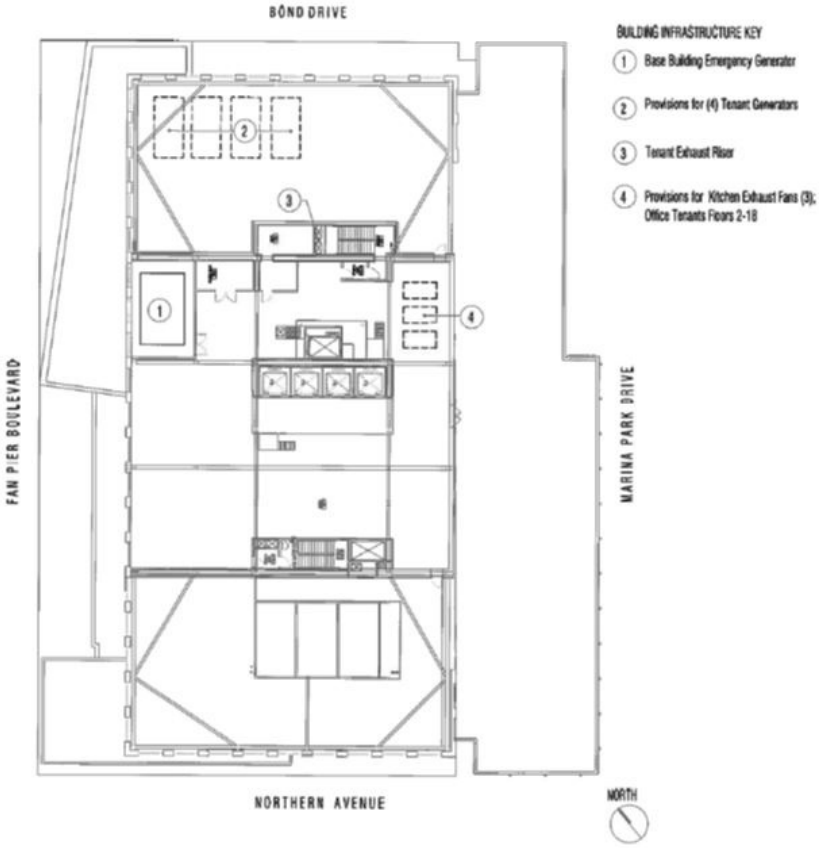


BUILDING INFRASTRUCTURE KEY

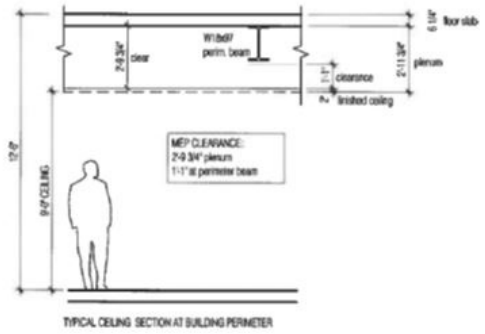
1. Elevator Lobby - transition for high/low bank occurs at floor 10
2. Cardreader security at tenant elevators, (8) total
3. Tenant corridor layout (if required)
4. Cardreaders at egress stairs by tenant
5. Cardreader at tenant entries, by tenant
6. Service Elevator
7. (1) shower room per floor, by owner
8. Tel-Data: (1) 4" conduit line
9. Tel-Data: (2) 4" conduit sleeves
10. Base Building Electric Room , bus duct riser location
11. Tenant Electric Panel Board Location
12. CW, 1" capped for tenant use
13. 4" sanitary line, capped
14. 12 " gas riser
15. Sprinkler loop, owner installed
16. HW main for tenant VAV: 2 1/2" HWR, 2 1/2" HWS main
17. Main Mechanical Room
18. Medium Pressure ring duct, owner installed
19. Space available for tenant office kitchen exhaust; (2) 28x12 and (1) 18x18
20. General exhaust riser; capped duct at each floor (1) 24x14

TYPICAL FLOOR, OFFICE TOWER, INFRASTRUCTURE KEY PLAN

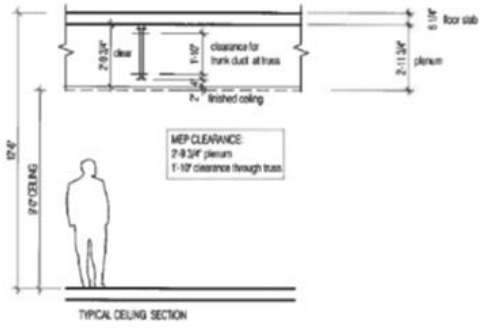
EXHIBIT 4



PENTHOUSE / ROOF PLAN INFRASTRUCTURE KEY PLAN
EXHIBIT 5

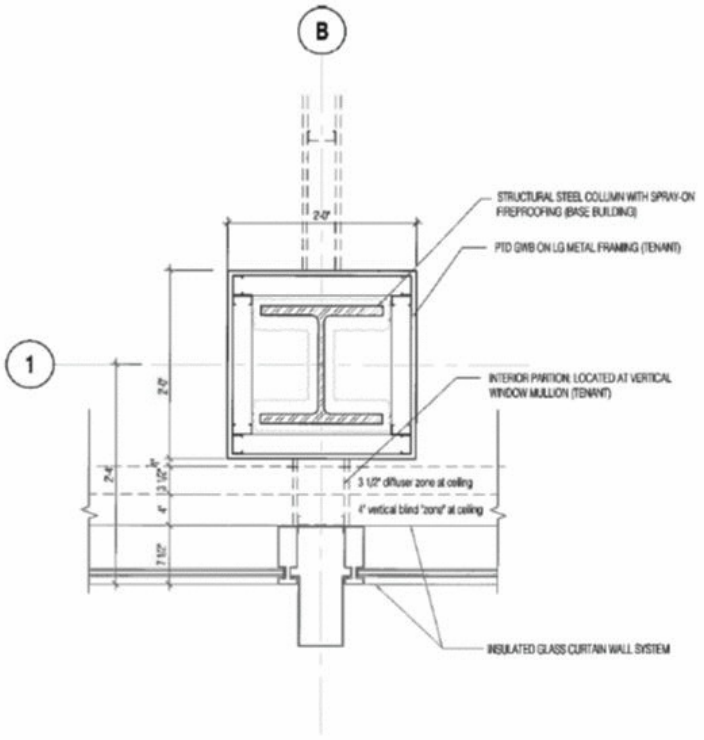


TYPICAL CEILING SECTION AT BUILDING PERIMETER

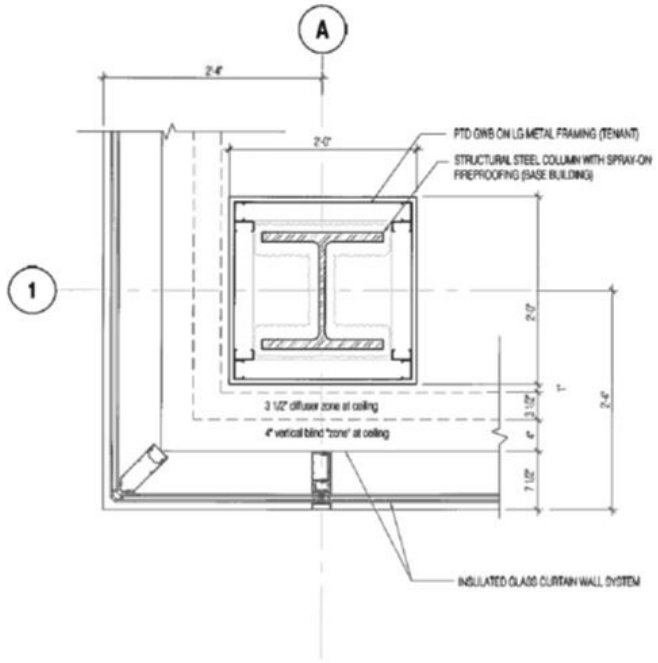


TYPICAL CEILING SECTION

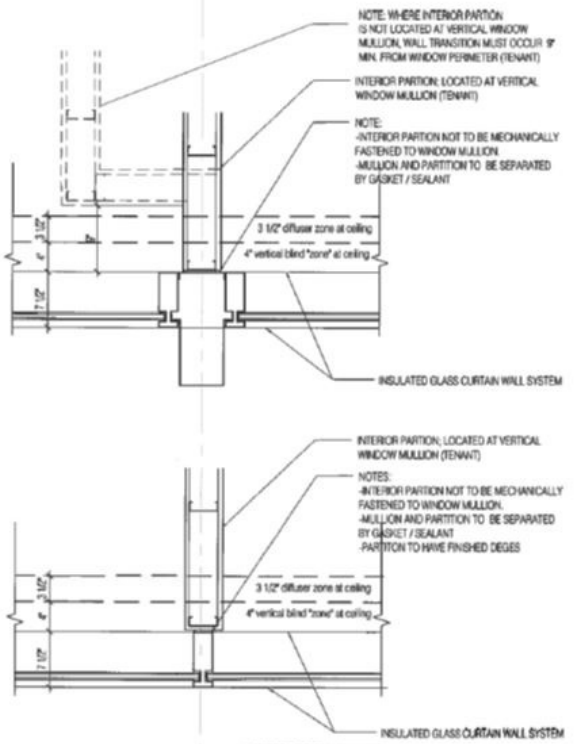
TYPICAL FLOOR SECTION , CEILING / PLENUM DIMENSIONS
EXHIBIT 6



COLUMN ENCLOSURE AT CURTAINWALL
EXHIBIT 7

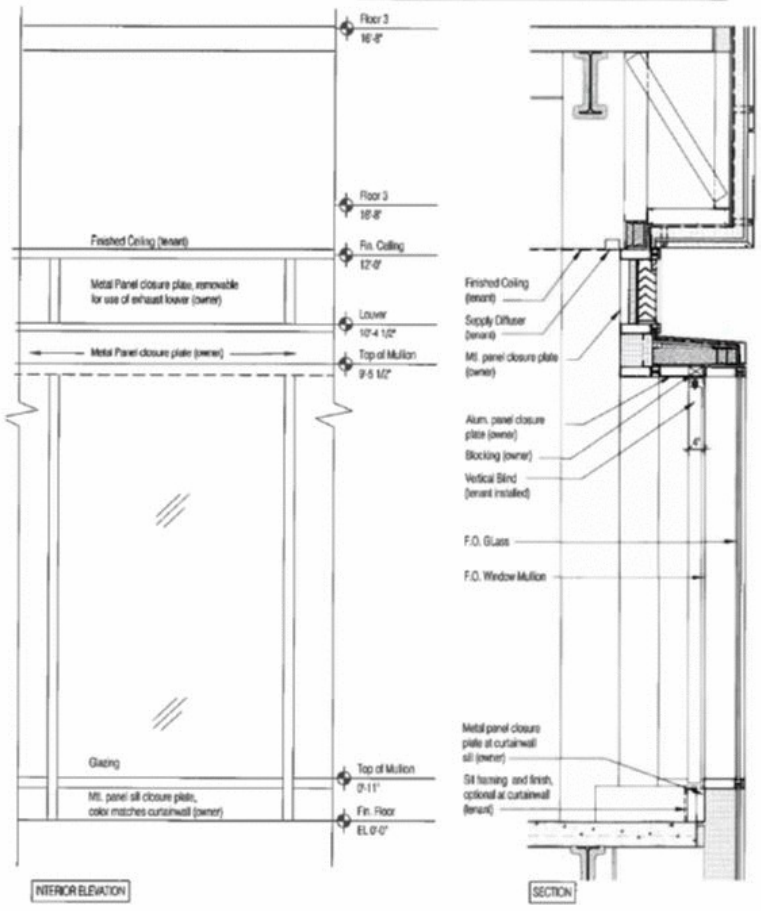


COLUMN ENCLOSURE AT CURTAINWALL - CORNER CONDITION
EXHIBIT 8



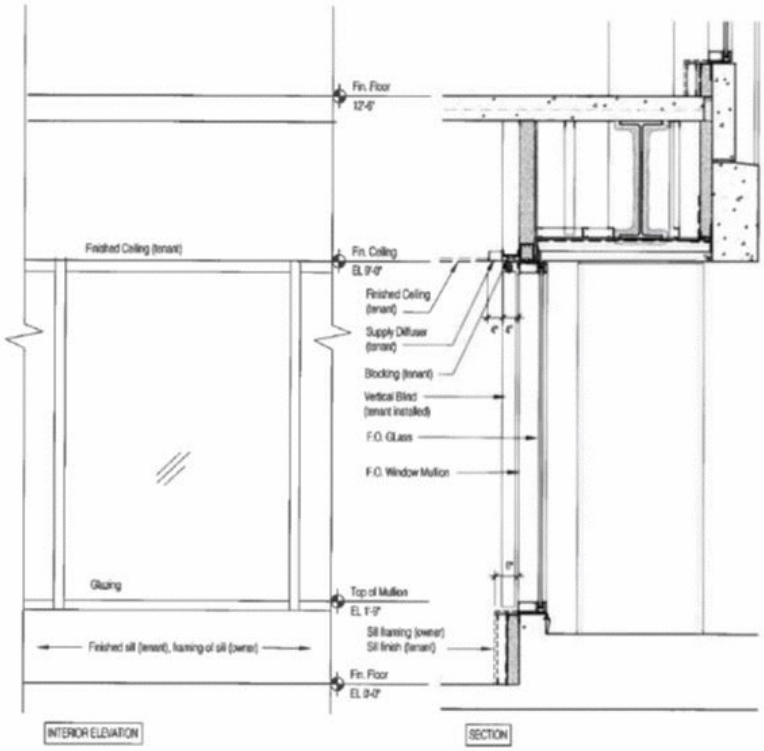
INTERIOR PARTITION / CURTAIN WALL DETAIL

EXHIBIT 9



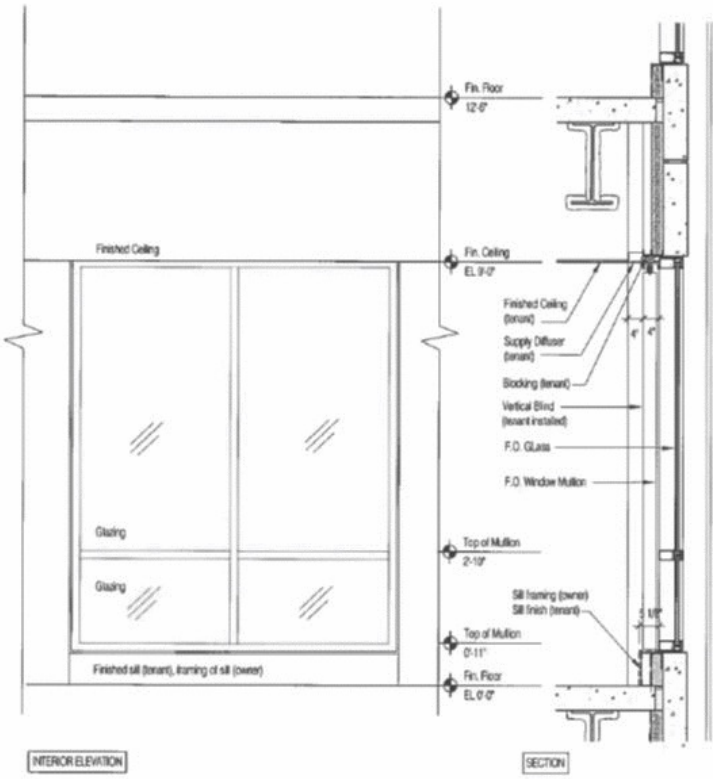
HEAD AND SILL DETAIL - BAY WINDOW , FLOOR 2

EXHIBIT 10



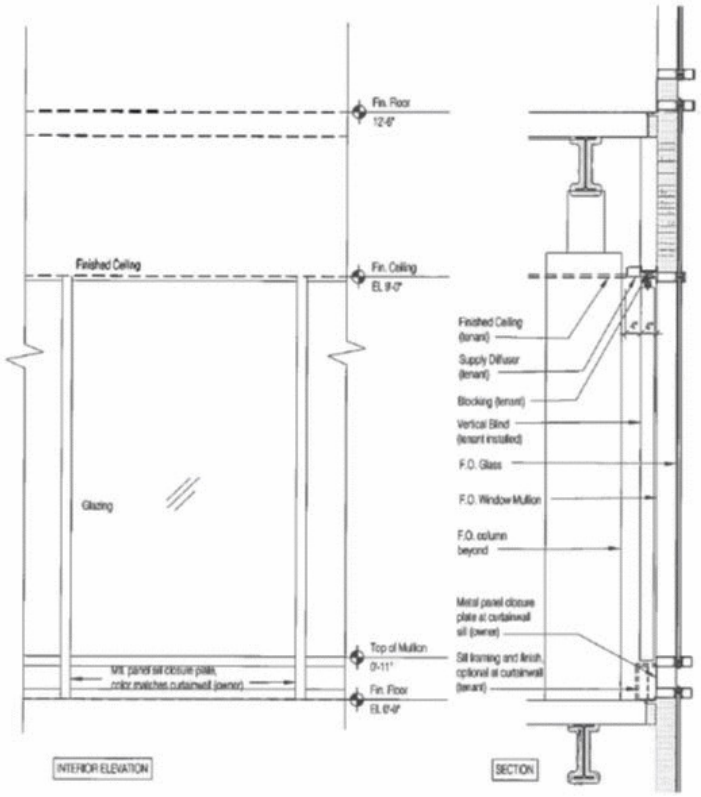
HEAD AND SILL DETAIL -RIBBON WINDOW, FLOOR 3

EXHIBIT 11



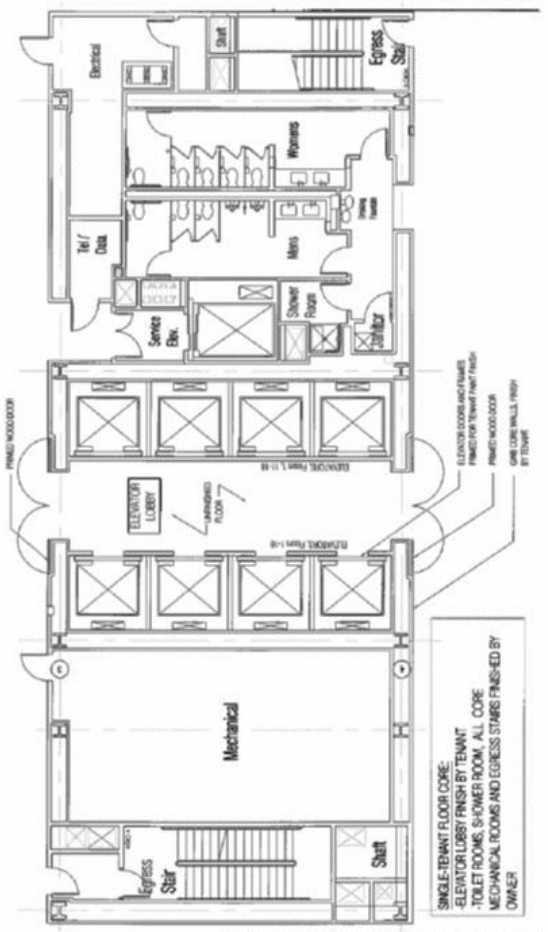
HEAD AND SILL DETAIL - TYPICAL PUNCHED OPENING, FLOORS 4-18

EXHIBIT 12



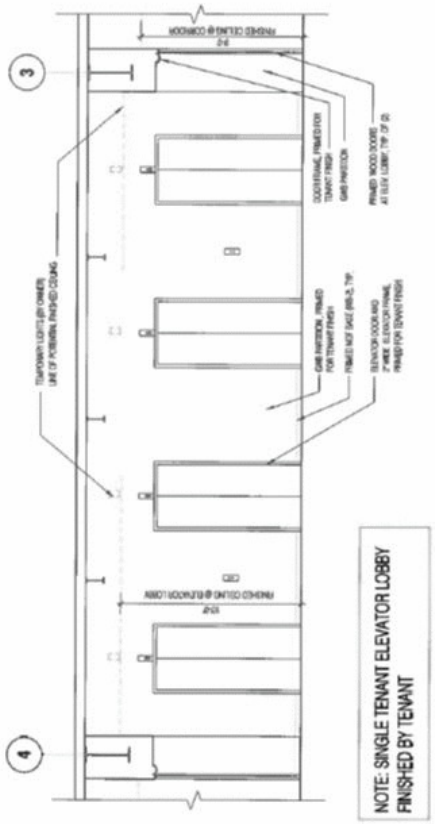
HEAD AND SILL DETAIL - TYPICAL CURTAINWALL CONDITION, FLOORS 2-18

EXHIBIT 13

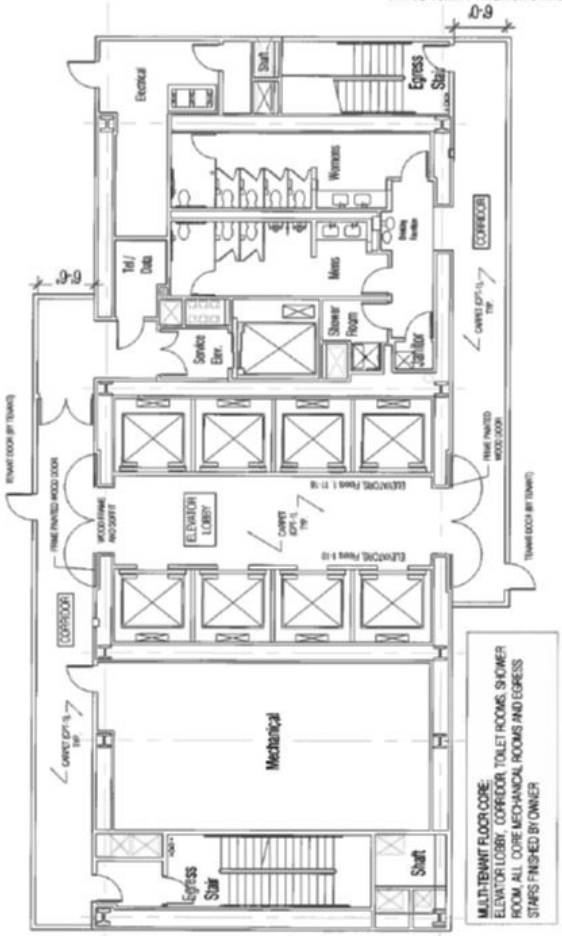


ELEVATOR LOBBY - SINGLE TENANT FLOOR

EXHIBIT 14

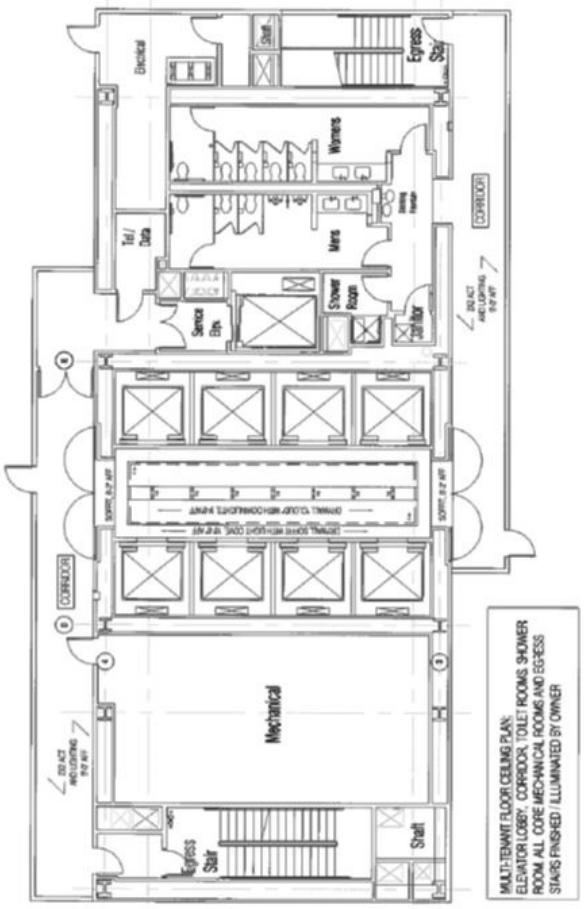


ELEVATOR LOBBY - SINGLE TENANT FLOOR
EXHIBIT 15

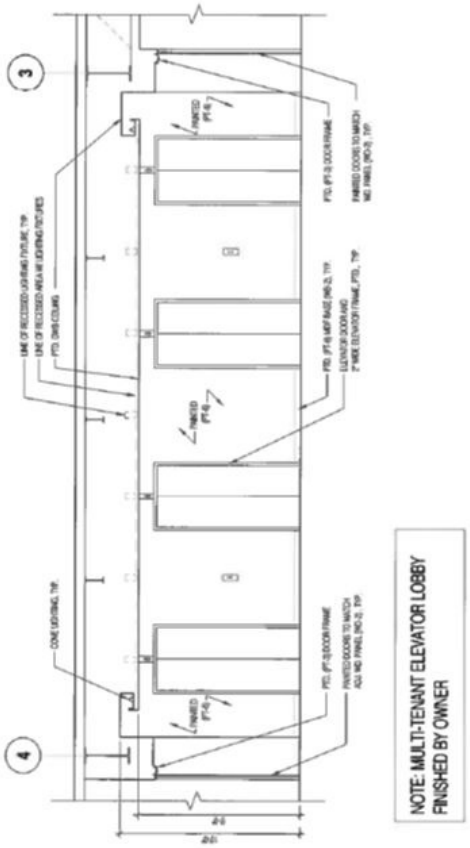


ELEVATOR LOBBY - MULTI TENANT FLOOR PLAN

EXHIBIT 16



ELEVATOR LOBBY - MULTI TENANT CEILING PLAN
EXHIBIT 17



ELEVATOR LOBBY - MULTI TENANT ELEVATION
EXHIBIT 18

3. SUSTAINABILITY (LEED)

3.1 - Introduction

One Marina Park Drive has been designed under the guidelines of the LEED Core & Shell system (LEED-CS) of the U.S. Green Building Council. LEED stands for Leadership in Energy and Environmental Design. Since The Owner has the goal of obtaining a Silver Level certification, One Marina Park Drive is being designed, and will be built to a level of efficiency and sustainability above and beyond standard practice. Areas in which this building excels are as follows:

- *Site Selection* – the building is located on a site with reduced impact on the environment
- *Energy Efficiency* – energy efficient features have been incorporated in the design; the mechanical systems have been designed and will be commissioned and operated to minimize energy use
- *Water Efficiency* – irrigation, cooling towers and restrooms make more efficient use of water
- *Indoor Environmental Quality* – Low VOC finishes, high efficiency filters, high outside air rates, and plenty of daylight are among the features contributing to a high indoor environmental quality
- *Environmentally-considered materials* – One Marina Park Drive specified a percentage of sustainable materials above industry standard including items with recycled content, sustainable wood, and locally found materials requiring less transportation to the site.

Following is a detailed description of the environmentally sensitive strategies used in the design, construction, and operation of One Marina Park Drive and no-cost/low-cost ideas that will allow you to conserve energy and water, lower utility costs, and to increase the indoor environmental quality in your own tenant space.

3.2 - Project Site

What Are the Sustainable Qualities of the One Marina Park Drive Building Site?

Site Selection. An urban location has lower environmental impact than a green field. In addition, Fan Pier plays a significant role in the revitalization of the Seaport District.

Mass Transit/ Parking Capacity One Marina Park Drive is in close proximity to subway stations, public water transportation, and a number of bus stops. Proximity to mass transit reduces the need for car use, therefore reducing pollution and traffic congestion.

Brownfield redevelopment. The site was a former rail year / shipping pier; contaminants were safely removed from the site

Erosion Control: Measures were implemented during construction so that storm water, wind, and vehicles did not carry sediment from the site to the storm water system draining to Boston Harbor.

High Density Development without forgoing Open Space. One Marina Park Drive is a high-rise construction project located in an area with more than 120,000 square feet of development per acre of land. High-density development reduces urban sprawl with its ensuing environmental disturbance. The completed site will provide open space for 56% of the site area.

Protect or Restore Habitat. At least 20% of the site area will be vegetated with native or adapted plants. This creates an oasis inside the City for butterflies and birds – it restores habitat.

Heat Island Effect – non-Roof. Paved areas around the building have light color, reducing the amount of heat absorbed and then re-radiated by overheated pavement. This type of heat generation, both from pavement and roofs (see below) accounts for the creation of urban "heat islands" where summer temperatures are significantly higher than in adjoining green fields.

Heat Island Effect – Roof. The roofs and terraces are either vegetated or light color, to reduce the amount of heat absorbed and re-radiated.

3.3 - Energy Efficiency

What Is Energy Efficient about One Marina Park Drive?

There are several technologies that have been implemented to save energy and money.

Commissioning – During the design process, the project was reviewed to ensure that all heating, cooling and ventilation systems were efficiently designed and specified. Before tenant occupancy the system will be tested.

Energy Efficient Windows – "Low E" tinted glass has been specified in order to retain more heat within the Building during winter and reduce heat gain in the summer when compared to conventional glass. The aluminum frames and mullions were designed with an insulating connection between the exterior and interior surfaces, to reduce the loss of heat.

Insulation – One Marina Park Drive has well-insulated exterior walls and roofs that reduce both heat loss and heat gain.

Lighting – Energy efficient lighting is used throughout the building. Fluorescent lamps, where appropriate, provide excellent light, while using as little as one quarter of the energy and lasting up to 10 times longer than an equivalent incandescent lamp.

Premium Efficiency Motors – Premium efficiency motors and variable speed drives will be utilized for the central MEP systems to reduce energy consumption.

Cooling Tower with VFD Fans – Variable speed control cooling tower fan results in energy savings during periods of low demand on the cooling tower – when the desired set-point for the leaving cooling water can be achieved with the fans operating at lower speed. Low-speed operation for fans uses less electricity.

Multiple Compressor DX units – Each floor is served by one or more Direct Expansion (DX) units, that provide cooled air to the Core & Shell and the tenant spaces. These units have high efficiency – and also have multiple compressors. As the need for cooling increases, the compressors stage on, one-by-one. This type of load tracking increases the operating efficiency – and part-load operation is the prevalent condition for all HVAC equipment. The DX units will also contain "free cooling" energy saving water coils that will operate with the water side economizer system. The free cooling coils will initially operate in conjunction with the compressors when outdoor air temperature is favorable to produce 70°F +/- water at the cooling towers; thereby reducing energy consumption.

Measurement & Verification – The building monitors the efficiency of the HVAC systems to ensure maximum performance. In addition, the Building Management System is sized to accommodate feeds from the tenant spaces; tenants will have the ability to monitor the energy use of subsystems in their spaces, with the goal of better controlling their energy use and cost.

What Is Energy Efficient about my tenant space?

Since the core and shell is energy-efficient, operating expenses for cooling, heating and for the lighting of common areas will be lower than if the building were merely Code-compliant.

Exterior Wall Construction – Superior glazing and well-insulated walls have been specified for One Marina Park Drive. The curtain wall for the building will feel warmer in winter, and will admit less heat in summer than the older generation of buildings. This improves the comfort of occupants in perimeter spaces. In general, if a person is close to a more efficient wall/window system, that person will feel comfortable at a somewhat lower temperature in winter and somewhat higher temperature in summer.

Space Temperature Control by Central Building Energy Management System – Wall or column mounted sensors in each space provide temperature data to the building's energy management system (BMS). The BMS controls the flow of warm or cool air from the air conditioning system to each space based on the information provided by the sensors and the set-point temperatures programmed into the BMS. During normally unoccupied hours, the BMS is also programmed to raise temperatures in the cooling season and lower temperatures in heating season to save energy.

Supply Air Temperature Reset Control – The control for the Air Conditioning units (ACs)can be set to satisfy the zone that needs most cooling out of all the zones that it serves. This method of control saves energy and improves comfort by reducing or eliminating instances of spaces being overcooled. It is recommended that CO_2 sensors are installed by the tenant to fully take advantage of modulated ventilation.

Demand Modulated Ventilation– A constant flow of outdoor air is necessary to maintain air quality within any occupied building. However, providing outdoor air at the correct temperature and humidity year-round can result in significant energy consumption. CO_2 monitoring can modulate the outside air based on the number of people in the space. Less outside air is supplied during times of low occupancy; more during periods of high occupancy. This strategy saves energy by only heating and cooling the quantity of outside air necessary to provide good indoor air quality at all times.

The floor by floor HVAC systems located within the Building are equipped with modulating outside air dampers that allow them to increase or decrease the rate of outside air supplied to spaces.

To fully use this feature, the tenant to install CO_2 sensors, a minimum of one per floor, that can be integrated with the base building system in order to modulate ventilation..

What else can I do to lower my energy bill?

Closing Shades. During the summer months, close the shades to reduce the heat gain from direct sunlight.

Compact Fluorescent Lamps (CFL). If you provide employees with desk lamps, use CFL bulbs instead of the traditional incandescent. CFLs are three times as efficient and last ten times longer—you will replace an incandescent bulb five to ten times before you need to replace a CFL. Avoid using halogen lamps, because they convert most of the electricity running through them into heat rather than light.

The color rendition of CFL's is often described in terms of temperature (e.g. "warm" and "cool"). Warm-colored CFL's give off a light much like that of an incandescent bulb. CFL's advertised as

"natural daylight" or "sunlight" are cooler in color. For more information, go to www.energystar.gov/index.cfm?c=cfls.pr_cfls.

Fluorescent lamps that contain mercury and should be recycled to avoid releases of mercury to the environment. To find out more about lamp recyclers visit: http://www.lamprecycle.org/. But it is best to procure fluorescent lamps that have very low mercury content.

Purchase Equipment with the ENERGY STAR® Label. ENERGY STAR® equipment represents the top 25th percentile of energy efficiency in that product category. For more information, go to www.energystar.gov .

Minimize Phantom Loads. Electronic equipment such as computers, copiers and printers, but also including other appliances that you may have in auxiliary spaces (e.g., microwaves, refrigerators, VCR's, DVD players, and cell phone chargers) draw energy while plugged in, even if turned off. The energy draw is called "standby losses" or "phantom load" and can contribute up to 15 percent of a typical electricity bill. Devices with transformers at the plug, or along the cord, incur the greatest standby losses, without offering a "standby amenity," like a clock. Products carrying the Energy Star® label have lower standby loses than their competitors. For more information on this topic, go to www.standby.lbl.gov.

Where feasible, switch off after use the power strip into which electronic equipment is plugged.

3.4 - Water Efficiency

By implementing some simple water-saving strategies, One Marina Park Drive has reduced its water consumption by an excess of 30%. These strategies are described below along with ways in which you too can help save water.

What Types of Water-Saving Strategies are being at One Marina Park Drive?

Low-Flow Urinals. The restroom facilities will be equipped with low flow urinals.

Low-flow urinals are like conventional urinals, but they have a flush system that cleans the bowl with a smaller flush.

Sensor-Operated Faucets. The faucet operates by means of an infrared sensor. Once the user enters the sensor's effective range and then steps away, the unit initiates the use cycle. This results in a more hygienic and water-efficient fixture.

Low Flow Shower Heads. Reduced flow showerheads reduce water by introducing more air to uphold the pressure in fixture.

3.5 - Indoor Environmental Quality

One Marina Park Drive is being built to provide superior indoor air quality. The following provides an overview of the systems and design strategies employed to improve indoor quality:

Tobacco Smoke Control. Smoking is prohibited in the building. The outdoor area designated for smoking is located away from your lobby entrance.

Air Filtering: Outside air is conditioned and filtered with high efficiency filters (MERV 13), removing typical airborne contaminants. This creates an interior environment that is comfortable for tenants.

Increased Outdoor Air Rates. The latest standard for indoor air quality, the ASHRAE Standard 62-2004, mandates a minimum amount of outside air, deemed adequate for good IAQ. One Marina Park Drive F has 30% higher outside air rates.

CO_2 Monitoring. Indoor air quality can also be improved by the use of Carbon dioxide (CO_2) sensors. The amount of carbon dioxide (CO_2) is indicative of the number of people in a space. The base building HVAC system has been designed to increase the amount of outside air when the occupancy is high and decrease it when the spaces are sparsely occupied, or unoccupied. This results in providing more fresh air when it is needed. Tenant installed CO_2 sensors, integrated with the base building HVAC system directs the mechanical system to vary the ventilation rates based on occupancy per floor.

To use this feature, the tenant will need to install CO_2 sensors in strategic locations: large assembly or conference areas or at least one CO_2 sensor per floor. Up to four tenant CO_2 sensors per floor can be connected to the base building HVAC system.

Low-VOC Adhesives, Sealants, Paints and Coatings. All adhesives, sealants, paints and carpet installed in the building are "low-VOC", indicating that that they off-gas (emit) very little pollutants and odors.

Carpets. All carpets installed in the building Core & Shell meet the testing and product requirements of the Carpet and Rug Institute's "Green Label Plus" Program. All carpet cushion installed in the building Core & Shell meet the requirements of the Carpet and Rug Institute's "Green Label" Program. These programs ensure low emission levels from carpeting.

Urea-formaldehyde Free. All composite wood used inside the public areas of the building (including the architectural work, rough carpentry, and finish carpentry) is selected without the use of urea-formaldehyde bonding agents in the manufacturing process. Most composite wood is manufactured with urea formaldehyde resins, which, as indicated earlier, are considered to be unhealthy.

Lobby Walk-off Mats. Building walk off mats at the entrance lobby will help remove dust and particles from visitors' shoes. This will reduce the quantity of material in the air and keep the building cleaner overall.

Indoor Air Quality Plan. During construction, the contractors employ procedures developed to foster good indoor air quality to:

Prevent construction dust, debris and volatile gases from entering the air conditioning and ventilation system;

Prevent soft and absorptive materials from absorbing the pollutants and odors given off by wet-applied products like paint and adhesives;

Protect materials from any moisture absorption that could support the growth of mold and fungus.

What else can I do to maintain good indoor air quality in my tenant space?

Green Housekeeping Green Housekeeping is about achieving high performance by using products that are low in toxicity and odor. Many of the typical cleaning agents available kill bacteria, but create new health risks and inconveniences. Here are some simple steps for healthy housekeeping:

Do Not Use Harsh Chemicals Unless Necessary. Powerful cleaning agents do not necessarily perform better than less toxic alternatives. For example, combined cleaners and disinfectants are often highly toxic and acidic, but do not disinfect well. Disinfectants generally require 15 minutes of contact time on a clean (not soiled) surface to work effectively. For most applications, routine cleaning and soil removal with a mild detergent of a neutral pH is sufficient and appropriate. Disinfection is rarely required. Even the Center for Disease Control (CDC) only recommends cleaning and soil removal with a mild detergent of a neutral pH for hospital floors.

Healthy and Safe Cleaning Products. Look for products that contain little or none of the following: Chlorine, Petrochemical solvents (benzene, toluene, xylene, etc.), Glycol ethers, Phosphates, Acids,

Caustics, Dyes, Perfumes

Low VOC Finishes and Furniture Products with low volatile organic content ("low-VOC") have been used in the renovation of the building and will continue to be used for all additional renovations and touch-ups. Low-VOC products emit lower levels of odor and release less toxic pollutants into the air than conventional products.

We recommend that you check the VOC (volatile organic compound) content of products before purchasing to minimize the unnecessary introduction of odors and chemical emissions (such as from solvents). This information may not be on the label or even readily available, however, it can be found in the technical data and/or in the Material Safety Data sheet (MSD) for each product. Your sales person can obtain this information if requested, or you can look it up on the manufacturer's website.

Urea-Formaldehyde We also recommend looking for composite wood and agrifiber board products that do not contain 'added' urea-formaldehyde, or that have been tested and certified by Green Guard or another certifying body to verify that the emissions from the product are low and not harmful.

Furniture and Furnishings Upholstered furniture is made, generally, with some type of foam and/or down and feathers. Some foams emit irritant chemicals. We suggest that you ask the manufacturer what foam has been used in furniture before purchasing. Avoid products made with TDI foams (toluene diisocyanate). Products which are made with MDI (methyl diphenyl isocyanate) are preferred. In addition, avoid foams which have been treated with PBDE's (polybrominated fire retardants). These chemicals are known as POP's (persistent organic pollutants).

Carpet and Flooring Wool or nylon woven carpets and rugs are made with much less adhesive than 'tufted' goods and can help to maintain good indoor air quality. Install these products over a natural hair and jute cushion, or use low-VOC adhesives per the noted chart. Avoid carpet and flooring products made with PVC (polyvinyl chloride) backing, as this product emits toxic fumes (*hydrogen chloride gas*) in the case of a building fire.
All carpets should be kept clean using a high efficiency vacuum cleaner so that they do not absorb and then re-emit VOCs and dust.

Low-Toxic Pest Management In your tenant space, the best way to control pests is to keep the environment unsuitable for their habitation. Sponge up excess moisture and clean up any "food sources" such as crumbs and spills. Do not leave food out overnight, especially uncovered. If you have a pest problem, contact building management.

Office Layout / Tenant Improvement Design The building offers control of temperature and lighting in multiple occupancy spaces that are part of the Core & Shell.
The large glass façade offers generous daylight and views. As a tenant, you can maximize the effect of these features by following these guidelines:

- Consider locating enclosed offices and conference rooms close to the core and open-office areas to the perimeter. The enclosed offices would have glass partitions toward the exteriors.

- Alternately, if perimeter areas receive enclosed offices, consider providing them with glass partitions toward the interiors.

3.6 - Environmentally Considered Materials

Choosing materials that contain recycled content and are made of rapidly renewable materials will reduce the quantity of raw materials extracted and disposed of in the ever-growing waste stream. Buying materials that are extracted or manufactured locally will reduce transport associated energy

Tenant Recycling Program In an effort to reduce the amount of waste material that ends up in the already over-burdened landfills, the building will implement a recycling program. All clean paper, corrugated cardboard, glass, plastics, and metals will be deposited in separate bins labeled accordingly located in each tenant space. An outside service will pick up this material.

What Types of Sustainable Materials Were Used at One Marina Park Drive?

Concrete and Masonry. Concrete is composed of aggregate, water, and cement-an energy-intensive material. At One Marina Park Drive, the cement in the concrete has been partially replaced by fly ash or ground granulated blast furnace (GGBF) slag. Replacing cement with fly ash and slag not only reduces the embodied energy of the concrete, it diverts what would otherwise be considered waste from the ever-growing waste stream.

Fly ash is a bi-product of coal burning at electric utility plants. When mixed at certain ratio it may increase the strength of the material.

GGBF slag is a bi-product of iron blast furnaces.

Steel and Metal. Virgin steel and metal are energy intensive materials. Using recycled metal reduces the embodied energy of the material. The steel and metal materials used in the building are composed of a combination of post-industrial and post-consumer recycled steel and metal. This includes structural and decorative metals, doors, frames, and steel decking.

Aluminum. The aluminum storefronts are composed of recycled content.

Wood. All of the engineered wood used for either architectural work or finished carpentry contains recycled material.

Wood used for architectural work and finish and rough carpentry within the public areas of the building is certified by the Forest Stewardship Council (FSC). FSC certified wood has been reaped from forests that maintain sustainable harvesting practices. For more information visit: http://www.fsc.org/en/.

Gypsum Board. The gypsum board is partially composed of recycled material; the paper face is 100% composed of recycled material.

Insulation. The thermal insulation is composed of a combination of post-industrial and post-consumer recycled material.

Construction Waste Management. Building construction generates enormous quantities of waste, a majority of which can be recycled. A construction waste management plan was implemented during construction to ensure the maximum possible recycling of waste. The recycled materials include metals, concrete, wood, ceiling tile and cardboard. The goal is to divert at least 75% of the waste volume away from the dump sites, for re-use.

Carpet: The multi-tenant corridors will be outfitted with carpet which is composed of post-industrial and post-consumer recycled products.

Additional products where recycled content is being considered: Ceramic Tile, Acoustical Panels, Vinyl and Linoleum Flooring

What Types of Products Can I Choose that Are Sustainable?

Furniture, Furnishings, and Building Materials

Reuse- Use salvaged, refurbished, or reused materials throughout your tenant space. Reusing building products and materials reduces demand for virgin materials, thereby reducing impacts associated with the extraction and processing of virgin resources. Reusing materials diverts materials that would otherwise end up in the waste stream.

Rapidly Renewable Materials- When available, purchase wood or products, including furniture and furnishings, which are made of rapidly renewable materials. Using products made of rapidly renewable materials ensures that you are not contributing to the depletion of our earth's natural resources. Materials considered rapidly renewable are those that are harvested in a 10-year or shorter cycle and may include: bamboo, cork, and straw.

Forest Stewardship Council Certified Wood- One option is to purchase products that are manufactured with wood that has been certified by the Forest Stewardship Council (FSC). The Forest Stewardship Council (FSC) is an international network that promotes responsible management of the world's forests. You can find more information about the FSC certification as well as locate distributors and manufacturers by visiting: http://www.fsc.org/en/.

Recycled Content- When available, purchase engineered wood or products, including furniture and furnishings that are manufactured with engineered wood that is composed of recycled content.

Local Materials- to the extent possible, purchase materials manufactured and/or extracted locally- within 500 miles of Boston. Purchasing locally not only reduces the environmental impacts associated with the transportation, it supports the regional economy as well.

3.7 LEED for Commercial Interiors (LEED – CI) Summary and Tenant Recommendations

LEED for Commercial Interiors (LEED-CI) is part of a comprehensive suite of LEED "green building" rating tools that the U.S. Green Building Council is developing to promote "green" design, construction, and operations practices in buildings nationwide. LEED for Core and Shell developments (LEED-CS), and LEED-CI are companion rating systems that establish "green building" criteria for commercial office real estate for use by both developers and tenants. The sustainability goals for LEED-CI are similar to those of LEED-CS.

Some of the benefits this program bring are a reduction in operating and maintenance costs, better occupant health and productivity, possible reduction of liability related to indoor environmental health, and possible availability of tax credits/incentives.

Given that One Marina Park Drive is expected to be LEED-CS certified above industry standards, tenants will benefit by having the ability to design an interior office space with a framework of LEED-CI "points" already established.

A LEED-CI checklist has been included outlining the Seven (7) "YES" and Twenty Five (25) "Possible" interior/tenant points that have been made possible by One Marina Park Drive's sustainable design practices.

LEED-CI

LEED-CI Version 2.0 Registered Project Checklist

Project Name:

Project Address:

Yes	?	No			Possible Points	7
			Sustainable Sites			
3			Credit 1	**Site Selection - Select a LEED Certified Building - OR -**		3
				Locate the tenant space in a building with following characteristics (up to 3 points):		
			Option 1A	**Brownfield Redevelopment**		1/2
			Option 1B	**Stormwater Management: Rate and Quantity**		1/2
			Option 1C	**Stormwater Management: Treatment**		1/2
			Option 1D	**Heat Island Reduction, Non-Roof**		1/2
			Option 1E	**Heat-Island Reduction, Roof**		1/2
			Option 1F	**Light Pollution Reduction**		1/2
			Option 1G	**Water Efficient Irrigation: Reduce by 50%**		1/2
			Option 1H	**Water Efficient Irrigation: No Potable Use or No Irrigation**		1/2
			Option 1I	**Innovative Wastewater Technologies**		1/2
			Option 1J	**Water Use Reduction: 20% Reduction**		1/2
			Option 1K	**Onsite Renewable Energy**		1/2 to 1
			Option 1L	**Other Quantifiable Environmental Performance**		1/2 to 3
1			Credit 2	**Development Density and Community Connectivity**		1
1			Credit 3.1	**Alternative Transportation, Public Transportation Access**		1
1			Credit 3.2	**Alternative Transportation, Bicycle Storage & Changing Rooms**		1
1			Credit 3.3	**Alternative Transportation, Parking Availability**		1

Yes	?	No			Possible Points	2
	2		**Water Efficiency**			
	1		Credit 1.1	**Water Use Reduction** - 20% Reduction		1
	1		Credit 1.2	**Water Use Reduction** - 30% Reduction		1

Yes	?	No			Possible Points	12
	6		**Energy & Atmosphere**			
			Prereq 1	**Fundamental Commissioning**		Required
			Prereq 2	**Minimum Energy Performance**		Required
			Prereq 3	**CFC Reduction in HVAC&R Equipment**		Required
			Credit 1.1	**Optimize Energy Performance** - Lighting Power		3
	1		Credit 1.2	**Optimize Energy Performance** - Lighting Controls		1
	1		Credit 1.3	**Optimize Energy Performance** - HVAC		2
	1		Credit 1.4	**Optimize Energy Performance** - Equipment and Appliances		2
	1		Credit 2	**Enhanced Commissioning**		1
	2		Credit 3	**Energy Use, Measurement & Payment Accountability**		2
			Credit 4	**Green Power**		1

Yes	?	No			
	5		**Materials & Resources**	Possible Points	14
			Prereq 1	**Storage and Collection of Recyclables**	Required
			Credit 1.1	**Tenant Space, Long Term Commitment**	1
	1		Credit 1.2	**Building Reuse, Maintain 40% of Interior Non-Structural Components**	1
	1		Credit 1.3	**Building Reuse, Maintain 60% of Interior Non-Structural Components**	1
	1		Credit 2.1	**Construction Waste Management, Divert 50% From Landfill**	1
	1		Credit 2.2	**Construction Waste Management, Divert 75% From Landfill**	1
			Credit 3.1	**Resource Reuse, 5%**	1
			Credit 3.2	**Resource Reuse, 10%**	1
			Credit 3.3	**Resource Reuse, 30% Furniture and Furnishings**	1
	1		Credit 4.1	**Recycled Content, 10% (post-consumer + 1/2 pre-consumer)**	1
	1		Credit 4.2	**Recycled Content, 20% (post-consumer + 1/2 pre-consumer)**	1
	1		Credit 5.1	**Regional Materials, 20% Manufactured Regionally**	1
	1		Credit 5.2	**Regional Materials, 10% Extracted and Manufactured Regionally**	1
			Credit 6	**Rapidly Renewable Materials**	1
			Credit 7	**Certified Wood**	1

Yes	?	No			
	8		**Indoor Environmental Quality**	Possible Points	17
			Prereq 1	**Minimum IAQ Performance**	Required
			Prereq 2	**Environmental Tobacco Smoke (ETS) Control**	Required
	1		Credit 1	**Outside Air Delivery Monitoring**	1
	1		Credit 2	**Increased Ventilation**	1
	1		Credit 3.1	**Construction IAQ Management Plan, During Construction**	1
			Credit 3.2	**Construction IAQ Management Plan, Before Occupancy**	1
			Credit 4.1	**Low-Emitting Materials, Adhesives and Sealants**	1
			Credit 4.2	**Low-Emitting Materials, Paints and Coatings**	1
			Credit 4.3	**Low-Emitting Materials, Carpet Systems**	1
			Credit 4.4	**Low-Emitting Materials, Composite Wood and Laminate Adhesives**	1
			Credit 4.5	**Low-Emitting Materials, Systems Furniture and Seating**	1
			Credit 5	**Indoor Chemical and Pollutant Source Control**	1
			Credit 6.1	**Controllability of Systems, Lighting**	1
			Credit 6.2	**Controllability of Systems, Temperature and Ventilation**	1
	1		Credit 7.1	**Thermal Comfort** - Compliance	1
	1		Credit 7.2	**Thermal Comfort** - Monitoring	1
	1		Credit 8.1	**Daylight & Views** - Daylight 75% of Spaces	1
	1		Credit 8.2	**Daylight & Views** - Daylight 90% of Spaces	1
	1		Credit 8.3	**Daylight & Views** - Views for 90% of Seated Spaces	1

Yes	?	No			
	1		**Innovation & Design Process**	Possible Points	5
	1		Credit 1.1	**Innovation in Design**	1
			Credit 1.2	**Innovation in Design**	1
			Credit 1.3	**Innovation in Design**	1
			Credit 1.4	**Innovation in Design**	1
			Credit 2	**LEED™ Accredited Professional**	1

Yes	?	No		
7	25		**Totals (pre-certification estimates)**	Possible Points 57

Certified 21 to 26 points Silver 27 to 31 points Gold 32 to 41 points Platinum 42 to 57 points

Exhibit K

Form of Commencement Date Confirmation

COMMENCEMENT DATE CONFIRMATION

Attached to and made a part of the Lease dated the 29th day of April, 2015 (the "Lease"), by and between **FALLON CORNERSTONE ONE MPD LLC**, a Delaware limited liability company, as "LANDLORD," and **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation, as "TENANT."

LANDLORD AND TENANT do hereby declare that possession of the Premises was accepted by TENANT on the 30th day of April, 2015, which date is agreed to be the Commencement Date. The Lease is now in full force and effect, and as of the date The Rent Commencement Date is hereby established as March 1, 2016. The Term of this Lease shall expire on February 28, 2023, unless sooner terminated or further extended as provided in the Lease.

LANDLORD:

FALLON CORNERSTONE ONE MPD LLC,
a Delaware limited liability company

By: MASSACHUSETTS MUTUAL LIFE INSURANCE COMPANY,
a Massachusetts corporation,
its Member

By: CORNERSTONE REAL ESTATE ADVISERS LLC,
a Delaware limited liability company,
its Authorized Agent

By: /s/Linda C. Houston
Name: Linda C. Houston
Title: Senior Vice President

TENANT:
KERYX BIOPHARMACEUTICALS, INC.,
a Delaware corporation

By: /s/ Brian Adams
Name: Brian Adams
Title: General Counsel

Exhibit 21.1

Keryx Biopharmaceuticals, Inc.
List of Subsidiaries

Name of Subsidiary	State/Jurisdiction of Incorporation
ACCESS Oncology, Inc.	Delaware
Accumin Diagnostics, Inc.	Delaware
AOI Pharma, Inc.	Delaware
AOI Pharmaceuticals, Inc.	Delaware
Neryx Biopharmaceuticals, Inc.	Delaware
Online Collaborative Oncology Group, Inc.	Delaware
Keryx Biomedical Technologies Ltd.	Israel
Keryx (Israel) Ltd.	Israel
Keryx Biopharma UK Ltd.	United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the following registration statements of our reports dated March 1, 2017, with respect to the consolidated balance sheets of Keryx Biopharmaceuticals, Inc. and Subsidiaries (the "Company"), as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended December 31, 2016, and the effectiveness of Keryx Biopharmaceuticals, Inc. internal control over financial reporting, which appear in this annual report on Form 10-K of the Company for the year ended December 31, 2016:

- Form S-8 dated February 5, 2001 (File No. 333-55006)
- Form S-8 dated September 29, 2004 (File No. 333-119377)
- Form S-8 dated April 6, 2006, as amended (File No. 333-133052)
- Form S-8 dated July 31, 2007 (File No. 333-145003)
- Form S-8 dated March 25, 2010 (File No. 333-165710)
- Form S-8 dated August 2, 2013 (File No. 333-190358)
- Form S-8 dated March 11, 2016 (File No. 333-210116)
- Form S-8 dated August 23, 2016 (File No. 333-213267)
- Form S-3 dated November 9, 2016, as amended (File No. 333-214513)

/s/ UHY LLP
New York, New York
March 1, 2017

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory P. Madison, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

Date: March 1, 2017

/s/ Gregory P. Madison

Gregory P. Madison
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott A. Holmes, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

Date: March 1, 2017

/s/ Scott A. Holmes

Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
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 of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, Gregory P. Madison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2017

/s/ Gregory P. Madison

Gregory P. Madison
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
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 of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, Scott A. Holmes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2017

/s/ Scott A. Holmes

Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer