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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[x] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

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: 001-33221

HERON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	94-2875566
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
123 SAGINAW DRIVE REDWOOD CITY, CA	94063
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:
(650) 366-2626

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

Title of each class:	Name of each exchange on which registered:
Common Stock, par value $0.01 per share	The NASDAQ Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [x] 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 [x]

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 [x] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [x] No [ ]

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

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

Large accelerated filer [x] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [ ]
(Do not check if a 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 [x]

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2015 totaled approximately $957,876,000 based on the closing price of $31.16 as reported by The NASDAQ Capital Market. As of February 4, 2016, there were 36,231,685 shares of the Company's common stock ($0.01 par value) outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement related to its 2016 Annual Stockholders' Meeting to be held on or about June 21, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such Definitive Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates. Except as expressly incorporated by reference, the registrant's Definitive Proxy Statement shall not be deemed to be part of this report.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. You can identify forward-looking statements by the use of the words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project,” “will,” “should,” “may,” “plan,” “assume” and other expressions which predict or indicate future events and trends and which do not relate to historical matters. You should not rely on forward-looking statements, because they involve known and unknown risks, uncertainties and other factors, some of which are beyond the control of the Company. These risks, uncertainties and other factors may cause the actual results, performance or achievements of the Company to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that might cause these differences include the following:

- Estimates of the outcome of our New Drug Application (“NDA”) resubmission to the U.S. Food and Drug Administration (“FDA”) for SUSTOL® (granisetron) Injection, extended release (“SUSTOL”) and potential regulatory approval for and commercial launch of SUSTOL;

- the possibility that the FDA might not interpret the results of our Phase 3 MAGIC study for SUSTOL for the prevention of delayed chemotherapy induced nausea and vomiting (“CINV”) associated with highly emetogenic chemotherapy regimens to be sufficient to support as broad a label indication as we might desire;

- the anticipated progress of our current research and development programs for HTX-011, HTX-019 and any other research and development programs we may pursue, including the completion of ongoing clinical trials, initiation of new clinical trials and preclinical testing and the results of clinical and stability studies;

- whether safety and efficacy results of our clinical trials and other required tests for approval provide data to warrant further development and potential regulatory approval of SUSTOL or any of our other product candidates;

- if approved, the market conditions during the commercial launch of SUSTOL, or other future product candidates;

- our ability to successfully market, commercialize and achieve market acceptance for SUSTOL or other future product candidates, including our positioning relative to competing products;

- our ability to successfully develop and achieve regulatory approval for other future product candidates utilizing our proprietary Biochronomer® drug delivery technology (“Biochronomer technology”);

- our ability to establish key collaborations for our products and any other future product candidates;

- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;

- unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment;

- our ability to successfully establish and maintain key vendor relationships necessary to manufacture our products;

- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;

- uncertainties associated with obtaining and enforcing patents to protect our products, and our ability to successfully defend ourselves against unforeseen third-party infringement claims;
- our estimates regarding our capital requirements; and
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities.

These forward-looking statements were based on information, plans and estimates at the date of this Annual Report on Form 10-K, and we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. In addition, please see the “Risk Factors” section of this Annual Report on Form 10-K. These risk factors may be updated from time to time by our future filings under the Securities Exchange Act of 1934 (the “Exchange Act”). You should carefully review all information therein.

PART I

In this Annual Report on Form 10-K, all references to "Heron," the "Company," "we," "our," "us" and similar terms refer to Heron Therapeutics, Inc. Heron Therapeutics®, the Heron logo, SUSTOL® and Biochronomer® are our trademarks. All other trademarks appearing or incorporated by reference into this Annual Report on Form 10-K are the property of their respective owners.

ITEM 1. BUSINESS.

Overview and Business Strategy

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents. Our goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use.

We are currently developing pharmaceutical products for patients suffering from cancer or pain. SUSTOL is being developed for the prevention of both acute and delayed CINV associated with moderately emetogenic chemotherapy ("MEC") or highly emetogenic chemotherapy ("HEC"). Our NDA for SUSTOL is pending review with the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") goal date of January 17, 2016. In January 2016, we were notified by the FDA that it would not take action on the SUSTOL NDA by the PDUFA goal date and that the FDA anticipates taking action on the SUSTOL NDA in late February 2016.

In addition to SUSTOL, we are currently developing several other pharmaceutical products for patients suffering from cancer or pain. HTX-019, also being developed for the prevention of CINV, is an intravenous formulation of aprepitant, a neurokinin-1 ("NK_1") receptor antagonist. HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is being developed for the prevention of post-operative pain.

Development Pipeline:

Product Candidates	Target Indication	Development Status
SUSTOL	Chemotherapy-induced nausea and vomiting	Pending NDA action
HTX-019	Chemotherapy-induced nausea and vomiting	Bioequivalence study complete
HTX-011	Post-operative pain management	Phase 2 ongoing

Chemotherapy-Induced Nausea and Vomiting

CINV is one of the most debilitating side effects of chemotherapy, often attributed as a leading cause of premature discontinuation of cancer treatment. Most chemotherapy agents cause some degree of nausea and vomiting. However, the chemotherapy

regimens that cause the worst degree of nausea and vomiting are categorized into two groups: MEC and HEC. Despite advancements in the field, CINV remains a major problem for cancer patients and their caregivers.

Two of the systems that regulate the body's emetic (nausea and vomiting) response are the 5-hydroxytryptamine type 3 ("5-HT_3") receptor system and the NK_1 receptor system. Chemotherapy triggers the release of 5-hydroxytryptamine (5-HT) (also known as serotonin) from cells in the small intestine, which acts on two sites: stimulating 5-HT_3 receptors on neurons in the gastrointestinal tract and stimulating 5-HT_3 receptors in the brain that control vomiting. Chemotherapy also causes the release of a molecule known as substance P, which acts on the NK_1 receptors in the brain to reinforce the desire to vomit. These systems, along with other central and peripheral neurotransmitters such as dopamine and prostaglandins, work in concert to escalate the sensation of nausea and induce vomiting, constituting the body's natural reflex to try to protect itself from foreign toxins. 5-HT_3 receptor antagonists, such as SUSTOL, and NK_1 receptor antagonists, such as HTX-019, act synergistically on two of the critical pathways involved in the vomiting reflex to alleviate one of the key treatment-limiting side effects of chemotherapy.

In its 2011 guidelines for the prevention of CINV following the administration of MEC or HEC regimens, the American Society of Clinical Oncology ("ASCO") recommends the use of 5-HT_3 receptor antagonists, often in combination with other agents such as corticosteroids and/or NK_1 receptor antagonists to achieve optimal control of CINV symptoms ("2011 ASCO CINV Guidelines").

Nausea and vomiting that occurs within the first 24 hours following the administration of chemotherapy regimens is considered acute CINV, while nausea and vomiting on days 2-5 following the administration of chemotherapy regimens is considered delayed CINV. A particular unmet medical need exists for patients suffering from CINV during the delayed phase. None of the currently available 5-HT_3 receptor antagonists have demonstrated sufficient efficacy to gain approval for the prevention of delayed CINV associated with HEC.

Current CINV Therapies

Currently available 5-HT_3 receptor antagonists include: ALOXI® (palonosetron, marketed by Eisai, Inc. in conjunction with Helsinn Healthcare S.A.); AKYNZEO® (palonosetron combined with the NK_1 receptor antagonist netupitant, marketed by Eisai); SANCUSO® (granisetron transdermal patch, marketed by ProStrakan Group Plc); and generic products including ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN) and granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL). Generic palonosetron may become available in the third quarter of 2018. Currently, ALOXI is the only 5-HT_3 receptor antagonist approved for the prevention of delayed CINV associated with MEC regimens. No 5-HT_3 receptor antagonist is approved for the prevention of delayed CINV associated with HEC regimens.

NK_1 receptor antagonists are also administered for the prevention of CINV, in combination with 5-HT_3 receptor antagonists, to augment the therapeutic effect of the 5-HT_3 receptor antagonist. Currently available NK_1 receptor antagonists include: EMEND® (aprepitant, marketed by Merck & Co, Inc.); EMEND® for Injection (fosaprepitant, marketed by Merck & Co); and VARUBI™ (rolapitant, marketed by Tesaro, Inc.).

According to Transparency Market Research, sales of therapeutics for the prevention of CINV approximated $620 million in 2013, and sales of such therapeutics are expected to reach approximately $1 billion in 2020.

SUSTOL

SUSTOL, which utilizes our Biochronomer technology, is our novel, long-acting formulation of granisetron for the prevention of CINV. Granisetron, an FDA-approved 5-HT_3 receptor antagonist, was selected due to its broad use by physicians based on a well-established record of safety and efficacy. SUSTOL has been shown to maintain therapeutic drug levels of granisetron for five days with a single subcutaneous injection and is being developed for the prevention of both acute and delayed CINV associated with MEC or HEC. While other 5-HT_3 receptor antagonists are indicated for the prevention of CINV, we believe SUSTOL is the first agent in the class to demonstrate efficacy in reducing the incidence of delayed CINV in patients receiving HEC in a randomized Phase 3 study.

SUSTOL New Drug Application Resubmission

In May 2009, we filed an NDA for SUSTOL with the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. In March 2010, we received our first Complete Response Letter ("CRL"), which stated that the May 2009 NDA requesting approval of SUSTOL could not be approved as it was initially submitted. The primary points raised in the initial CRL were: certain points related to the dosing system; certain identified deficiencies in the chemistry, manufacturing, and controls ("CMC") review; the request that we perform additional studies regarding bioequivalence and metabolic rates and human factors; and the request that we perform a thorough QT study. In September 2012, we resubmitted the NDA seeking approval for SUSTOL, and, in March 2013, the FDA issued a second CRL. In the March 2013 CRL, the FDA identified several issues precluding the approval of SUSTOL, including an issue related to the CMC review and deficiencies at certain of our contract manufacturers. The FDA also requested that we repeat human factors testing using commercially equivalent material and provide data to allow reanalysis of our 2008 Phase 3 pivotal clinical trial results under the revised 2011 ASCO CINV Guidelines. In July 2015, we resubmitted our NDA for SUSTOL to the FDA. In our recent resubmission, we believe that we addressed the issues raised in the March 2013 CRL. In addition, the resubmission included the results of our Phase 3 MAGIC study. We currently expect the FDA to complete its review of our SUSTOL NDA in late February 2016.

SUSTOL Phase 3 MAGIC Clinical Trial

Our MAGIC study was a prospective, randomized, placebo-controlled, two-arm, Phase 3 study that randomized 942 patients undergoing HEC treatment for various tumor types. The study was initiated in 2014 and completed in May 2015. In the study, HEC regimens were defined by the 2011 ASCO CINV Guidelines and included cisplatin regimens of ^{3} 50 mg/m^2 among other agents. MAGIC, which was conducted entirely in the U.S. at 83 community oncology centers, is the first and only Phase 3 CINV study in which patients in the comparator arm received the standard-of-care, three-drug regimen used for prophylaxis in a HEC population.

On day 1 of the first treatment cycle, patients were randomized 1:1 to receive either: (i) SUSTOL administered subcutaneously plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg; or (ii) IV ondansetron 0.15 mg/kg (up to 16 mg) plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg. On day 2 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg once (QD), and, on days 3 and 4 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg twice daily (BID). The primary endpoint of the study was the proportion of patients who achieved a Complete Response, defined as no emesis and no rescue medications, during the delayed phase of CINV, occurring 24-120 hours following administration of HEC regimens.

The study's primary endpoint was achieved. The percentage of patients who achieved a Complete Response was significantly higher in the SUSTOL group (64.7%) compared to the ondansetron group (56.6%), which produced an absolute treatment difference of 8% (95% CI 1.7-14.4; p = 0.014), equating to a relative 14% Complete Response rate improvement. Among patients within the high-risk cisplatin stratum, delayed-phase Complete Response was greater in the SUSTOL group (65.3%) versus the ondansetron group (54.7%), demonstrating an absolute treatment difference of 11% (95% CI -1.4-22.7), equating to a relative 19% Complete Response rate improvement. The study's secondary endpoints demonstrated numerical superiority in the SUSTOL group compared to the ondansetron group, but failed to reach statistical superiority. Key additional endpoints demonstrated that a significantly greater proportion of patients did not require rescue medication in the delayed phase with the SUSTOL regimen versus the ondansetron regimen (p = 0.013), patient-reported satisfaction with nausea and vomiting control was significantly greater with the SUSTOL regimen versus the ondansetron regimen in the delayed phase (p = 0.040), rates of no nausea were numerically higher in the SUSTOL regimen versus the ondansetron regimen in the delayed and overall phases, and a post hoc analysis indicated SUSTOL was associated with significantly less frequent nausea in the delayed (p = 0.032) and overall phases (p = 0.048). Adverse events reported in the study were generally mild-to-moderate in severity and of short duration, with the most common being injection site reactions.

SUSTOL 2008 Phase 3 Pivotal Clinical Trial

SUSTOL was previously the subject of a pivotal Phase 3 clinical trial, which was completed in 2008. The results from this study comprised the foundation for the original SUSTOL NDA. In this study, we enrolled more than 1,300 patients and successfully demonstrated that SUSTOL's efficacy in preventing CINV was statistically non-inferior to that of ALOXI. The study was designed to demonstrate the safety and efficacy of SUSTOL in the treatment of CINV following the administration of HEC or MEC regimens and to establish an effective dose for SUSTOL. Four primary efficacy endpoints were selected: non-inferiority to ALOXI for the prevention of acute and delayed CINV following administration of MEC regimens and acute CINV following administration of HEC regimens; and superiority for the prevention of delayed CINV following administration of HEC regimens.

The trial stratified patients into two groups, one receiving MEC regimens and the other receiving HEC regimens. In each emetogenic group, patients were randomized during Cycle 1 to receive SUSTOL high dose (10 mg granisetron), SUSTOL low dose (5 mg granisetron) or the currently approved dose of ALOXI. For up to three subsequent treatment cycles (Cycles 2–4), the patients were re-randomized to receive either of the two SUSTOL doses.

Patients in the SUSTOL high-dose group achieved Complete Response rates numerically higher than, and statistically non-inferior to, ALOXI across all four assessments. A pharmacokinetic analysis conducted in a sub-group of patients showed that a single SUSTOL 10 mg dose maintained blood levels of granisetron at therapeutic level for the entire five-day period. Patients receiving the 5 mg dose of SUSTOL did not demonstrate non-inferiority to ALOXI for all endpoints, and SUSTOL did not achieve the superiority endpoint for the delayed CINV assessment following administration of HEC regimens in either group. ALOXI is not FDA approved for the prevention of delayed CINV following administration of HEC regimens; therefore, in order to receive FDA approval for this indication, we were required to demonstrate that SUSTOL was statistically superior to ALOXI. Collectively, the Phase 3 efficacy and safety data demonstrated that the 10 mg dose is the most effective dose, and, therefore, it was selected for the SUSTOL NDA. SUSTOL was generally well tolerated, with a side effect profile consistent with previous human use of granisetron, and only one serious adverse event was reported as possibly attributed to SUSTOL.

Other Clinical Programs

HTX-019 (NK_1 Receptor Antagonist for CINV Prevention)

HTX-019 is a proprietary intravenous formulation of aprepitant, an NK_1 receptor antagonist, for the prevention of CINV. NK_1 receptor antagonists are used in combination with 5-HT_3 receptor antagonists. At present, the only injectable NK_1 receptor antagonist approved in the U.S., EMEND for Injection (fosaprepitant), contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions, infusion site reactions or other adverse reactions in some patients. HTX-019 is formulated without polysorbate 80, and, in a recently completed bioequivalence study in healthy volunteers, HTX-019 was shown to have a substantially improved safety profile compared to IV fosaprepitant. An assessment of safety found HTX-019 to be safe and well-tolerated, and the pharmacokinetic profile of HTX-019 was comparable to IV fosaprepitant in the study. The FDA has stated that achieving bioequivalence to IV fosaprepitant would be sufficient for regulatory approval of HTX-019 under the 505(b)(2) pathway. As such, we intend to file an NDA for HTX-019 in the second half of 2016. According to FactSet Research Systems, Inc., in 2015, Merck & Co's EMEND and EMEND for Injection generated U.S. sales of approximately $535 million.

HTX-011 (Post-Operative Pain Management)

HTX-011, which utilizes our Biochronomer technology, is a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. By delivering sustained levels of both a potent anesthetic and an anti-inflammatory agent, HTX-011 was designed to provide extended pain relief while potentially reducing the need for systemically administered pain medications such as opioids, which carry the risk of abuse, addiction and other harmful side effects.

In September 2015, we reported positive, top-line results from a randomized, placebo-controlled, double-blind, Phase 2 clinical trial of HTX-011 in patients undergoing bunionectomy. The primary and all key secondary endpoints in this study were achieved with a high degree of statistical significance. The primary endpoint, the difference as compared to placebo in pain intensity as measured by the Summed Pain Intensity (SPI) score in the first 24 hours post-surgery (SPI 0-24), was achieved ($p < 0.0001$). HTX-011 also produced significantly reduced pain intensity scores after the first 48 hours and 72 hours post-surgery. In addition, the time to first use of opioid rescue medication was significantly increased in the HTX-011 group compared to the placebo group ($p < 0.0001$), and there were significantly more patients receiving no opioid rescue medication in the HTX-011 group compared to the placebo group ($p < 0.0001$). HTX-011 was generally well-tolerated in the study. The most frequent adverse events reported were headache, nausea, vomiting, erythema, cellulitis, dizziness and hypoxia, none of which were considered drug-related.

In February 2016, we initiated a placebo-controlled, dose-finding, Phase 2 clinical trial in approximately 100 patients undergoing abdominoplasty, which is evaluating the safety and efficacy of HTX-011. HTX-011 is also currently being evaluated in a placebo-controlled, dose-finding, Phase 2 clinical trial in approximately 100 patients undergoing inguinal hernia repair.

We plan to further develop HTX-011 within a broad-based development program targeting the wide range of surgical procedures with significant potential for post-operative pain. We plan to target several surgical settings in the first half of 2016 in preparation for an End-of-Phase 2 meeting with the FDA in the second half of 2016. According to Decision Resources Group,

the addressable market for HTX-011 consisted of approximately 23 million procedures annually in the U.S. in 2012 and is expected to increase to 29 million in 2021.

Biochronomer Technology

All of our product candidates utilize our innovative science and technology platforms, including our proprietary Biochronomer technology, which can deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period of days to weeks with a single subcutaneous injection. Our Biochronomer technology consists of bioerodible polymers that have been the subject of comprehensive animal and human toxicology studies that have established them to be safe and well tolerated. When injected into subcutaneous tissue, the polymers undergo controlled hydrolysis, resulting in a controlled, sustained release of the pharmacological agent encapsulated within the Biochronomer-based composition. Furthermore, more than one pharmacological agent can be incorporated into our Biochronomer technology such that multimodal therapy can be delivered with a single injection.

Clinical Supplies and Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so to meet the preclinical and clinical requirements of our product candidates and for all of our commercial needs. We currently have long-term commercial supply agreements with certain third-party manufacturers. Our manufacturing and processing agreements require that all third-party contract manufacturers and processors produce active pharmaceutical ingredients and finished products in accordance with the FDA's current Good Manufacturing Practices ("cGMP") and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

With regard to SUSTOL, we use third-parties for each stage of the manufacturing process. We source the granisetron from independent suppliers. We use a different third-party supplier to manufacture our proprietary polymer, and another third-party supplier formulates, fills and packages our final product. To date, SUSTOL has been manufactured in small quantities for preclinical studies and clinical trials. If SUSTOL is approved for commercial sale, we will need to manufacture the product in larger quantities than produced for these preclinical and clinical trials. Significant scale-up of manufacturing requires additional process development and validation studies, which the FDA must review and approve. We are currently in the process of completing this scale-up and validation work. If approved, the commercial success of SUSTOL, in the near-term, will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture. If SUSTOL receives regulatory approval, we plan to scale-up manufacturing through our third-party manufacturers for SUSTOL with the objective of realizing important economies of scale. These scale-up activities could take time to implement, require additional capital investment, process development and validation studies, and FDA approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

Sales and Marketing

We have completed building our sales and marketing organization to support the commercial launch of SUSTOL, if approved, in the U.S. in the second quarter of 2016. Because of the early stage of our other pharmaceutical development programs, we have not yet developed sales and marketing strategies for any other product candidates that we may successfully develop.

Customers, Distribution and Markets

We do not currently sell or distribute pharmaceutical products and consequently there is no market for our products.

Competition

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors in the field are many in number and include major and mid-sized pharmaceutical and biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies. Any products that we may develop or discover will compete in highly competitive markets. Our potential competitors in these markets may succeed in developing products that could render our product candidates obsolete or non-competitive.

SUSTOL, if approved, will face significant competition upon commercial launch. In particular, competition may come from ALOXI, a 5-HT_3 receptor antagonist, and AKYNZEO, an oral formulation of palonosetron combined with the NK_1 receptor antagonist netupitant, both manufactured by Eisai; ProStrakan's SANCUSO , as well as generic forms of granisetron (formerly marketed as KYTRIL) and ondansetron (formerly marketed as ZOFRAN). If we are able to successfully develop HTX-019 for the treatment of CINV, we will compete with other NK_1 receptor antagonists, such as Merck's EMEND® for Injection (fosaprepitant) and Tesaro's VARUBI™ (rolapitant).

With respect to our pain management program, if we are able to successfully develop HTX-011 for the treatment of post-operative pain, we will compete with marketed products such as Pacira Pharmaceuticals Inc.'s EXPAREL® (bupivacaine liposome injectable suspension).

Intellectual Property

Our success will depend in large part on our ability to:

- obtain and maintain international and domestic patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our patents;
- preserve our trade secrets; and
- operate without infringing the patents and proprietary rights of other parties.

We intend to continue to seek appropriate patent protection for the product candidates in our research and development programs and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations.

We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. As of December 31, 2015, we had a total of 15 issued U.S. patents and an additional 47 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2017 and March 2026. The product SUSTOL is covered by patents in the U.S. and in foreign countries. Currently, the product SUSTOL is covered by seven patents issued in the U.S. and by 24 patents issued in foreign countries including Austria, Belgium, Canada, Denmark, the EU, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, Taiwan, and United Kingdom. U.S. patents covering SUSTOL have expiration dates ranging from May 2021 to November 2024; foreign patents covering SUSTOL have expiration dates ranging from May 2021 to September 2025. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our policy is to actively seek patent protection in the United States and to pursue equivalent patent claims in selected foreign countries, thereby seeking patent coverage for novel technologies and compositions of matter that may be commercially important to the development of our business.

Although we believe that our rights under patent applications we own provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Any patents or patent rights that we obtain may be circumvented, challenged or invalidated by our competitors.

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

Government Regulation

Pharmaceutical Regulation

If and when we market any pharmaceutical products in the U.S., they will be subject to extensive government regulation. Likewise, if we seek to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation.

In the United States, the FDA regulates pharmaceutical products. FDA regulations govern the testing, research and development activities, manufacturing, quality, storage, advertising, promotion, labeling, sale and distribution of pharmaceutical products. Accordingly, there is a rigorous process for the approval of new drugs and ongoing oversight of marketed products. We are also subject to foreign regulatory requirements governing clinical trials and drug products if products are tested or marketed abroad. The approval process outside the United States varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

See Item 1A. Risk Factors of this Annual Report on Form 10-K for a discussion of the factors that could adversely impact our development of commercial products and industry regulation.

Regulation in the United States

The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our product candidates will ever obtain approval. The FDA approval process for new drugs includes, without limitation:

- preclinical studies;
- submission in the U.S. of an Investigational New Drug application ("IND"), for clinical trials conducted in the U.S.;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the product;
- review of an NDA in the U.S.; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's current cGMP regulations.

The FDA monitors the progress of trials conducted in the U.S. under an IND and may, at its discretion, re-evaluate, alter, suspend or terminate testing based on the data accumulated to that point and the FDA's risk/benefit assessment with regard to the patients enrolled in the trial. The FDA may also place a hold on one or more clinical trials conducted under an IND for a drug if deems warranted. Furthermore, even after regulatory approval of an NDA is obtained, under certain circumstances, such as later discovery of previously unknown problems, the FDA can withdraw approval or subject the drug to additional restrictions.

Preclinical Testing

Preclinical studies include laboratory evaluation of the product and animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to Good Laboratory Practices, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results.

An IND is the request for authorization from the FDA to administer an investigational new drug product to humans. The IND includes information regarding the preclinical studies, the investigational product's chemistry and manufacturing, supporting data and literature and the investigational plan and protocol(s). Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. An IND must become effective before human clinical trials begin. We have filed INDs in the U.S. and Clinical Trial Applications ("CTAs") in the EU, and we may file additional INDs and CTAs in the future. We cannot assure that submission of any additional IND or CTAs for any of our preclinical product candidates will result in authorization to commence clinical trials.

Clinical Trials

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator and in accordance with a clinical trial protocol, which sets forth details, such as the study objectives, enrollment criteria and the safety and effectiveness criteria to be evaluated. Each clinical trial must be

reviewed and approved by an independent institutional review board ("IRB") in the U.S. or ethics committee in the EU at each institution at which the study will be conducted. The IRB or ethics committee will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the proposed clinical trial. In addition, clinical trials in the U.S. must be performed according to good clinical practices, which are enumerated in FDA regulations and guidance documents. Some studies include oversight by an independent group of experts, known as a data safety monitoring board, which authorizes whether a study may move forward based on certain data from the study and may stop the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds.

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 is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. 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 in the U.S. typically are conducted in sequential phases: Phases 1, 2, 3 and 4. The phases may overlap. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

In Phase 1 clinical trials, the investigational product is usually tested on a small number of healthy volunteers to determine safety, any adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects. Follow-on Phase 1b clinical trials may also evaluate efficacy with respect to trial participants.

In Phase 2 clinical trials, the investigational product is usually tested on a limited number of patients (generally up to several hundred) to preliminarily evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning Phase 3 clinical trials.

In Phase 3 clinical trials, the investigational product is administered to an expanded patient population to confirm proof of concept and efficacy claims, provide evidence of clinical efficacy and to further test for safety, generally at multiple clinical sites.

In Phase 4 clinical trials or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. The FDA may require a commitment to conduct post-approval Phase 4 studies as a condition of approval. Additional studies and follow-up may be conducted to document a clinical benefit where drugs are approved under accelerated approval regulations and based on surrogate endpoints. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. Failure to timely conduct of Phase 4 clinical trials and follow-up could result in withdrawal of approval for products approved under accelerated approval regulations.

We cannot assure that any of our current or future clinical trials will result in approval to market our products.

Clinical Data Review and Approval in the U.S.

The data from the clinical trials, together with preclinical data and other supporting information that establishes a drug candidate's safety, are submitted to the FDA in the form of an NDA, or NDA supplement (for approval of a new indication if the

product candidate is already approved for another indication). Under applicable laws and FDA regulations, the FDA reviews the NDA within 60 days of receipt of the NDA to determine whether the application will be accepted for filing based on the FDA's threshold determination that the NDA is sufficiently complete to permit substantive review. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable.

The FDA has established internal substantive review goals of ten months for most NDAs. 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 based on 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 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 an 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 expedited approval of drugs that treat serious diseases and that fill an unmet medical need based on a surrogate endpoint. The FDA, however, is not legally required to complete its review within these periods, and these performance goals may change over time.

If the FDA approves the NDA, it will issue an approval letter authorizing the commercial marketing of the drug with prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. 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. In many cases, the outcome of the review, even if generally favorable, is not an actual approval, but a "complete response" that generally outlines the deficiencies in the submission, which may require substantial additional testing or information before the FDA will 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. We currently expect to receive correspondence from the FDA with respect to the potential regulatory approval of SUSTOL for commercial sale in late February 2016.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and requires the expenditure of substantial financial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Success in early stage clinical trials does not ensure success in later stage clinical trials. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages, or have conditions placed on it that restrict the commercial applications, advertising, promotion or distribution of these products.

Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the safety or effectiveness of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA may also request or require additional Phase 4 clinical trials after a product is approved. The results of Phase 4 clinical studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system. Any products manufactured or distributed by us pursuant to FDA approvals would be subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we, or our present or future suppliers, will be able to comply with the cGMP regulations and other FDA regulatory requirements.

In addition, both before and after approval is sought, we are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion for our products. In addition, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing cGMP. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

The FDA closely regulates the marketing and promotion of drugs. Approval may be subject to post-marketing surveillance and other record-keeping and reporting obligations, and involve ongoing requirements. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Clinical Trial Conduct and Product Approval Regulation in Non-U.S. Jurisdictions

In addition to regulations in the United States, we may be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Our clinical trials conducted in the EU must be done under an IMPD, and the oversight of an ethics committee. If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. There is no assurance that any future

FDA approval of any of our product candidates will result in similar foreign approvals or vice versa. The process for clinical trials in the EU is similar, and trials are heavily scrutinized by the designated ethics committee.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and allows approval of NDAs that rely, at least in part, on studies that were not conducted by or for the applicant and to which the applicant has not obtained a right of reference. Such studies can be provided by published literature, or the FDA can rely on previous findings of safety and efficacy for a previously approved drug. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. Section 505(b)(2) applications may be submitted for drug products that represent a modification (e.g., a new indication or new dosage form) of an eligible approved drug. In such cases, the additional information in 505(b)(2) applications necessary to support the change from the previously approved drug is frequently provided by new studies submitted by the applicant. Because a Section 505(b)(2) application relies in part on previous studies or previous FDA findings of safety and effectiveness, preparing 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical trials. The FDA may approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical trials and delays.

The FDA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity during which the FDA will not approve, and may not even review, a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by one or more patents that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a certification with respect to each such patent. If the 505(b)(2) applicant certifies that a listed patent is invalid, unenforceable or not infringed by the product that is the subject of the Section 505(b)(2) application, it must notify the patent holder and the NDA holder. If, within 45 days of providing this notice, the NDA holder sues the 505(b)(2) applicant for patent infringement, the FDA will not approve the Section 505(b)(2) application until the earlier of a court decision favorable to the Section 505(b)(2) applicant or the expiration of 30 months. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

Drug Enforcement Agency Regulation

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Some of these hazardous materials are considered to be controlled substances and subject to regulation by the U.S. Drug Enforcement Agency ("DEA"). Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act ("CSA"). The CSA governs, among other things, the distribution,

recordkeeping, handling, security and disposal of controlled substances. We must be registered by the DEA in order to engage in these activities, and we are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of the DEA registration, injunctions or civil or criminal penalties.

Third-Party Payor Coverage and Reimbursement

Although none of our current product candidates have been approved or commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures, from time to time, propose and adopt initiatives aimed at cost containment. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;
- fluctuating decisions on which drugs to include in formularies;
- revising drug rebate calculations under the Medicaid program or requiring that new or additional rebates be provided to Medicare, Medicaid and other federal or state healthcare programs; and
- reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new drug therapies before they will reimburse health care providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the United States, the lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit widespread use and lower potential product revenues.

Anti-Kickback, Fraud and Abuse and False Claims Regulation

Upon commercial launch of a product in the United States, we will be subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. Healthcare providers,

physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Arrangements with third-party payors and customers may expose us to applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

Regulations under applicable federal and state healthcare laws and regulations include the federal health care programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral or purchase of any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. In addition, the False Claims Act ("FCA") imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a *qui tam* action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened many of these laws. For example, the Patient Protection and Affordable Care Act ("PPACA"), among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

The continuing interpretation and application of these laws could have a material adverse impact on our business and our ability to compete should we commence marketing a product.

Federal and State Sunshine Laws

In the event we receive approval of a product candidate for marketing, we will need to comply with federal "sunshine" laws, now known as Open Payments, that require transparency regarding financial arrangements with health care providers. This would include the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians and teaching hospitals. Failure to submit required information can result in civil monetary penalties. A number of states have laws that require the implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other health care professionals and entities.

Foreign Corrupt Practices Act

In addition, we may in the future be subject to the Foreign Corrupt Practices Act of 1997 ("FCPA"). The FCPA and other similar anti-bribery laws in other jurisdictions, such as the U.K. Bribery Act, generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission ("SEC"). A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Patient Privacy and Data Security

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, and to govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe products we may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations. We are not a HIPAA covered entity, do not intend to become one, and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to civil and criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Environmental, Health and Safety Laws

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations. Further, in the future, we may open manufacturing facilities that would likely be subject to environmental and health and safety authorities in the relevant jurisdictions. These authorities typically administer laws which regulate, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health,

safety and welfare of employees and members of the public. Violations of these laws could subject us to strict liability, fines or liability to third parties.

Other Laws

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of The NASDAQ Stock Exchange, on which our shares are traded. We are also subject to various laws, regulations and recommendations relating to safe working conditions, laboratory practices and the experimental use of animals.

Employees

As of February 4, 2016, we had 148 full-time employees; 74 are involved in our research and development activities, 54 are involved in our commercial activities and 20 are involved in administration, human resources, finance, legal and information technology. We believe that we are able to attract skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are covered by a collective bargaining agreement and management considers relations with our employees to be good.

Company Information

We were founded in February 1983 as a California corporation under the name AMCO Polymerics, Inc. (“AMCO”). AMCO changed its name to Advanced Polymer Systems, Inc. (“APS”) in 1984 and was reincorporated in the state of Delaware in 1987. APS changed its name to A.P. Pharma, Inc. (“APP”) in May 2001. In January 2014, APP changed its name to Heron Therapeutics, Inc.

Our common stock is traded on The NASDAQ Capital Market under the symbol HRTX.

Our principal offices are located at 123 Saginaw Drive, Redwood City, California 94063. Our telephone number is (650) 366-2626. Our website address is www.herontx.com. We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ITEM 1A. RISK FACTORS.

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Annual Report on Form 10-K. If any of the following events, described as risks, actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment.

Risks Related to our Business

We are substantially dependent upon the approval and success of SUSTOL® (granisetron) Injection, extended release.

The success of our business is dependent upon our ability to develop and commercialize our most advanced product candidate, which we intend to market as SUSTOL, subject to regulatory approval. We have invested a significant portion of our time and financial resources in the development of SUSTOL, which is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting ("CINV") associated with moderately emetogenic chemotherapy ("MEC") or highly emetogenic chemotherapy ("HEC"). In May 2015, we reported positive top-line results from our Phase 3 MAGIC study, which evaluated the efficacy and safety of SUSTOL for the prevention of delayed CINV associated with HEC regimens. SUSTOL, when administered as part of a three-drug regimen with NK_1 receptor antagonist fosaprepitant and corticosteroid dexamethasone, demonstrated a statistically significant benefit in the prevention of delayed CINV compared to the currently recommended, standard-of-care, three-drug regimen. Results from the MAGIC study were included in our New Drug Application ("NDA") for SUSTOL, which we resubmitted to the U.S. Food and Drug Administration ("FDA") on July 17, 2015. The FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of January 17, 2016. In January 2016, we were notified by the FDA that it would not take action on our SUSTOL NDA by the PDUFA date and that the FDA anticipates taking action in late February 2016.

Our ability to generate revenue in the next one to two years and our future success, in large part, depends on the approval, scope of the approved product label and successful commercialization of SUSTOL. We will not be able to commercialize SUSTOL until we obtain regulatory approval in the U.S. In September 2012, we resubmitted the NDA seeking approval for SUSTOL with the FDA. In March 2013, we received a Complete Response Letter ("CRL") from the FDA pertaining to our resubmission of our NDA for SUSTOL. In the CRL, the FDA identified several remaining issues that need to be addressed prior to approval of our NDA for SUSTOL, including issues relating to: manufacturing of SUSTOL, the administration of SUSTOL and our analysis of efficacy data for SUSTOL under more recent guidelines classifying chemotherapy regimens. We believe we have addressed the issues, although there can be no assurance that the FDA will agree. The FDA's review of our resubmission may not produce positive decisions as to whether:

- SUSTOL is safe and effective in its proposed use(s) and whether its benefits outweigh the risks;

- the labeling for SUSTOL can include our desired product indications covering acute and delayed CINV, for use in both HEC and MEC regimens; and

• the methods used in manufacturing SUSTOL and the controls used to maintain its quality are adequate to preserve chain of identity, strength, quality and purity.

Delays in obtaining regulatory approval for SUSTOL, or the issuance of another CRL by the FDA, would, among other consequences, delay the launch of SUSTOL and impact our ability to raise additional capital, which would have a material adverse effect on our business and financial condition.

If SUSTOL is approved, but does not attain market acceptance by healthcare professionals and patients, our business and results of operations will suffer.

Even if SUSTOL receives regulatory approval for commercial sale by the FDA, the revenue that we may receive from the sale of SUSTOL may be less than expected and will depend on many factors that are outside of our control. Factors that may affect revenue from SUSTOL, if approved, include:

• the scope of our approved product label;

• the perception of physicians and other members of the health care community of the safety and efficacy and cost-competitiveness relative to that of competing products;

• the cost-effectiveness of our product;

• acceptance by institutional formulary committees;

• patient and physician satisfaction with our product;

• our ability to have SUSTOL manufactured at a commercial production level successfully and on a timely basis;

• the cost and availability of raw materials;

• the size of the potential market for our product;

• our ability to obtain adequate reimbursement from government and third-party payors;

• unfavorable publicity concerning our product or similar products;

• the introduction, availability and acceptance of competing treatments;

• adverse event information relating to our product or similar classes of drugs;

• product liability litigation alleging injuries relating to the product or similar classes of drugs;

• product labeling or product insert language required by the FDA or regulatory authorities in other countries;

• our ability to access third parties to manufacture and distribute our product on acceptable terms;

- regulatory developments related to the manufacture or continued use of our product;
- any post-approval study requirements and the results thereof;
- the extent and effectiveness of sales and marketing and distribution support for our product;
- our competitors' activities, including decisions as to the timing of competing product launches, pricing and discounting; and
- any other material adverse developments with respect to the potential commercialization of our product.

Our revenue will be adversely affected if, due to these or other factors, our commercialization of SUSTOL does not achieve the acceptance and demand to sustain product revenue growth. If we are unable to successfully commercialize SUSTOL, we may not be able to earn sufficient revenues to continue our business.

We have yet to receive regulatory approval for a product utilizing our proprietary drug delivery technology.

Our proprietary Biochronomer® drug delivery technology has not yet been proven through commercial approval, and successful launch, of a product utilizing this technology. We may not be able to substantiate the commercial viability of our drug delivery technology for a variety of reasons, including:

- the failure to receive regulatory approval of a drug utilizing the delivery technology;
- the inability to show consistent results in the quality or quantity of product manufactured utilizing this delivery technology; and
- the inability to manufacture drugs using this delivery platform at a cost effective price.

In the event we are unable to demonstrate commercial success and viability of products utilizing this delivery technology, our prospects for success and growth would be significantly harmed.

Our product platforms or product development efforts may not produce safe, efficacious or commercially viable products and, if we are unable to develop new products, our business may suffer.

Our long-term viability and growth will depend upon the successful development of products from our research and development activities. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early-stage clinical trials does not ensure that later-stage or larger-scale clinical trials will be successful. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials and compliance with extensive current good clinical practices ("cGCP") requirements.

In addition, because we fund the development of our product candidates, we may not be able to continue to fund all such development efforts to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals,

or market any approved products. If our delivery technologies or product development efforts fail to result in the successful development and commercialization of product candidates or if new products do not perform as anticipated, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

We rely on third parties to do our preclinical testing and conduct our clinical trials, and their failure to perform their obligations in a timely and competent manner may delay development and commercialization of our product candidates and our business could be substantially harmed.

We have used contract research organizations ("CROs") to oversee our clinical trials for SUSTOL, HTX-011 and our other product candidates, and we expect to use the same or similar organizations for our future clinical trials and pipeline programs. There can be no assurance that these CROs will perform their obligations at all times in a competent or timely fashion, and we must rigorously oversee their activities in order to be confident in their conduction of these trials on our behalf. If the CROs fail to commit resources to our product candidates, our clinical programs related to our product candidates could be delayed, terminated or unsuccessful, and we may not be able to obtain regulatory approval for or successfully commercialize them. Different cultural and operational issues in foreign countries could cause delays or unexpected problems with patient enrollment or with the data obtained from those locations. If we experience significant delays in the progress of our clinical trials or experience doubts with respect to the quality of data derived from our clinical trials, we could face significant delays in gaining necessary product approvals.

We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, and the Animal Welfare Act requirements. We, our CROs, and other third parties are required to comply with cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in the clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our ongoing or future clinical trials comply with GCP requirements. In addition, any of our clinical trials must be conducted with product produced under GCP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs and other third parties we may engage to support our development programs, are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner, or may fail to perform at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the preclinical results or clinical data they obtain is compromised due to the failure to adhere to test requirements, our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If our suppliers and contract manufacturers fail to manufacture SUSTOL in a timely manner or fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for SUSTOL.

We are dependent on third-party manufacturers for the manufacture of our product candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the approval or manufacturing of SUSTOL or any of our product candidates could be delayed, which could harm our results of operations. To date, we have relied on third parties to manufacture and perform important pre-commercialization manufacturing activities for SUSTOL. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture SUSTOL are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes of our third-party suppliers and manufacturers, and data supporting the stability of SUSTOL. If our third-party suppliers and manufacturers are not in compliance with current Good Manufacturing Practice ("cGMP") requirements, the approval by regulatory authorities for us to begin marketing a product may be delayed, existing product batches may be compromised, and we may experience delays in the availability of SUSTOL for commercial distribution.

For example, our most recent CRL from the FDA regarding our NDA resubmission for SUSTOL stated that the NDA could not be approved due to, among other issues, deficiencies observed during an inspection of the facilities used by our third-party suppliers and manufacturers to produce SUSTOL. If the FDA is not satisfied with our response and corrective actions taken by these third parties, we may be required to complete additional manufacturing development activities or provide other information to the FDA, which could cause substantial delays in obtaining regulatory approval for SUSTOL, increase our costs and have a material adverse effect on our business and financial condition.

If our suppliers and contract manufacturers are unable to manufacture in commercially viable quantities, we could face delays in our ability to commercialize SUSTOL, and our costs will increase.

To date, SUSTOL has been manufactured primarily in small quantities for clinical trials. If in the future, SUSTOL or any of our product candidates are approved for commercial sale, we will need to be able to consistently manufacture our products in larger quantities, and be able to show equivalency for the FDA in the manufacture of product at commercial scale as compared to development batch size. The commercial success of our products will be dependent upon the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture in a process that is validated by the FDA. If SUSTOL receives regulatory approval, we plan to scale-up manufacturing for SUSTOL in order to realize important economies of scale. These scale-up activities take time to implement, require additional capital investment, process development and validation studies, and regulatory approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scale-up activities.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time, including product loss due to material failure, equipment failure, vendor error, operator error, labor shortages, inability to obtain material, equipment or transportation, physical or electronic security breaches and natural disasters. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. We may not be able to resolve any such problems in a timely manner, if at all.

We expect to depend on third party suppliers and contract manufacturers for manufacturing SUSTOL, as well as any future products that we develop; if our contract manufacturers do not perform as expected, our business could suffer.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of any product, including SUSTOL. Our ability to progress and commercialize SUSTOL, as well as any other products or product candidates that we may develop will depend in part on our ability to arrange for other parties to manufacture our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and eventual commercialization, if approved. We currently rely on a small number of third-party manufacturers to produce compounds used in our product development activities and expect to continue to do so to meet the preclinical and clinical requirements of our potential products and for all of our commercial needs. Certain contract manufacturers are, at the present time (and are expected to be for the foreseeable future), our sole resource to manufacture certain key components of SUSTOL, as well as key components for product candidates in clinical and preclinical testing in our research and development program. Although we entered into a single-source, long-term commercial manufacturing agreement for the manufacture of SUSTOL and have a long-term agreement for the manufacture of our bioerodible polymer, we may not be able to successfully negotiate long-term agreements with any additional third parties and thereby reduce or remove our dependence on a single supplier. We may have difficulties with these manufacturer relationships, and we may not be able to find replacement contract manufacturers on satisfactory terms or on a timely basis. Also, due to regulatory and technical requirements, we may have limited ability to shift production to a different third party should the need arise. We cannot be certain that we could reach agreement on reasonable terms, if at all, with such a manufacturer. Even if we were to reach agreement, the transition of the manufacturing process to a different third party could take a significant amount of time and money, and may not be successful.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements. They may be required to pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our products and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, or fail to scale up manufacturing processes in a timely manner, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in an enforcement action, such as product recall, or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

SUSTOL, HTX-011, HTX-019 or any of our other product candidates may be in competition with other products for access to the facilities of third parties. Consequently, SUSTOL, HTX-011, HTX-019 or any of our other product candidates may be subject to manufacturing delays if our contractors give other companies' products greater priority than our products. For this and

other reasons, our third-party contract manufacturers may not be able to manufacture SUSTOL, HTX-011, HTX-019 or any of our other product candidates in a cost-effective or timely manner. If not manufactured in a timely manner, the clinical development of any of our product candidates or their submission for regulatory approval could be delayed, and our ability to deliver products to market on a timely basis could be impaired. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

Certain of the components used in the manufacture of SUSTOL, HTX-011, HTX-019 and our other product candidates are sourced from a single vendor.

Some of the critical materials and components used in manufacturing SUSTOL, HTX-011, HTX-019 and our other product candidates are sourced from single suppliers. An interruption in the supply of a key material could significantly delay commercialization of SUSTOL, if approved, our research and development process or increase our expenses for commercialization or development products. Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in the technologies in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source of a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required or if the materials traditionally have not been used in pharmaceutical products.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may be unable to generate product revenue.

We are currently in the initial stages of developing an internal sales organization for the sale, marketing and distribution of SUSTOL, or for any other products we may develop. In order to successfully commercialize SUSTOL or any other product, we must build our sales, marketing, distribution and other non-technical capabilities or make arrangements with third parties to perform these services. The establishment and development of a sales organization to market SUSTOL and our other product candidates will be expensive and time consuming and could delay product launch, and we cannot be certain that we will be able to successfully develop this capacity. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

If we are unable to recruit and retain skilled employees, we may not be able to achieve our objectives.

We depend on a small number of key management and technical personnel. Retaining our current employees and recruiting qualified personnel to perform future research and development and commercialization work will be critical to our success. Competition is always present for highly skilled and experienced personnel, and an inability to recruit or retain sufficient skilled personnel could result in delays in our business growth and development and adversely impact our research and development or commercial activities. If we lose key members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result.

Our business strategy may include acquisitions of other businesses, products or product licenses. We may not be able to successfully manage such activities.

We may engage in strategic transactions that could cause us to incur contingent liabilities, commitments, or significant expense. In the course of pursuing strategic opportunities, we may evaluate potential acquisitions or investments in strategic technologies, products, or businesses. Future acquisitions or investments could subject us to a number of risks, including, but not limited to:

- our inability to appropriately evaluate and take into consideration the potential uncertainties associated with the other party to such a transaction, including but not limited to the prospects of that party and their existing products or product candidates and regulatory approvals;

- difficulties associated with realizing the perceived potential for commercial success with respect to any acquired technology, product, or business;

- our ability to effectively integrate any new technology, product, and/or business including personnel, intellectual property or business relationships into our company;

- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs and/or assumption of liabilities; and

- the distraction of our management from our existing product development programs and initiatives in pursuing an acquisition.

In connection with an acquisition, we must estimate the value of the transaction by making certain assumptions that may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Any strategic transaction we may pursue may not result in the benefits we initially anticipate, and/or result in costs that end up outweighing the benefits, and may adversely impact our financial condition and be detrimental to our future business prospects.

Our business strategy may include entry into collaborative agreements. We may not be able to enter into collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our current business strategy may include the entry into collaborative agreements for the development and commercialization of our products and product candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators'

resources that will be devoted to our research activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators we may work with in the future, we may rely significantly on them to, among other activities:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market for or with us for any commercial products that result from our collaborations.

If we do not consummate collaborative agreements, we may use our financial resources more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative relationships, our business prospects could suffer.

Risks Related to our Financial Condition

We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

We have incurred significant operating losses and negative cash flows from operations and had an accumulated deficit of $412.8 million through December 31, 2015. Even if SUSTOL is approved, we expect to continue to generate substantial losses over at least the next several years as we:

- continue to build a sales and marketing organization and commence commercialization of SUSTOL, if approved;
- expand product development activities with respect to our product candidates;
- conduct preclinical development and clinical trials for our product candidates;
- pursue regulatory approvals for any current or future product candidates; and
- engage in commercialization efforts for any future approved product candidates.

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, on:

- the number of product candidates we pursue;
- the progress of our research and development programs for our product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our product candidates, whether such approvals are obtained and the scope of any approved product label;

- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the costs of potential litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

To achieve and sustain profitability, we must, alone or in cooperation with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. If SUSTOL is approved for commercialization, we must successfully launch and commercialize the product. If SUSTOL is not approved, we will likely experience significant delays before we begin to recognize meaningful levels of revenue, if ever. We will incur substantial expenses in our efforts to develop and commercialize our products and we may never generate sufficient revenue to become profitable or to sustain profitability.

Additional capital may be needed in the future to enable us to implement our business plan, and we may be unable to raise capital, which would force us to limit or cease our operations and related product development programs.

In June 2015, we completed an underwritten public offering of 5,520,000 shares of our common stock for net proceeds of approximately $128.2 million, and as of December 31, 2015, we had cash, cash equivalents and short-term investments of $131.2 million. We believe that our current working capital is sufficient to fund operations through 2016, including pursuing regulatory approval for SUSTOL in the U.S. and, if approved, making significant investments to support commercialization, and completing Phase 2 and 3 clinical studies currently ongoing and expected to commence in 2016 relative to our HTX-011 and HTX-019 product candidates. In the event that we pursue preclinical and/or clinical development in other areas, potentially acquire other strategic assets, if SUSTOL is not approved or if the degree of commercial success of SUSTOL is less than expected, we may need to raise additional capital, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we may receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, development program progress, interest rates and other factors. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities. Our capital requirements going forward will depend on numerous factors, including but not limited to: the scope, rate of progress, results and costs of preclinical testing and clinical trials; an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program, including the timing of clinical trials; the time, cost and outcome involved in seeking other regulatory approvals; scientific progress in our research and development programs; the magnitude and scope of our research and development programs; our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates; the cost and timing of establishing sales, marketing and distribution capabilities if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

We may not be able to raise additional capital when needed or desired, or we may need to raise additional capital on unfavorable terms, which could result in dilution to existing stockholders.

We may not be able to raise sufficient additional capital when we need it on favorable terms, or at all. If we are unable to obtain adequate funds, we may be required to curtail significantly or cease our operations.

The timing and degree of any future capital requirements will depend on many factors, including:

- the status of regulatory approval of any pending applications with the FDA, or other regulator, as the case may be, and the costs involved with pursuing regulatory approvals;
- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of preclinical testing and clinical trials;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates;
- the cost and timing of establishing sales and marketing capabilities if we commercialize any products independently; and
- the cost of establishing supply arrangements for clinical and commercial development of our product candidates and any products that we may develop.

If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment, and such issuance may adversely affect the market price of our common stock. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. Our Senior Secured Convertible Notes (“Convertible Notes”) also include restrictions on our use of cash and financial activities. In the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products on terms that are not favorable to us or require us to enter into a collaboration arrangement that we would otherwise seek to develop and commercialize ourselves. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs and reduce personnel-related and other costs, which would have a material adverse effect on our business.

Provisions contained in our Convertible Notes limit our ability to incur additional indebtedness.

The Convertible Notes are secured by substantially all of our assets, including our bank and investment accounts, and the terms of the Convertible Notes require us to seek approval from the holders of the Convertible Notes before taking certain actions, including incurring additional indebtedness or modifying the terms of existing indebtedness. The Convertible Notes also include events of default which include any default of our financial obligations under certain material contracts we may enter into. In addition, potential third-party lenders may be unwilling to subordinate new debt to the Convertible Notes. As a

result, we may not be able to raise funds through the issuance of debt in the future, which could impair our ability to finance our business obligations or pursue business expansion initiatives.

We could be exposed to significant product liability claims that could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our product candidates and products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time.

Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our products, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could also significantly harm our reputation and delay market acceptance of our products.

The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.

Our investments of cash, cash equivalents and short-term investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

Risks Related to our Industry

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we have incurred significant expenses in developing SUSTOL and, even if approved and depending on the scope of the approved product label, it may not result in a commercially viable product. Before obtaining regulatory approvals for the commercial sale of any products, we, or our potential partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and will continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials.

The outcome of clinical testing is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later stage clinical trials. In addition, regulations are not static, and regulatory agencies, including the FDA, alter their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfying FDA, and other regulatory agencies', requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product candidate. Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials. Factors that could impede our ability to generate commercially viable products through the conduct of clinical trials include:

- insufficient funds to conduct clinical trials;
- the inability to find partners, if necessary, for support including research, development, manufacturing or clinical needs;
- the failure of tests or studies necessary to submit an NDA, such as bioequivalence studies in support of a 505(b)(2) regulatory filing, or stability studies, to meet the required standards;
- the failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- the failure by us or third-party investigators, CROs, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- the failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- any delay in completion of clinical trials, resulting in increased costs; and
- the inability to obtain regulatory approval of our product candidates following completion of clinical trials, or delays in obtaining such approvals.

There can be no assurance that if our clinical trials are successfully initiated and completed we will be able to obtain approval by the FDA in the U.S. or similar regulatory authorities elsewhere in the world in a timely manner, if at all. If we fail to successfully develop and commercialize one or more of our product candidates, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

Delays in clinical testing could increase our costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Before we can receive regulatory approval for the commercial sale of our potential products, the FDA and comparable authorities in non-U.S. jurisdictions require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Significant delays in preclinical and clinical testing could materially impact our product development costs and delay

regulatory approval of our product candidates. Our ability to complete clinical trials in a timely manner could be impacted by, among other factors:

- delay or failure in reaching agreement with the FDA or comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delay or failure in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board ("IRB") approval or the approval of other reviewing entities, including comparable foreign entities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in obtaining clinical materials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- feedback from the FDA, the IRB, data safety monitoring boards, or comparable foreign entities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol;
- decision by the FDA, the IRB, comparable foreign regulatory entities, or recommendation by a data safety monitoring board or comparable foreign regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug;
- manufacturing issues, including problems with manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials; and
- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

Our failure to successfully establish, recruit for, and oversee our clinical trials could delay our product development effects and negatively impact our business. If we experience delays in the completion of any ongoing study, the commercial prospects of HTX-011, HTX-019 or any of our other product candidates could be harmed, and our ability to generate product revenue will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidates' development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may not obtain regulatory approval for any of our product candidates. Regulatory approval may also be delayed or revoked or may impose limitations on the indicated uses of a proposed product. If we are unable to obtain regulatory approval for SUSTOL or any of our other product candidates, our business will be substantially harmed.

The process for obtaining approval of a new drug is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. The regulatory process is uncertain, can take many years and requires the expenditure of substantial resources. Any product that we or our potential future collaborative partners develop must receive all necessary regulatory agency approvals or clearances before it may be marketed in the U.S. or other countries. Human pharmaceutical products are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the U.S. and similar health authorities in foreign countries. We may not receive necessary regulatory approvals or clearances to market SUSTOL or any other product candidate in the U.S. or in other jurisdictions, as a result of changes in regulatory policies prior to approval or other events. Additionally, data obtained from preclinical and clinical activities, or from stability or bioequivalence studies, are susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances.

SUSTOL or any of our other product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;

- failure to demonstrate that the product candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- the failure of third-parties to manage and conduct the trials or perform necessary oversight to meet expected deadlines or to comply with regulatory requirements;
- failure to demonstrate that the product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable non-U.S. regulatory authority may require additional preclinical or clinical data to support approval, such as confirmatory studies and other data or studies to address questions or concerns that may arise during the FDA review process.

Even if granted, regulatory approvals may include significant limitations on the uses for which products may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in warning letters, imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruption of clinical trials or manufacturing, injunctions and criminal prosecution.

In addition, the marketing and manufacturing of products are subject to continuing FDA review, and later discovery of previously unknown problems with a product, its manufacture or its marketing may result in the FDA requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market.

Failure to obtain regulatory approval in international jurisdictions would prevent SUSTOL or any of our other product candidates from being marketed abroad.

In the event we pursue the right to market and sell SUSTOL or any other product candidates in jurisdictions other than the U.S., we would be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements in each foreign country. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that

country. In the event we choose to pursue them, we may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we are unable in the future to obtain approval of a product candidate by regulatory authorities in non-U.S. jurisdictions, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Even if SUSTOL or any of our other product candidates receives regulatory approval, it may still face future development and regulatory difficulties. If we fail to comply with continuing federal, state and foreign regulations, we could lose our approvals to market drugs, and our business would be seriously harmed.

Even if we obtain regulatory approval for SUSTOL or any of our other product candidates, it would be subject to ongoing requirements of the FDA and comparable foreign regulatory authorities, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping, and reporting of safety and other post-market information. Following initial regulatory approval of any drugs we may develop, including SUSTOL, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that may be reported after drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Additionally, such regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use or other inappropriate sales and marketing activities. Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice, and the Department of Health and Human Services' Office of Inspector General. Violations of applicable advertising and promotion laws and regulations, including promotion of products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business. If SUSTOL is approved, we will also be required to comply with the requirements to submit to governmental authorities information on payments to physicians and certain other third parties; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business.

We cannot predict whether any commercial use of our product candidates, if approved, will produce undesirable or unintended side effects that have not been evident in clinical trials conducted for such product candidates to date. Additionally, incidents of product misuse may occur. These events, including the reporting of adverse safety events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

We face intense competition from other companies developing products in the CINV indication, including those with potentially competitive delivery technologies.

SUSTOL, if approved, will face significant competition upon commercial launch. In particular, competition may come from ALOXI, a 5-HT_3 receptor antagonist and AKYNZEO®, an oral formulation of palonosetron combined with the NK_1 receptor antagonist netupitant, both manufactured by Eisai; ProStrakan's SANCUSO® (granisetron transdermal patch), as well as generic forms of granisetron (formerly marketed as KYTRIL) and ondansetron (formerly marketed as ZOFRAN). If we are able to successfully develop HTX-019 for the treatment of CINV, we will compete with other NK_1 receptor antagonists, such as Merck's EMEND® for Injection (fosaprepitant) and Tesaro's VARUBI™ (rolapitant).

With respect to our pain management program, if we are able to successfully develop HTX-011 for the treatment of post-operative pain, we will compete with marketed products such as Pacira Pharmaceuticals Inc.'s EXPAREL® (bupivacaine liposome injectable suspension**)**.

Smaller or early stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient

registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Our products may face competition from lower cost generic products offered by our competitors.

Pricing for therapeutics can be extremely competitive, and strict formulary guidelines enforced by payors may create significant challenges in the acceptance and profitability of branded products. The market for generic products can be very lucrative, and it is dominated by companies that may have much larger distribution capabilities than we may have in the future. It can be very difficult to predict the timing of the launch of generic products given the commonality of litigation with manufacturers over anticipated patent expiration. Our inability to accurately foresee and plan for generic product launches that may compete with our products may significantly impact our potential revenues from such products. Upon the expiration or loss of patent protection for a branded product, or upon the “at-risk” launch (despite pending patent infringement litigation against the generic product) by a manufacturer of a generic version of a drug that may compete with one of our products, we could quickly lose a significant portion of our sales of that product. The inability for a branded product we may sell to successfully compete against generic products could negatively impact sales of our product, reduce our ability to grow our business, and significantly harm our business prospects.

If we cannot establish pricing of our product candidates acceptable to the U.S. or foreign governments, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales will be severely hindered.

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect our ability to generate adequate revenues and gross margins to make the products we develop commercially viable. Our ability to commercialize any product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of such products and related treatments and for what uses reimbursement will be provided.

In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, reducing the cost of prescription pharmaceuticals and reforming the Medicare and Medicaid systems. For example, the 2010 Patient Protection and Affordable Care Act (“PPACA”) encourages comparative effectiveness research. Any adverse findings for our products from such research may negatively impact reimbursement available for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly asking manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Further, the trend toward managed health care in the U.S., which could significantly influence the purchase of health care services and products, may result in lower prices for our products, if they are approved for marketing. While we cannot predict whether any legislative or regulatory proposals affecting our business will

be adopted, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

If we cannot arrange for adequate third-party reimbursement for our products, our future revenue will suffer.

In both domestic and foreign markets, sales of our potential products, including SUSTOL, will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. Reimbursement policies utilized by our collaborators or ourselves may be challenged by regulatory entities, with resultant fines, negative publicity and the need to implement changes that reduce the utilization of our products. If any products we develop do not receive adequate reimbursement, our revenue could be severely limited.

The pharmaceutical industry is subject to significant regulation and oversight pursuant to anti-kickback laws, false claims statutes, and anti-corruption laws, which may result in significant additional expense and limit our ability to commercialize our products. In addition, any failure to comply with these regulations could result in substantial fines or penalties.

In the U.S., upon commercial launch of a product, we will be subject to health care fraud and abuse regulations that are enforced by both the federal government and the states in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product with marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products with marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following:

- the Federal health care programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

- 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 federal health care programs that are false or fraudulent. This false claims liability may attach in the event that a company is found to have knowingly submitted false average sales price, best price or other pricing data to the government or to have unlawfully promoted its products;

- federal "sunshine" laws, now known as Open Payments, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians and teaching hospitals; and

• 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.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened many of these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

In addition, a number of states have laws that require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other health care professionals and entities. Similarly, the federal Physician Payments Sunshine Act within PPACA requires pharmaceutical companies to report to the federal government certain payments to physicians and teaching hospitals. The Physician Payments Sunshine Act provisions required manufacturers that participate in federal health care programs to begin collecting such information after a six-month period following commercial launch of a product; however state law equivalents may require compliance beginning at commercial launch.

In addition, we may in the future be subject to the Foreign Corrupt Practices Act of 1997 (“FCPA”). The FCPA and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Changes in laws affecting the healthcare industry could also adversely affect our revenues and profitability, including new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, healthcare availability, and product pricing and marketing. Changes in FDA regulations and regulations issued by other regulatory agencies inside and outside of the U.S., including new or different approval requirements, timelines and processes, may also delay or prevent the approval of product candidates, require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from

government-funded healthcare programs, like Medicare and Medicaid, 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. 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 or regulations, 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Health care reform could increase our expenses and adversely affect the commercial success of our products.

The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately upon enactment of the law, and others of which are scheduled to take effect over the next several years. For example, the PPACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U.S. The PPACA also requires increased disclosure obligations—including those required under the "sunshine" laws—and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. These and other aspects of the PPACA, including the regulations that may be imposed in connection with the implementation of the PPACA, could increase our expenses and adversely affect our ability to successfully commercialize our products and product candidates.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We are subject to certain data privacy and security requirements, which are very complex and difficult to comply with at times. Any failure to ensure adherence to these requirements could subject us to fines and penalties, and damage our reputation.

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, which govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe products we may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). We are not a HIPAA covered entity, do not intend to become one, and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

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, as well as personally identifiable information of clinical trial participants and employees. Similarly, our 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. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Our use of hazardous materials could subject us to liabilities, fines and sanctions.

Our laboratory and clinical testing sometimes involve use of hazardous, radioactive or otherwise toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials.

Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from

these materials. In the event of an accident, we could be held liable for any damages that result, and we could also be subject to fines and penalties and such liability and costs could exceed our financial resources. If we fail to comply with these regulations and standards or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. Compliance with environmental and other laws may be expensive and current or future regulations may impair our product development efforts.

Risks Related To Our Intellectual Property

If we are unable to adequately protect or enforce our intellectual property rights, we may lose valuable assets or incur costly litigation to protect our rights.

Our success will depend in part on our ability to obtain patents and maintain trade secret protection, as well as successfully defending these patents against challenges, while operating without infringing the proprietary rights of others. We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. As of December 31, 2015, we had a total of 15 issued U.S. patents and an additional 47 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2017 and March 2026. The product SUSTOL is covered by patents in the U.S. and in foreign countries. Currently, the product SUSTOL is covered by seven patents issued in the U.S. and by 24 patents issued in foreign countries including Austria, Belgium, Canada, Denmark, the EU, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, Taiwan, and United Kingdom. U.S. patents covering SUSTOL have expiration dates ranging from May 2021 to November 2024; foreign patents covering SUSTOL have expiration dates ranging from May 2021 to September 2025. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our policy is to actively seek patent protection in the United States and to pursue equivalent patent claims in selected foreign countries, thereby seeking patent coverage for novel technologies and compositions of matter that may be commercially important to the development of our business. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our existing patents may not cover future products, additional patents may not be issued, and current patents, or patents issued in the future, may not provide meaningful protection or prove to be of commercial benefit.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications may not issue into patents, and any issued patents may not provide sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive technologies or may be held invalid if challenged or circumvented. Patent applications in the U.S. are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. laws.

We may enter into collaborative agreements which may subject us to obligations that must be fulfilled and require us to manage complex relationships with third parties. In the future, if we are unable to meet our obligations or manage our relationships with our collaborators under these agreements our revenue may decrease. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration, requiring us to divert management time and resources to such dispute.

Because the patent positions of pharmaceutical and biotechnology companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to products and processes, including ours, in the U.S., remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. The recently enacted America Invents Act, which reformed certain patent laws in the U.S., may create additional uncertainty. Patents, if issued, may be challenged, invalidated or circumvented. As more products are commercialized using our proprietary product platforms, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We may infringe on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to the composition of a variety of polymers, specific products, product groups and processing technology, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. Therefore, there is risk that third parties may make claims of infringement against our products or technologies. We may not be able to design around the patented

technologies or inventions of others, and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing the proprietary rights of others, we will not be able to develop or commercialize some or all of our product candidates, and consequently will not be able to earn product revenue.

There is considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by any future manufacture, use or sale of our products. In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights. We may have to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patent or trademark applications. For example, in the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file Abbreviated New Drug Applications (“ANDA”) and, in doing so, certify that their products either do not infringe the innovator’s patents or that the innovator’s patents are invalid. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known as “Paragraph IV” litigation in the U.S. These litigations could result in new or additional generic competition to any of our products that may be marketed in the future and a potential reduction in product revenue.

If we are required to defend ourselves in a patent-infringement lawsuit, we could incur substantial costs, and the lawsuit could divert management attention, regardless of the lawsuit’s merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to redesign affected products or obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the U.S. or in countries outside the U.S., or litigation against our partners may be costly and time-consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Risks Related To Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets, in general, and in particular with respect to biotech and life sciences companies, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations

may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility. Our stock price may be particularly volatile given the stage of our business, which is pre-commercial and subject to more speculation by stock market investors.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and our company's resources.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, our certificate of incorporation and our bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include authorizing the issuance of "blank check" preferred stock without any need for action by stockholders.

In addition, Section 203 of Delaware General Corporation Law, which is applicable to us, may discourage, delay or prevent a change in control of our company by prohibiting stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain approvals are obtained.

Conversion of our Convertible Notes would result in substantial dilution for our existing stockholders.

Our outstanding Convertible Notes bear interest at a rate of 6% per annum, payable quarterly in cash or in kind, at the election of the holders of the Convertible Notes. The Convertible Notes are convertible into shares of our common stock at a rate of 1,250 shares for every $1,000 of principal and accrued interest that is being converted. In the event the holders of the Convertible Notes were to opt to convert in full the outstanding principal and accrued interest due under the Convertible Notes as of December 31, 2015, we would be required to issue an aggregate of 7,086,560 shares, representing approximately 16% of our outstanding shares, after giving effect to such conversion. This would result in substantial dilution of our existing stockholders.

Concentration in stockholder ownership could influence strategic actions.

Our directors, executive officers, principal stockholders and affiliated entities currently beneficially own or control a significant percentage of our outstanding common stock. In addition, certain of our principal stockholders hold outstanding warrants that are exercisable for additional shares of our common stock. Based on information set forth in a Schedule 13D/A filed with the SEC on June 12, 2015, Tang Capital Partners, LP and its affiliates' ("TCP") beneficial ownership in our common stock, as determined in accordance with Rule 13d-3 of the Exchange Act, was approximately 14%, excluding the exercise of outstanding warrants. In addition, as of December 31, 2015, TCP has the right to acquire 5,669,248 shares upon conversion of the Convertible Notes. Kevin C. Tang, the Managing Director of Tang Capital Management, LLC, the general partner of Tang Capital Partners, LP, is also chairman of our Board of Directors.

Such a substantial concentration of common stock ownership or control could significantly influence corporate actions on various strategic matters, including, for example, receptivity to collaborations and merger or sale overtures to the extent that stockholder approval is required for such transactions. Further, covenants contained in the Convertible Notes would require approval from the noteholders for any change of control transaction we might consider. Accordingly, we may only be able to pursue transactions that are supported by these large stockholders. In addition, the conversion of the Convertible Notes, the exercise of these warrants, or the sale by our current stockholders of a substantial number of shares, or the expectation that such exercises or sales may occur, could significantly reduce the market price of our common stock.

Future utilization of net operating loss carry-forwards may be impaired due to recent changes in ownership.

We believe our net operating losses and tax attributes may be subject to limitation under Section 382 of the Internal Revenue Code of 1986. As a result, our deferred tax assets, and related valuation allowance, have been reduced for the estimated impact of the net operating losses and credits that we currently estimate may expire unused. Utilization of our remaining net operating loss and research and development credit carry-forwards may still be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions for ownership changes after December 31, 2015, including those that may come in conjunction with future equity financings or market trades by our stockholders.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to uncertainty;

- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our stockholders.

These actions could cause the market price of our common stock to experience periods of volatility.

If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our common stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the NASDAQ Stock Market or other regulatory authorities.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our current and future earnings to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We lease 26,067 square feet of laboratory, office and warehouse space in Redwood City, California under a lease expiring on November 30, 2016. We have the option to extend the lease for an additional three years. In addition, we currently lease 1,898 square feet of office space in Jersey City, New Jersey and 3,419 square feet of office space in San Diego, California. The lease for the Jersey City office space began on July 1, 2015 and expires on December 31, 2016. The lease for the San Diego office space was extended in 2015 for an additional nine-month period ending on March 31, 2016. In 2016, we further extended the San Diego office lease for an additional four-month period ending on July 31, 2016. The annual rent expense for all properties is approximately $1.4 million. We believe our facilities are adequate and suitable for our current needs, and that we will be able to obtain new or additional leased space in the future when necessary.

ITEM 3. LEGAL PROCEEDINGS.

We are not currently a party to any legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Information About Our Common Stock

Shares of our common stock traded on the OTC Bulletin Board under the symbol "APPA.OB" until January 10, 2014. Our shares traded on the OTC Bulletin Board under the symbol "APPAD" following our one-for-twenty reverse stock split effective January 13, 2014. On January 23, 2014, our common stock was approved for listing and began trading on The NASDAQ Capital Market under the symbol "HRTX".

Set forth below are the high and low sales prices for our common stock for each full quarterly period within the two most recent fiscal years.

Year Ended December 31, 2015	High	Low
First Quarter	$16.49	$ 7.09
Second Quarter	$34.03	$10.60
Third Quarter	$42.25	$20.82
Fourth Quarter	$31.32	$20.84

Year Ended December 31, 2014	High	Low
First Quarter	$15.82	$ 8.42
Second Quarter	$15.50	$10.02
Third Quarter	$12.70	$ 8.22
Fourth Quarter	$10.49	$ 6.51

Stockholders

The number of record holders of our common stock as of February 3, 2016 was approximately 408.

Dividend Policy

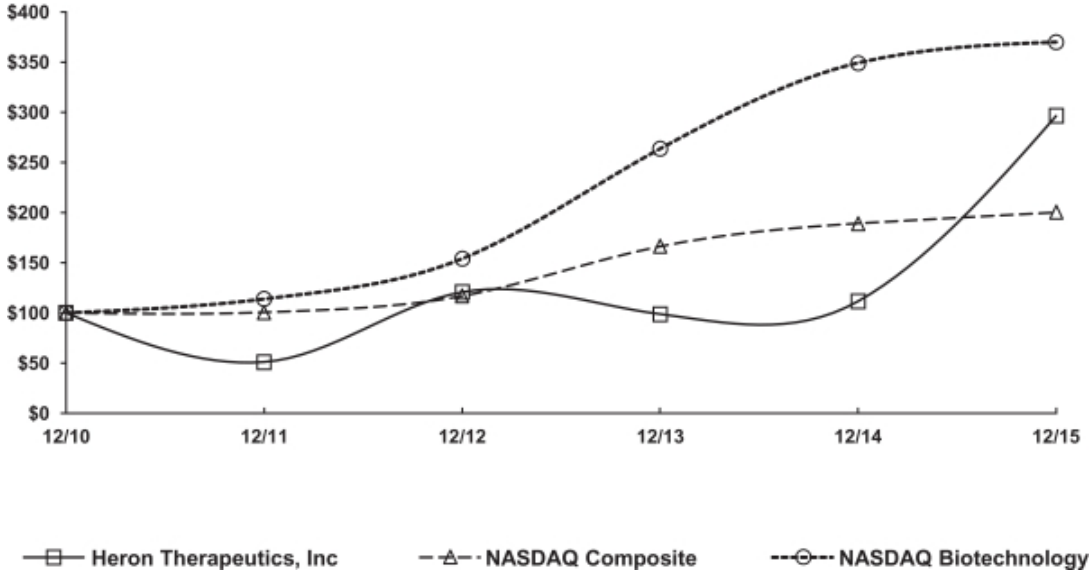
We have never paid dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

Stock Performance Graph

The following is not deemed “filed” with the SEC and is not to be incorporated by reference into any filing we make under the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation by reference language in such filing.

The following graph shows the value of an investment of $100 on December 31, 2010 in Heron Therapeutics, Inc. common stock, the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index. All values assume reinvestment of the pretax value of dividends paid by companies included in these indices and are calculated as of December 31st of each year. Our common stock has traded on The NASDAQ Capital Market since January 2014. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Heron Therapeutics, Inc, the NASDAQ Composite Index
and the NASDAQ Biotechnology Index



* $100 invested on 12/31/10 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/10	12/11	12/12	12/13	12/14	12/15
Heron Therapeutics, Inc	**$100.00**	**$ 50.98**	**$120.79**	**$ 98.63**	**$111.48**	**$295.88**
NASDAQ Composite	**100.00**	**100.53**	**116.92**	**166.19**	**188.78**	**199.95**
NASDAQ Biotechnology	**100.00**	**113.92**	**153.97**	**263.29**	**348.49**	**369.06**

Issuer Purchases of Securities

None.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 6. SELECTED FINANCIAL DATA.

The following Selected Financial Data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 and the Consolidated Financial Statements and Notes included in Item 8 of this Annual Report on Form 10-K.

Years Ended December 31, (In thousands, except per share amounts)	2015	2014	2013	2012	2011
Statements of Operations Data:					
Revenues:					
Contract revenue	$ —	$ —	$ —	$ —	$ 646
Operating expenses:					
Research and development	61,183	54,833	32,516	15,174	8,207
General and administrative	35,742	19,728	21,941	8,657	3,501
Loss from operations	(96,925)	(74,561)	(54,457)	(23,831)	(11,062)
Other income (expense)	(666)	(1,806)	(826)	(599)	(373)
Loss from continuing operations	(97,591)	(76,367)	(55,283)	(24,430)	(11,435)
Gain (loss) from discontinued operations	—	—	—	1,082	(379)
Net loss	$ (97,591)	$ (76,367)	$ (55,283)	$ (23,348)	$ (11,814)
Basic and diluted net loss per common share – loss from continuing operations	$ (2.95)	$ (2.87)	$ (3.42)	$ (2.00)	$ (1.90)
Basic and diluted net loss per common share – net loss	$ (2.95)	$ (2.87)	$ (3.42)	$ (1.91)	$ (1.96)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	33,081	26,569	16,163	12,223	6,013
Balance Sheet Data:					
Cash and cash equivalents	$ 75,180	$ 72,675	$ 72,287	$ 53,506	$ 17,974
Short-term investments	55,986	—	—	—	—
Working capital	115,016	60,112	65,933	49,936	14,547
Total assets	137,845	76,682	75,937	55,972	19,445
Long-term liabilities	—	—	—	—	—
Accumulated deficit	(412,828)	(315,237)	(238,870)	(183,587)	(160,239)
Total stockholders' equity	118,110	63,062	68,945	51,818	15,752

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

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. You can identify forward-looking statements by the use of the words "believe," "expect," "anticipate," "intend," "estimate," "project," "will," "should," "may," "plan," "assume" and other expressions which predict or indicate future events and trends and which do not relate to historical matters. You should not rely on forward-looking statements, because they involve known and unknown risks, uncertainties and other factors, some of which are beyond the control of the Company. These risks, uncertainties and other factors may cause the actual results, performance or achievements of the Company to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that might cause these differences include the following:

- Estimates of the outcome of our New Drug Application ("NDA") resubmission to the U.S. Food and Drug Administration ("FDA") for SUSTOL® (granisetron) Injection, extended release ("SUSTOL") and potential regulatory approval for and commercial launch of SUSTOL;

- the possibility that the FDA might not interpret the results of our Phase 3 MAGIC study for SUSTOL for the prevention of delayed chemotherapy induced nausea and vomiting ("CINV") associated with highly emetogenic chemotherapy ("HEC") regimens to be sufficient to support as broad a label indication as we might desire;

- the anticipated progress of our current research and development programs for HTX-011, HTX-019 and any other research and development programs we may pursue, including the completion of ongoing clinical trials, initiation of new clinical trials and preclinical testing and the results of clinical and stability studies;

- whether safety and efficacy results of our clinical trials and other required tests for approval provide data to warrant further development and potential regulatory approval of SUSTOL or any of our other product candidates;

- if approved, the market conditions during the commercial launch of SUSTOL or other future product candidates;

- our ability to successfully market, commercialize and achieve market acceptance for SUSTOL or other future product candidates, including our positioning relative to competing products;

- our ability to successfully develop and achieve regulatory approval for other future product candidates utilizing our proprietary Biochronomer® drug delivery technology ("Biochronomer technology");

- our ability to establish key collaborations for our products and any other future product candidates;

- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;

- unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment;

- our ability to successfully establish and maintain key vendor relationships necessary to manufacture our products;

- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;

- uncertainties associated with obtaining and enforcing patents to protect our products, and our ability to successfully defend ourselves against unforeseen third-party infringement claims;

- our estimates regarding our capital requirements; and

- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities.

These forward-looking statements were based on information, plans and estimates at the date of this Annual Report on Form 10-K, and we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes. In addition, please see the “Risk Factors” section of this Annual Report on Form 10-K. These risk factors may be updated from time to time by our future filings under the Exchange Act. You should carefully review all information therein.

Introduction

Management’s discussion and analysis of financial condition and results of operations is provided as a supplement to the Consolidated Financial Statements and Notes, included in Item 8 of this Annual Report on Form 10-K, to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

- *Overview*. This section provides a general description of our business and operating expenses.

- *Critical accounting policies and estimates*. This section contains a discussion of the accounting policies that we believe are important to our financial condition and results of operations and that require significant judgment and estimates on the part of management in their application. In addition, all of our significant accounting policies, including the critical accounting policies and estimates, are summarized in Note 2 to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

- *Results of operations*. This section provides an analysis of our results of operations presented in the accompanying consolidated statements of comprehensive loss by comparing the results for the year ended December 31, 2015 to the results for the year ended December 31, 2014 and comparing the results for the year ended December 31, 2014 to the results for the year ended December 31, 2013.

- *Liquidity and capital resources*. This section provides an analysis of our cash flows and a discussion of our outstanding commitments and contingencies that existed as of December 31, 2015. Included in this discussion is our financial capacity to fund our future commitments and a discussion of other financing arrangements.

Overview

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents. Our goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use.

Research and Development Expense

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation, fees paid to outside service providers and consultants, facilities costs and materials used in the clinical and preclinical trials and research and development.

At this time, due to the risks inherent in the clinical trial process, we are unable to estimate, with any certainty, the costs we will incur in the continued development of our product candidates. Other than costs for outsourced services associated with our clinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred.

We expect our research and development expenses to increase in 2016 to support our ongoing research and development efforts for our product candidates, including costs for our ongoing phase 2 program for HTX-011, costs associated with the continued development of HTX-019 and costs associated with preclinical development efforts. The lengthy process of completing our clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Our SUSTOL NDA is currently being reviewed by the FDA, and if approved, we expect SUSTOL to be commercially available in the second quarter of 2016.

General and Administrative Expense

General and administrative expense primarily consists of salaries, stock-based compensation and other related costs for personnel in executive, commercial operations, finance and accounting, business development, investor relations, legal and human resource functions. Other general and administrative costs include professional fees for legal, information technology, accounting and other general corporate purposes, pre-commercialization costs and facility costs not otherwise included in research and development expense.

We expect our general and administrative expenses to increase in 2016 to support the commercial launch of SUSTOL, if approved by the FDA. The commercial launch process requires the expenditure of substantial resources. As noted above, if SUSTOL is approved, we expect it to be commercially available in the second quarter of 2016.

Other Income (Expense)

Other income (expense) primarily consists of interest expense and amortization of debt discount related to our Senior Secured Convertible Notes (“Convertible Notes”). In addition, other income (expense) includes impairment of fixed assets, gains (losses) from the disposal of fixed assets and interest income earned on our cash, cash equivalents and short-term investments.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to accrued clinical liabilities, income taxes and stock-based compensation. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Clinical Liabilities

We review and accrue clinical costs based on work performed, which relies on estimates of the services received from other parties and related expenses incurred. Clinical trial-related contracts vary significantly in duration, and may be for a fixed amount, based on the achievement of certain contingent events or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or a combination of these approaches. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs, however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of 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 estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and financial statement purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. In doing so, we consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. A valuation allowance is provided when it is more likely than not that the deferred tax assets will not be realized. At December 31, 2015, we established a valuation allowance to offset our net deferred tax assets due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets.

Additionally, we believe that our deferred tax assets may have been limited in accordance with a provision of the Internal Revenue Code of 1986, whereby net operating loss and tax credit carryforwards available for use in a given period are limited upon the occurrence of certain events, including a significant change in ownership interests. As a result, our deferred tax assets and related valuation allowance were reduced for the estimated impact of the net operating losses and credits that may expire unused.

Should there be a change in our ability to recover our deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

Stock-Based Compensation

We generally grant equity-based awards under our stockholder-approved, stock-based compensation plans. We have granted, and may in the future grant, options and restricted stock awards to employees, directors, consultants and advisors under our 2007 Amended and Restated Equity Incentive Plan. In addition, all of our employees are eligible to participate in our 1997 Employee Stock Purchase Plan, which enables employees to purchase common stock at a discount through payroll deductions. Prior to our relisting on The NASDAQ Capital Market in January 2014, we issued non-plan stock option grants to certain employees, as set forth under Item 12 of this Annual Report on Form 10-K. These non-plan stock option grants were registered with the Securities and Exchange Commission (“SEC”) on Form S-8.

We estimate the fair value of stock options granted using the Black-Scholes option pricing model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option pricing model requires the input of subjective assumptions, including each option’s expected life and price volatility of the underlying stock. Expected volatility is based on our historical stock price volatility. The expected life of employee stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method.

As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. Changes in assumptions used under the Black-Scholes option pricing model could materially affect our net loss and net loss per share.

New Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Results of Operations

Years Ended December 31, 2015 and 2014

Research and Development Expense

Research and development expense consisted of the following (in thousands):

December 31,	2015	2014
SUSTOL related costs	$24,438	$33,758
HTX-011 related costs	9,834	3,189
HTX-019 related costs	5,070	495
New product development related costs	3,162	3,077
Personnel and related costs	10,216	7,868
Stock-based compensation expense	4,701	3,329
Facility related costs	1,952	1,716
Other	1,810	1,401
Total research and development expense	$61,183	$54,833

For the year ended December 31, 2015, research and development expense increased to $61.2 million from $54.8 million for the same period in 2014. This increase was primarily a result of an increase of $6.6 million in research and development expense for clinical and manufacturing costs associated with our Phase 1 and Phase 2 clinical studies for HTX-011 and an increase of $4.6 million in costs associated with the development of HTX-019. The increase was also due to an increase of $2.3 million in salaries and related expense for personnel and increased stock-based compensation expense of $1.4 million. These increases were partially offset by a decrease of $9.3 million in SUSTOL related costs, as our Phase 3 clinical program was completed in May 2015.

General and Administrative Expense

For the year ended December 31, 2015, general and administrative expense increased to $35.7 million compared to $19.7 million for the year ended December 31, 2014, primarily as a result of an increase of $7.5 million in costs for SUSTOL launch preparation activities and an increase in stock-based compensation expense of $4.9 million. For the years ended December 31, 2015 and 2014, general and administrative expense included $17.3 million and $8.7 million, respectively, for costs associated with commercial operations. General and administrative expenses consist primarily of salaries and related expenses, SUSTOL launch preparation costs, professional fees and insurance expense.

Other Income (Expense)

Other income (expense) was ($0.7 million) for the year ended December 31, 2015, compared to ($1.8 million) for the year ended December 31, 2014. Other income (expense) decreased in 2015 primarily due to the write-off of impaired manufacturing related equipment of approximately $0.9 million recorded in 2014. For the year ended December 31, 2015, other income (expense) consisted primarily of interest expense and amortization of debt discount related to our Convertible Notes.

Years Ended December 31, 2014 and 2013

Research and Development Expense

Research and development expense consisted of the following (in thousands):

December 31,	2014	2013
SUSTOL related costs	$33,758	$22,037
HTX-011 related costs	3,189	—
HTX-019 related costs	495	—
New product development related costs	3,077	800
Personnel and related costs	7,868	5,029
Stock-based compensation expense	3,329	2,562
Facility related costs	1,716	1,600
Other	1,401	488
Total research and development expense	$54,833	$32,516

For the year ended December 31, 2014, research and development expense increased to $54.8 million compared to $32.5 million for the year ended December 31, 2013. The increase was primarily a result of an increase in SUSTOL related costs due to the Phase 3 MAGIC Study in 2014, manufacturing development costs and other SUSTOL related activities. In addition, the increase in research and development expense was due to costs associated with new product development, including our pain management program targeting the relief of post-operative pain. Finally, the increase in research and development expense was due to an increase in personnel and related costs of approximately $2.8 million, primarily due to additional personnel to support the increased development activities noted above and an increase in non-cash, stock-based compensation expense of approximately $0.8 million.

General and Administrative Expense

For the year ended December 31, 2014, general and administrative expense decreased to $19.7 million compared to $21.9 million for the year ended December 31, 2013, primarily as a result of higher stock-based compensation expense in 2013 resulting from the resignation of our former chief executive officer in August 2013 and the hiring of certain senior executives in May 2013. This decrease was partially offset by an increase in personnel and other costs in 2014 to support increased development efforts. For the year ended December 31, 2014, general and administrative expenses consist primarily of salaries and related expenses, professional fees, pre-commercialization costs and insurance expense.

Other Income (Expense)

Other income (expense) was ($1.8 million) for the year ended December 31, 2014, compared to ($0.8 million) for the year ended December 31, 2013. Other income (expense) increased in 2014 primarily due to the write-off of impaired manufacturing related equipment of approximately $0.9 million. The remainder of the balance consisted primarily of interest expense and amortization of debt discount related to our Convertible Notes, which was comparable between 2014 and 2013.

Liquidity and Capital Resources

As of December 31, 2015, we had approximately $131.2 million in cash, cash equivalents and short-term investments, compared to $72.7 million in cash as of December 31, 2014. The net increase in cash, cash equivalents and short-term investments of approximately $58.5 million was primarily due to the cash proceeds of approximately $128.2 million received from the common stock offering completed in June 2015 and $9.5 million received from stock option exercises, offset by the use of cash to fund our operations including: the continued development of SUSTOL and other product candidates; personnel costs and other general corporate purposes.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock and other securities.

In November 2013, we completed a public offering of common stock whereby we received approximately $57.8 million in proceeds, net of issuance costs.

In June 2014, we completed a public offering of common stock and pre-funded warrants whereby we received approximately $58.9 million in proceeds, net of issuance costs.

In June 2015, we completed a public offering of common stock whereby we received approximately $128.2 million in proceeds, net of issuance costs.

We believe that our current working capital is sufficient to fund operations through 2016, including pursuing regulatory approval for SUSTOL in the U.S. and, if approved, making significant investments to support commercialization, and completing Phase 2 and 3 clinical studies currently ongoing and expected to commence in 2016 for our HTX-011 and HTX-019 product candidates. In the event that we pursue preclinical and/or clinical development in other areas, potentially acquire other strategic assets, or if SUSTOL is not approved or is not as commercially successful as expected, we may need to raise additional capital. If we do need to raise additional capital, we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we may receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, development program progress, interest rates and other factors. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities. Our capital requirements going forward will depend on numerous factors, including but not limited to: the scope, rate of progress, results and costs of preclinical testing and clinical trials; an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program, including the timing of clinical trials; the time, cost and outcome involved in seeking other regulatory approvals; scientific progress in our research and development programs; the magnitude and scope of our research and development programs; our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates; the cost and timing of establishing sales, marketing and distribution capabilities if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

We may not be able to raise sufficient additional capital when we need it on favorable terms, or at all. The sale of additional equity in the future may be dilutive to our stockholders. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms.

We have no current means of generating material cash flows from operations. There can be no assurance that our product development efforts related to any of our product candidates will be successful, that required regulatory approvals will be obtained, or that any products, if introduced, will be successfully marketed or achieve commercial acceptance. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. Our ability to obtain new financing may be constrained by our failure to achieve significant business objectives, covenants applicable to the Convertible Notes, and numerous other factors.

The following table summarizes our contractual obligations as of December 31, 2015.

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(In thousands)				
Operating lease obligations	$1,070	$ 1,067	$ 3	$ —	$ —
Purchase obligations	$3,851	$ 3,851	—	—	—
Total	$4,921	$ 4,918	$ 3	$ —	$ —

The holders of the Convertible Notes may require prepayment of the Convertible Notes at any time at each holder's option (see Note 6 of Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K).

We also enter into agreements from time to time with clinical sites and clinical research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based in part upon the number of patients enrolled and the length of their participation in the clinical trials. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. At this time, due to the variability associated with clinical site and contract research organization agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

At December 31, 2015, purchase obligations primarily consisted of commitments with third-party manufacturers in connection with the manufacturing of SUSTOL, as well as commitments with various vendors for clinical and preclinical studies. Approximately $3.2 million of the total purchase obligations were not included in our consolidated financial statements for the year ended December 31, 2015. We intend to use our current financial resources to fund our commitments under these purchase obligations.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, expenses, results of operations, liquidity, capital expenditures or capital resources.

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

The primary objective of our investment activities is to preserve our capital to fund operations. Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate-sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities, such as treasury-backed money market funds, corporate debt securities and commercial paper. As a result of the generally short-term nature of our investments, a 50-basis point movement in market interest rates would not have a material impact on the fair value of our portfolio as of December 31, 2015. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statement of comprehensive loss until the investment is sold or if a reduction in fair value is determined to be a permanent impairment. Our debt obligations on our Convertible Notes carry a fixed interest rate and, as a result, we are not exposed to interest rate risk on our convertible debt. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk and reinvestment risk. We do not have any material foreign currency obligations or other derivative financial instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Heron Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Heron Therapeutics, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, 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 consolidated financial statements audited by us present fairly, in all material respects, the financial position of Heron Therapeutics, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Heron Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 18, 2016 expressed an unqualified opinion thereon.

/s/ OUM & CO. LLP

San Francisco, California
February 18, 2016

HERON THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

December 31,	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 75,180	$ 72,675
Short-term investments	55,986	—
Prepaid expenses and other current assets	3,585	1,057
Total current assets	134,751	73,732
Property and equipment, net	3,049	2,820
Other assets	45	130
Total assets	$ 137,845	$ 76,682
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,300	$ 2,549
Accrued clinical liabilities	5,231	3,811
Accrued payroll and employee liabilities	4,828	2,731
Other accrued liabilities	4,154	2,931
Convertible notes payable to related parties, net of discount	2,222	1,598
Total current liabilities	19,735	13,620
Commitments and contingencies (see Note 5)		
Stockholders' equity:		
Preferred stock, $0.01 par value: 2,500 shares authorized; no shares issued or outstanding at December 31, 2015 and 2014	—	—
Common stock, $0.01 par value: 75,000 shares authorized; 36,106 and 29,227 shares issued and outstanding at December 31, 2015 and 2014, respectively	361	292
Additional paid-in capital	530,617	378,007
Accumulated other comprehensive loss	(40)	—
Accumulated deficit	(412,828)	(315,237)
Total stockholders' equity	118,110	63,062
Total liabilities and stockholders' equity	$ 137,845	$ 76,682

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share amounts)

Years Ended December 31,	2015	2014	2013
Operating expenses:			
Research and development	$ 61,183	$ 54,833	$ 32,516
General and administrative	35,742	19,728	21,941
Total operating expenses	96,925	74,561	54,457
Loss from operations	(96,925)	(74,561)	(54,457)
Other income (expense):			
Interest expense	(958)	(887)	(828)
Other income (expense), net	292	(919)	2
Total other expense	(666)	(1,806)	(826)
Net loss	(97,591)	(76,367)	(55,283)
Other comprehensive loss:			
Unrealized losses on short-term investments	(40)	—	—
Comprehensive loss	$(97,631)	$(76,367)	$(55,283)
Basic and diluted net loss per share	$ (2.95)	$ (2.87)	$ (3.42)
Shares used in computing basic and diluted net loss per share	33,081	26,569	16,163

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2012	15,111	$ 152	$ 235,253	$ —	$ (183,587)	$ 51,818
Issuance of common stock in a public offering, net	7,706	77	57,725	—	—	57,802
Conversion benefit included in Convertible Notes issued	—	—	291	—	—	291
Issuance of common stock under Employee Stock Purchase Plan	6	1	33	—	—	34
Issuance of common stock upon exercise of stock options	537	5	2,788	—	—	2,793
Issuance of common stock upon exercise of warrants	212	2	598	—	—	600
Stock-based compensation expense	—	—	10,890	—	—	10,890
Net loss	—	—	—	—	(55,283)	(55,283)
Balance, December 31, 2013	23,572	237	307,578	—	(238,870)	68,945
Issuance of common stock and pre-funded warrants in a public offering, net	4,751	47	58,869	—	—	58,916
Conversion benefit included in Convertible Notes issued	—	—	309	—	—	309
Issuance of common stock under Employee Stock Purchase Plan	12	—	91	—	—	91
Issuance of common stock upon exercise of stock options	588	5	3,096	—	—	3,101
Issuance of common stock upon exercise of warrants	304	3	(3)	—	—	—
Stock-based compensation expense	—	—	8,067	—	—	8,067
Net loss	—	—	—	—	(76,367)	(76,367)
Balance, December 31, 2014	29,227	292	378,007	—	(315,237)	63,062
Issuance of common stock in a public offering, net	5,520	55	128,144	—	—	128,199
Conversion benefit included in Convertible Notes issued	—	—	328	—	—	328
Issuance of common stock under Employee Stock Purchase Plan	31	—	257	—	—	257
Issuance of common stock upon exercise of stock options	1,042	11	9,524	—	—	9,535
Issuance of common stock upon exercise of warrants	286	3	(3)	—	—	—
Stock-based compensation expense	—	—	14,360	—	—	14,360
Net loss	—	—	—	—	(97,591)	(97,591)
Net unrealized loss on short-term investments	—	—	—	(40)	—	(40)
Comprehensive loss	—	—	—	—	—	(97,631)
Balance, December 31, 2015	36,106	$ 361	$ 530,617	$ (40)	$ (412,828)	$ 118,110

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

Years Ended December 31,	2015	2014	2013
Operating activities:			
Net loss	$(97,591)	$(76,367)	$(55,283)
Adjustments to reconcile net loss to net cash used for operating activities:			
Stock-based compensation	14,360	8,067	10,890
Depreciation and amortization	734	578	333
Amortization of debt discount	624	573	533
Impairment loss on property and equipment	—	905	—
(Gain) loss on disposal of property and equipment	(118)	17	—
Amortization of premium on short-term investments	89	—	—
Change in operating assets and liabilities:			
Prepaid expense and other current assets	(2,443)	(419)	(54)
Accounts payable	751	1,285	(426)
Accrued clinical liabilities	1,420	2,038	1,127
Accrued payroll and employee liabilities	2,097	165	2,153
Other accrued liabilities	1,551	2,876	(36)
Net cash used for operating activities	(78,526)	(60,282)	(40,763)
Investing activities:			
Purchases of short-term investments	(56,115)	—	—
Purchases of property and equipment	(1,086)	(1,438)	(1,685)
Proceeds from the sale of property and equipment	241	—	—
Net cash used for investing activities	(56,960)	(1,438)	(1,685)
Financing activities:			
Net proceeds from sale of common stock and/or pre-funded warrants	128,199	58,916	57,802
Proceeds from purchases under the Employee Stock Purchase Plan	257	91	34
Proceeds from stock option exercises	9,535	3,101	2,793
Proceeds from warrant exercises	—	—	600
Net cash provided by financing activities	137,991	62,108	61,229
Net increase in cash and cash equivalents	2,505	388	18,781
Cash and cash equivalents at beginning of year	72,675	72,287	53,506
Cash and cash equivalents at end of year	$ 75,180	$ 72,675	$ 72,287
Supplemental disclosure of cash flow information:			
Interest paid	$ —	$ —	$ —

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. We are developing novel, patient-focused solutions that apply our innovative science and technologies to already-approved pharmacological agents. Our goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use.

We are currently developing pharmaceutical products for patients suffering from cancer or pain. SUSTOL is being developed for the prevention of both acute and delayed CINV associated with moderately emetogenic chemotherapy or highly emetogenic chemotherapy. Our New Drug Application ("NDA") for SUSTOL is pending review with the U.S. Food and Drug Administration ("FDA"), and was assigned a Prescription Drug User Fee Act ("PDUFA") goal date of January 17, 2016. In January 2016, we were notified by the FDA that it would not take action on our SUSTOL NDA by the PDUFA date and that the FDA anticipates taking action in late February 2016. In addition to SUSTOL, we are currently developing several other pharmaceutical products for patients suffering from cancer or pain. HTX-019, also being developed for the prevention of CINV, is an intravenous formulation of aprepitant, a neurokinin-1 receptor antagonist. HTX-011, a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is being developed for the prevention of post-operative pain.

Liquidity

We have incurred significant operating losses and negative cash flows from operations, and we had an accumulated deficit of $412.8 million as of December 31, 2015. As of December 31, 2015, we had cash, cash equivalents and short-term investments of $131.2 million.

We believe that our current working capital is sufficient to fund operations through 2016, including pursuing regulatory approval for SUSTOL in the U.S. and, if approved, making significant investments to support commercialization, and completing Phase 2 and 3 clinical studies currently ongoing and expected to commence in 2016 relative to our HTX-011 and HTX-019 product candidates. In the event that we pursue preclinical and/or clinical development in other areas, potentially acquire other strategic assets, or if SUSTOL is not approved or has less commercial success than is expected, we may need to raise additional capital, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we may receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, development program progress, interest rates and other factors. If we are unable to obtain sufficient financing on acceptable terms or otherwise, we may be required to reduce or defer our activities. Our capital requirements going forward will depend on numerous factors, including but not limited to: the scope, rate of progress, results and costs of preclinical testing and clinical trials; an approval decision by the FDA with respect to SUSTOL; the timing of and costs associated with the commercial launch of SUSTOL, if approved; the degree of commercial success of SUSTOL; the number and characteristics of product development programs we pursue and the pace of each program, including the timing of clinical trials; the time, cost and outcome involved in seeking other regulatory approvals; scientific progress in our research and development programs; the magnitude and scope of our research and development programs; our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates; the cost and timing of establishing sales,

marketing and distribution capabilities if we commercialize products independently; the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and general market conditions.

We may not be able to raise sufficient additional capital when we need it on favorable terms, or at all. The sale of additional equity in the future may be dilutive to our stockholders. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying audited consolidated financial statements include the accounts of Heron Therapeutics, Inc. and its wholly owned subsidiary, Heron Therapeutics B.V., which was organized in the Netherlands in March 2015. Heron Therapeutics B.V. has no operations and no material assets or liabilities and there have been no significant transactions related to Heron Therapeutics B.V. since its inception.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (“GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Our critical accounting policies that involve significant judgment and estimates include accrued clinical liabilities, income taxes and stock-based compensation. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consist of cash and highly liquid investments with original maturities from purchase date of three months or less. Our bank accounts have been placed under a control agreement in accordance with our Senior Secured Convertible Notes (“Convertible Notes”).

Short-term investments consist of securities with maturities from purchase date of greater than three months. We have classified our short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income (loss) and realized gains and losses included in interest income. The cost of securities sold is based on the specific-identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, receivables, prepaid expenses, other current assets, accounts payable and accrued expenses, are carried at cost, which is considered to be representative of their respective fair values because of the short-term maturity of these instruments. Short-term available-for-sale investments are carried at fair value (see

Note 3 for further details regarding the fair value of financial instruments). Our Convertible Notes outstanding at December 31, 2015 do not have a readily available ascertainable market value, however, the carrying value is considered to approximate its fair value.

Concentration of Credit Risk

Cash, cash equivalents and short-term investments are financial instruments which potentially subject us to concentrations of credit risk. We deposit our cash in financial institutions. At times, such deposits may be in excess of insured limits. We may also invest our excess cash in money market funds, corporate debt securities and commercial paper. We have established guidelines relative to our diversification of our cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets (primarily five years). Leasehold improvements are stated at cost and amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term.

Impairment of Long-Lived Assets

If indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and records the impairment as a reduction in the carrying value of the related asset with a corresponding charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from actual results.

Accrued Clinical Liabilities

We review and accrue clinical costs based on work performed, which relies on estimates of the progress of the trials and the related expenses incurred. Clinical trial-related contracts vary significantly in duration, and may be for a fixed amount, based on the achievement of certain contingent events or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or contain a combination of these elements. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development costs, however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Research and Development Expenses

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation, fees paid to outside service providers and consultants, facilities costs and materials used in the clinical and preclinical trials and research and development.

Patent Costs

We incur outside legal fees in connection with filing and maintaining our various patent applications. All patent costs are expensed as incurred and are included in general and administrative expense in the consolidated statements of comprehensive loss.

Stock-Based Compensation Expense

We estimate the fair value of stock-based payment awards using the Black-Scholes option pricing model. This fair value is then amortized using the straight-line single-option method of attributing the value of stock-based compensation to expense over the requisite service periods of the awards. The Black-Scholes option pricing model requires the input of highly complex and subjective assumptions, including each option's expected life and price volatility of the underlying stock.

As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience.

Warrants

We have issued warrants to purchase shares of our common stock in conjunction with certain equity financings. The terms of the warrants were evaluated to determine the appropriate classification as equity or a liability.

Income Taxes

Accounting Standard Codification No. 740, *Accounting for Uncertainty in Income Taxes*, clarifies the accounting for uncertain tax positions. This provision requires that we recognize the impact of a tax position in our consolidated financial statements if the position is more likely than not to be sustained upon examination and on the technical merits of the position. The total amount of unrecognized tax benefits, if recognized, would affect other tax accounts, primarily deferred taxes in future periods, and would not affect our effective tax rate since we maintain a full valuation allowance against its deferred tax assets (see Note 8 for further details).

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Unrealized gains and losses on available-for-sale securities are included in other comprehensive net loss and represent the difference between our net loss and comprehensive net loss for all periods presented.

Earnings per Share

Basic earnings per share ("EPS") is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of common share equivalents. Diluted EPS is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, warrants and common stock underlying

Convertible Notes are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive.

Because we have incurred a net loss for all periods presented in the consolidated statements of comprehensive loss, outstanding stock options, warrants and common stock underlying Convertible Notes are not included in the computation of net loss per share because their effect would be anti-dilutive.

The following table includes the number of outstanding stock options, warrants and common stock underlying Convertible Notes not included in the computation as of the dates shown below (in thousands):

As of December 31,	2015	2014	2013
Stock options outstanding	8,435	7,918	6,356
Warrants outstanding	3,565	4,108	3,969
Common stock underlying Convertible Notes outstanding	7,087	6,677	6,291

Recent Accounting Pronouncements

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2015-17, *Income Taxes – Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17). ASU 2015-17 simplifies the classification of deferred tax assets and liabilities. ASU 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. ASU 2015-17 is effective for interim and annual periods beginning after December 15, 2016 and allows for early adoption using a full retrospective method or a prospective method. We plan to adopt the provisions of ASU 2015-17 in 2017. We do not expect the adoption of ASU 2015-17 to have a material impact on our results of operations or financial condition.

In January 2015, FASB issued ASU No. 2015-01, *Income Statement – Extraordinary and Unusual Items (Subtopic 225-20)* ("ASU 2015-01"). ASU 2015-01 eliminates the concept of extraordinary items from GAAP. FASB concluded that ASU 2015-01 will not result in a loss of information because although ASU 2015-01 will eliminate the requirements in Subtopic 225-20 for reporting entities to consider whether an underlying event or transaction is extraordinary, the presentation and disclosure guidance for items that are unusual in nature or occur infrequently will be retained and will be expanded to include items that are both unusual in nature and infrequently occurring. The amendments in ASU 2015-01 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. We adopted the provisions of ASU 2015-01 in the first quarter of 2015, which did not have a material impact on our results of operations or financial condition.

In August 2014, FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* ("ASU 2014-15"). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period, including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when

substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in ASU 2014-15 are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. We plan to adopt the provisions of ASU 2014-15 in 2016. We do not expect the adoption of this ASU to have a material impact on our results of operations or financial condition.

In June 2014, FASB issued ASU No. 2014-12, *Compensation – Stock Compensation (Topic 718)* ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The amendments in ASU 2014-12 may either be applied (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earlier annual period presented in the financial statements and to all new or modified awards thereafter. We plan to adopt the provisions of ASU 2014-12 in the first quarter of 2016. We do not expect the adoption of this ASU to have a material impact on our results of operations or financial condition.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, is as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We measure the following financial assets at fair value on a recurring basis. The fair values of these financial assets at December 31, 2015 (in thousands) were as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance at December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)*	Significant Other Observable Inputs (Level 2)*	Significant Unobservable Inputs (Level 3)
Money market funds	$ 67,089	$ 67,089	$ —	$ —
United States corporate debt securities	28,715	—	28,715	—
Foreign corporate debt securities	4,922	—	4,922	—
United States commercial paper	7,770	—	7,770	—
Foreign commercial paper	15,579	—	15,579	—
Total	$ 124,075	$ 67,089	$ 56,986	$ —

* There were no significant transfers between level 1 and level 2 investments for the year ended December 31, 2015.

As of December 31, 2015, we had cash equivalents consisting of $1,000,000 of available-for-sale securities with contractual maturities of less than three months. Short-term investments consisting of approximately $55,986,000 of available-for-sale securities with contractual maturities of one year or less. For the year ended December 31, 2014, we did not hold any investment securities and our cash equivalents consisted of money market funds.

A company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item such as debt issuance costs must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. Unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings and any changes in fair value are recognized in earnings. We have elected to not apply the fair value option to our financial assets and liabilities.

We consider the carrying amount of cash and cash equivalents, receivables, prepaid expenses and other current assets, accounts payable and accrued liabilities to be representative of their respective fair values because of the short-term nature of those instruments.

Unrealized gains and losses associated with our investments, if any, are reported in stockholders' equity. For the year ended December 31, 2015, we recorded approximately $40,000 in net unrealized losses associated with our short-term investments. There were no unrealized gains or losses for the years ended December 31, 2014 and 2013.

Realized gains and losses associated with our investments, if any, are reported in the statement of comprehensive loss. There were no realized gains or losses for the years ended December 31, 2015, 2014 and 2013.

4. Balance Sheet Details

Short-Term Investments

The following is a summary of our short-term, available-for-sale securities (in thousands):

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United States corporate debt	$ 28,750	$ —	$ (35)	$ 28,715
Foreign corporate debt	4,927	—	(5)	4,922
United States commercial paper	7,770	—	—	7,770
Foreign commercial paper	15,579	—	—	15,579
Total	$ 57,026	$ —	$ (40)	$ 56,986

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. We regularly monitor and evaluate the realizable value of our marketable securities. We did not recognize any impairment losses for the year ended December 31, 2015.

Property and Equipment

Property and equipment is comprised of the following (in thousands):

December 31,	2015	2014
Scientific equipment	$ 5,593	$ 4,793
Computer equipment and software	1,272	1,133
Furniture, fixtures and office equipment	352	351
Leasehold improvements	1,384	1,376
	8,601	7,653
Less: accumulated depreciation and amortization	(5,552)	(4,833)
	$ 3,049	$ 2,820

Depreciation and amortization expense for the years ended December 31, 2015, 2014 and 2013 was approximately $734,000, $578,000 and $333,000, respectively.

During the year ended December 31, 2014, we recognized $905,000 as an impairment loss due to the write-down of a piece of manufacturing-related equipment. As of December 31, 2014, the estimated fair value of the equipment was approximately $115,000. In 2015, we sold the equipment for cash proceeds of $241,000.

Accrued Payroll and Employee Liabilities and Other Accrued Expense

Accrued payroll and employee liabilities and other accrued expense consisted of the following (in thousands):

December 31,	2015	2014
Accrued employee salaries and benefits	$1,863	$ 719
Accrued bonuses	2,965	2,012
Total accrued payroll and employee liabilities	$4,828	$2,731

December 31,	2015	2014
Accrued consulting and professional fees	$3,914	$1,775
Accrued accounts payable	36	886
Deferred rent	61	105
Other accrued liabilities	143	165
Total other accrued expense	$4,154	$2,931

5. Commitments and Contingencies

Leases

We lease 26,067 square feet of laboratory, office and warehouse space in Redwood City, California under a lease expiring on November 30, 2016. We have the option to extend the lease for an additional three years. In addition, we currently lease 1,898 square feet of office space in Jersey City, New Jersey and 3,419 square feet of office space in San Diego, California. The lease for the Jersey City office space began on July 1, 2015 and expires on December 31, 2016, and the lease for the San Diego office space was extended in 2015 for an additional nine-month period ending on March 31, 2016. We believe our facilities are adequate and suitable for our current needs, and that we will be able to obtain new or additional leased space in the future when necessary. We also lease certain office equipment under operating lease arrangements.

Annual future minimum lease payments as of December 31, 2015 are as follows (in thousands):

	Operating Leases
Years ended December 31,	
2016	$ 1,067
2017	3
2018	—
2019	—
2020	—
Thereafter	—
Total	$ 1,070

Rent expense under all operating leases totaled approximately $1,502,000, $1,381,000 and $967,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

Clinical Development Agreements

We have entered into agreements with various vendors for the research and development of product candidates, which are generally cancellable anytime at our option. Under the terms of these agreements, the vendors provide a variety of services including conducting preclinical development, research, manufacturing clinical compounds, enrolling and recruiting patients, monitoring studies, data analysis and regulatory filing assistance. Payments under these agreements typically include fees for services and reimbursement of expenses. In addition, under certain agreements, we are subject to penalties in the event we permanently discontinue performance under these agreements.

Purchase Obligations

At December 31, 2015, our purchase obligations of $3,851,000 primarily consisted of commitments with third-party manufacturers in connection with the manufacturing of SUSTOL, as well as commitments with various vendors for clinical and preclinical studies. Approximately $3,192,000 of the total purchase obligations were not included in our consolidated financial statements for the year ended December 31, 2015. We intend to use our current financial resources to fund our commitments under these purchase obligations.

6. Convertible Notes to Related Parties

In April 2011, we entered into a Securities Purchase Agreement for a private placement of up to $4.5 million in Convertible Notes. We received a total of $4.3 million, net of issuance costs, from the issuance of these Convertible Notes.

The Convertible Notes are secured by substantially all of our assets, including placing our bank and investment accounts under a control agreement. The Convertible Notes bear interest at 6% per annum, payable quarterly in cash or in additional principal amount of Convertible Notes, at the election of the purchasers. The Convertible Notes mature on May 2, 2021, however, the holders of the Convertible Notes may require prepayment of the Convertible Notes at any time, at each holder’s option.

The Convertible Notes are convertible into shares of our common stock at a rate of 1,250 shares for every $1,000 of principal and accrued interest due under the Convertible Notes. There is no right to convert the Convertible Notes to the extent that, after giving effect to such conversion, the holder would beneficially own in excess of 9.99% of our outstanding common stock. Each holder of the Convertible Notes can increase or decrease this beneficial ownership conversion limit by written notice to us, which will not be effective until 61 days after delivery of the notice.

As of December 31, 2015, we were in compliance with all covenants under the Convertible Notes. Upon the occurrence of an event of default under the Convertible Notes, the holders of the Convertible Notes have the right to require us to redeem all or a portion of their Convertible Notes.

In 2011, we filed a registration statement with the Securities and Exchange Commission (“SEC”) to register for resale 3.5 million shares underlying the Convertible Notes. The registration statement was declared effective on July 29, 2011. The

Convertible Note holders have agreed to waive their right to require us to maintain the effectiveness of the registration statement and to register the additional shares underlying the Convertible Notes until they provide notice otherwise.

The Convertible Notes contain an embedded conversion feature that was in-the-money on the issuance dates. Based on an effective fixed conversion rate of 1,250 shares for every $1,000 of principal and accrued interest due under the Convertible Notes, the total conversion benefit at issuance exceeded the loan proceeds. Therefore, a debt discount was recorded in an amount equal to the face value of the Convertible Notes on the issuance dates and we began amortizing the resultant debt discount over the respective 10-year term of the Convertible Notes. During the year ended December 31, 2015, accrued interest of approximately $328,000 was paid-in-kind and rolled into the Convertible Note principal balance, which resulted in an additional debt discount of approximately $328,000. For the years ended December 31, 2015, 2014 and 2013, interest expense relating to the stated rate was approximately $333,000, $314,000 and $295,000, respectively, and interest expense relating to the amortization of the debt discount was approximately $624,000, $573,000 and $533,000, respectively.

As of December 31, 2015, the carrying value of the Convertible Notes was approximately $2,222,000, which is comprised of the $5,669,000 principal amount of the Convertible Notes outstanding, less debt discount of $3,447,000. If the $5,669,000 principal amount of Convertible Notes is converted, we would issue 7,086,560 shares of our common stock.

7. Stockholders' Equity

Amendments to Articles of Incorporation – Reverse Stock Split

Effective January 13, 2014, we amended our Certificate of Incorporation to change our name to Heron Therapeutics, Inc. and effected a 1-for-20 reverse split of our outstanding common stock. The name change and Reverse Stock Split were approved by our stockholders on September 19, 2013. As a result of the Reverse Stock Split, we amended our Certificate of Incorporation to reduce the total authorized shares of our common stock from 1,500,000,000 to 75,000,000 shares.

2013 Common Stock Offering

In November 2013, we sold approximately 7.7 million shares of our common stock at a public offering price of $8.00 per share. We received total net proceeds of approximately $57.8 million (net of approximately $3.9 million in issuance costs).

2014 Common Stock Offering

In June 2014, we sold approximately 4.8 million shares of our common stock at a public offering price of $11.75 per share. In addition, as a component of the offering, we sold 600,000 pre-funded warrants to purchase shares of our common stock at a public offering price of $11.74 per share. The pre-funded warrants have an exercise price of $0.01 per share and expire on June 30, 2021. We received total net proceeds of approximately $58.9 million (net of approximately $4.0 million in issuance costs) from the sale of the common stock and the pre-funded warrants.

2015 Common Stock Offering

In June 2015, we sold approximately 5.5 million shares of our common stock at a public offering price of approximately $24.75 per share. We received total net proceeds of approximately $128.2 million (net of approximately $8.4 million in issuance costs) from the sale of the common stock.

Warrants

Private Placement Warrants

In June 2011, we sold shares of common stock and warrants to purchase common stock in a private placement. A total of 4.0 million warrants to purchase common stock at an exercise price of $3.60 per share were issued as part of this private placement. The warrants were immediately exercisable and expire on July 1, 2016. The warrants may be exercised for cash only, or, if a registration statement is not then effective and available for the resale of the shares of common stock issuable upon exercise of the warrants, by surrender of such warrant, or a portion of such warrant, by way of cashless exercise. There is no right to exercise the warrants to the extent that, after giving effect to such exercise the holder would beneficially own in excess of 9.99% of our outstanding shares of common stock or such other limit as may be designated by any particular purchaser. Each holder of the warrants can amend or waive the foregoing limitation by written notice to us, with such waiver taking effect only upon the expiration of a 61-day notice period.

During the year ended December 31, 2015, warrant holders exercised 343,813 warrants under the cashless exercise provision in the warrant agreement, which resulted in the net issuance of 285,713 shares of common stock and no net cash proceeds to us. During the year ended December 31, 2014, warrant holders exercised 460,706 warrants under the cashless exercise provision in the warrant agreement, which resulted in the net issuance of 303,614 shares of common stock and no net cash proceeds to us. During the year ended December 31, 2013, we received $0.6 million for cash exercises of these warrants.

Outstanding Warrants

The following table summarizes all warrants outstanding as of December 31, 2015:

	Number of Shares Outstanding	Exercise Price	Expiration Date
Issued to private placement investors in July 2011	2,965,477	$ 3.60	07/01/2016
Issued in a public offering in June 2014	600,000	$ 0.01	06/30/2021
Total warrants outstanding	3,565,477		

The weighted-average exercise price of warrants outstanding as of December 31, 2014 was $3.00.

Common Stock Reserved for Future Issuance

Shares of our common stock reserved for future issuance as of December 31, 2015 were as follows:

	Number of Shares
Stock options outstanding	8,434,988
Stock options available for grant	3,880,849
Employee stock purchase plan	99,532
Warrants outstanding	3,565,477
Common stock underlying Convertible Notes outstanding	7,086,560
Total shares reserved for future issuance	23,067,406

Employee Stock Purchase Plan

In 1997 our stockholders approved our Employee Stock Purchase Plan (the “ESPP”). In December 2007, May 2009, June 2011, May 2014 and May 2015, our stockholders authorized increases in the number of shares reserved for issuance under the ESPP by 5,000, 10,000, 25,000, 25,000 and 100,000 shares, respectively, for a total of 175,000 shares reserved at December 31, 2015. Under the terms of the ESPP, employees can elect to have up to a maximum of 10% of their base earnings withheld to purchase our common stock. The purchase price of the stock is 85% of the lower of the closing prices for our common stock on: (i) the first trading day in the enrollment period, as defined in the ESPP, in which the purchase is made, or (ii) the purchase date. The length of the enrollment period is six months. Enrollment dates are the first business day of May and November. Approximately 36% of eligible employees participated in the ESPP in 2015. Under the ESPP, we issued 30,361, 12,028 and 5,630 shares in 2015, 2014 and 2013, respectively. The weighted-average exercise price per share of the purchase rights exercised during 2015, 2014 and 2013 was $8.46, $7.59 and $6.12, respectively. As of December 31, 2015, 75,468 shares of common stock have been issued under the ESPP and 99,532 shares of common stock are available for future issuance.

Stock Option Plans

We currently have one stock option plan from which we can grant options and restricted stock awards to employees, officers, directors and consultants. In December 2007, the stockholders approved our 2007 Equity Incentive Plan (the “2007 Plan”) at which time a maximum of 150,000 shares of common stock were available for grant. In May 2010, June 2011, May 2014 and May 2015, our stockholders approved amendments to our 2007 Plan to increase the maximum number of shares of common stock available for grant by 100,000, 4,500,000, 1,750,000 and 4,300,000 shares of common stock, respectively, resulting in an aggregate of 10,800,000 shares of common stock authorized for issuance as of December 31, 2015. At December 31, 2015, there were 3,880,849 shares available for future grant under the 2007 Plan. Any shares that are issuable upon exercise of options granted that expire, are cancelled, or that we receive pursuant to a net exercise of options, are available for future grant and issuance.

We also granted stock options and restricted stock awards under the 2002 Stock Incentive Plan (the “2002 Plan”) in prior years. The remaining shares available to be granted under the 2002 Plan expired in February 2012.

In 2014, 2013 and 2012, we granted options to certain employees outside of our stockholder approved stock option plans. All options to purchase our common stock were granted with an exercise price that equals fair market value of the underlying common stock on the grant dates and expire no later than ten years from the date of grant. The options are exercisable in accordance with vesting schedules that generally provide for them to be fully vested and exercisable four years after the date of grant, provided, however, that we have also issued stock options awards that are subject to performance vesting requirements. All stock option grants issued outside of our stockholder approved plans have been registered on Form S-8 with the SEC.

A summary of our stock option activity and related data follows:

	Outstanding Options	
	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2012	4,323,874	$ 8.46
Granted	4,256,971	8.08
Exercised	(537,029)	5.20
Cancelled	(1,688,135)	9.45
Balance at December 31, 2013	6,355,681	8.22
Granted	3,181,001	9.40
Exercised	(756,593)	6.34
Cancelled	(862,085)	9.88
Balance at December 31, 2014	7,918,004	8.69
Granted	2,134,505	28.95
Exercised	(1,042,343)	9.15
Cancelled	(575,178)	10.42
Balance at December 31, 2015	8,434,988	$ 13.64

For the year ended December 31, 2015, option holders exercised 1,042,343 stock options resulting in cash proceeds to us of approximately $9.5 million.

For the year ended December 31, 2015, options cancelled (included in the above table) consisted of 503,343 options forfeited with a weighted-average exercise price of approximately $9.16 and 71,835 options expired with a weighted-average exercise price of approximately $19.24.

As of December 31, 2015, options exercisable have a weighted-average remaining contractual term of 6.7 years. The total intrinsic value of stock option exercises, which is the difference between the exercise price and closing price of our common stock on the date of exercise, during the years ended December 31, 2015 and 2014, was approximately $13,882,000 and $3,377,000, respectively. As of December 31, 2015 and 2014, the total intrinsic value of options outstanding and exercisable

was approximately $46,603,000 and $14,654,000, respectively, which is the difference between the exercise price and closing price of our common stock.

	2015		2014		2013	
Years Ended December 31,	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Exercisable at end of year	2,587,392	$ 8.72	2,237,901	$ 9.01	1,770,597	$ 8.67
Options vested or expected to vest	8,059,481	$ 13.38	7,841,074	$ 8.69	6,292,296	$ 8.22

Exercise prices and weighted-average remaining contractual lives for the options outstanding as of December 31, 2015 were:

Options Outstanding	Range of Exercise Prices	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price of Options Exercisable
702,903	$ 3.80 – $ 7.00	6.31	$ 5.92	466,373	$ 5.38
2,302,688	$ 7.20	7.33	7.20	711,687	7.20
2,047,712	$ 7.61 – $ 9.05	8.30	8.91	711,561	8.84
1,702,732	$ 9.20 – $ 28.30	7.23	14.89	692,974	12.17
1,678,953	$28.73 – $128.00	9.71	30.23	4,797	42.60
8,434,988	$ 3.80 – $128.00	7.94	13.64	2,587,392	8.72

On December 31, 2015, we had reserved 8,434,988 shares of common stock for future issuance upon exercise of outstanding options granted under the 2002 Plan and the 2007 Plan, as well as the non-plan grants.

Valuation and Expense Information

The following table summarizes stock-based compensation expense related to stock-based payment awards granted pursuant to all of our equity compensation arrangements for the years ended December 31, 2015, 2014 and 2013 (in thousands):

December 31,	2015	2014	2013
Research and development	$ 4,701	$3,329	$ 2,562
General and administrative	9,659	4,738	8,328
Stock-based compensation expense included in operating expenses	$14,360	$8,067	$10,890

As of December 31, 2015, there was $63,865,000 of total unrecognized compensation cost related to non-vested, stock-based payment awards granted under all of our equity compensation plans and all non-plan option grants. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We expect to recognize this compensation cost over a weighted-average period of 2.3 years.

For the years ended December 31, 2015, 2014 and 2013, we estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

Options:

December 31,	2015	2014	2013
Risk-free interest rate	1.7%	1.9%	1.1%
Dividend yield	—%	—%	—%
Volatility	92.7%	99.0%	104.2%
Expected life (years)	6	6	6

ESPP:

December 31,	2015	2014	2013
Risk-free interest rate	0.1%	0.1%	0.1%
Dividend yield	—%	—%	—%
Volatility	86.7%	53.8%	76.0%
Expected life (months)	6	6	6

The weighted-average fair value of options granted was $21.92, $7.40 and $6.53 for the years ended December 31, 2015, 2014 and 2013, respectively.

The weighted-average fair value of shares purchased through the ESPP was $8.23, $3.06 and $3.01 for the years ended December 31, 2015, 2014 and 2013, respectively.

The risk-free interest rate assumption is based on observed interest rates on United States Treasury debt securities with maturities close to the expected term of our employee and director stock options and ESPP purchases.

The dividend yield assumption is based on our history and expectation of dividend payouts. We have never paid dividends on its common stock and we do not anticipate paying dividends in the foreseeable future.

We used our historical stock price to estimate volatility.

The expected life of employee and director stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. We have elected to use the simplified method, as

we do not have enough historical exercise experience to provide a reasonable basis upon which to estimate the expected term. The expected life for the ESPP purchase rights is six months, which represents the length of each purchase period.

8. Income Taxes

For the years ended December 31, 2015, 2014 and 2013, we did not record a provision for income taxes because we have incurred operating losses for all three years.

Deferred income tax assets and liabilities arising from differences between accounting for financial statement purposes and tax purposes, less valuation allowance at year-end are as follows (in thousands):

December 31,	2015	2014
Deferred tax assets:		
Net operating loss carryforward	$ 94,465	$ 59,513
Research and development credits	11,181	7,667
Stock-based compensation	6,726	5,128
Other, net	1,345	964
Total deferred tax assets	113,717	73,272
Valuation allowance for net deferred tax assets	(113,717)	(73,272)
Net deferred taxes	$ —	$ —

Taxes on income vary from the statutory federal income tax rate applied to earnings before tax on income as follows (in thousands):

December 31,	2015	2014	2013
Statutory federal income tax rate of 34%	$(33,181)	$(25,965)	$(18,796)
Stock-based compensation expense	894	551	513
NOL not benefitted	31,935	25,085	17,983
Other, net	352	329	300
Provision for taxes	$ —	$ —	$ —

A valuation allowance is provided when it is more likely than not that the deferred tax assets will not be realized. We have established a valuation allowance to offset net deferred tax assets at December 31, 2015 and 2014 due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets. The net change in the total valuation allowance for the year ended December 31, 2015 and 2014 was an increase of approximately $40,445,000 and $32,035,000, respectively.

At December 31, 2015, we had federal and California state net operating loss (“NOL”) carryforwards of approximately $242,769,000 and $233,305,000, respectively, expiring beginning in 2018 for federal and 2017 for California state purposes.

Approximately $4,235,000 of federal NOLs and $4,235,000 of state NOLs relate to stock-based compensation deductions in excess of book expense, the tax effect of which would be to credit additional paid-in capital, if realized. At December 31, 2015, we had federal and California state research credit carryforwards of approximately $7,434,000 and $5,639,000, respectively, expiring beginning in 2022 for federal. The California state credits can be carried forward indefinitely.

Internal Revenue Code section 382 places a limitation on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership) of a loss corporation. California has similar rules. Generally, after a control change, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 limitation. We have performed an IRC Section 382 analysis and determined there were ownership changes in 2007, 2011, and 2013. We are currently in the process of completing the IRC Section 382 analysis for 2015 and we do not expect an ownership change for the year ended December 31, 2015. The limitation in the Federal and state carryforwards associated with the NOL and credit carryforwards reduce the deferred tax assets, which are further offset by a full valuation allowance. The limitation can result in the expiration of the NOLs and credit carryforwards available as of December 31, 2015 before utilization.

We file U.S. and state income tax returns with varying statutes of limitations. The tax years from 1998 to 2015 remain open to examination due to the carryover of unused NOL carryforwards and tax credits.

For benefits to be realized, a tax position must be more likely than not to be sustained upon examination. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon settlement. It is our policy to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2015 and 2014, we had no accrued interest and penalties related to uncertain tax positions.

As of December 31, 2015 and 2014, we had unrecognized tax benefits of $120,000, and the amount that would impact our effective tax rate, before the consideration of the valuation allowance, is $120,000. We do not expect any material changes to the estimated amount of liability associated with its uncertain tax positions within the next 12 months.

9. Employee Benefit Plan

We have a defined contribution 401K plan (the “Plan”) covering substantially all of our employees. In the past three calendar years, we made matching cash contributions equal to 50% of each participant’s contribution during the Plan year up to a maximum amount equal to the lesser of 3% of each participant’s annual compensation or $7,950, $7,800 and $7,650 for the years 2015, 2014 and 2013, respectively. Such amounts were recorded as expense in the corresponding years. We may also contribute additional discretionary amounts to the Plan as we may determine. For the years ended December 31, 2015, 2014 and 2013, we contributed to the Plan approximately $251,000, $181,000 and $134,000, respectively. No discretionary contributions have been made to the Plan since its inception.

HERON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

10. Summary of Quarterly Consolidated Financial Data (unaudited)

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2015 and 2014:

(In thousands, except per share amounts)

2015	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Operating expenses:				
Research and development	$ 14,504	$ 16,175	$ 14,241	$ 16,263
General and administrative	5,856	6,839	8,250	14,797
Loss from operations	(20,360)	(23,014)	(22,491)	(31,060)
Interest income	22	26	61	65
Interest expense	(232)	(237)	(242)	(247)
Other expense	—	118	—	—
Net loss	$(20,570)	$(23,107)	$(22,672)	$(31,242)
Basis and diluted net loss per share	$ (0.70)	$ (0.74)	$ (0.63)	$ (0.87)

(In thousands, except per share amounts)

2014	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Operating expenses:				
Research and development	$ 11,628	$ 14,279	$ 14,731	$ 14,195
General and administrative	5,694	4,512	4,222	5,300
Loss from operations	(17,322)	(18,791)	(18,953)	(19,495)
Interest income	—	—	—	3
Interest expense	(216)	(220)	(224)	(227)
Other expense	—	—	(17)	(905)
Net loss	$(17,538)	$(19,011)	$(19,194)	$(20,624)
Basis and diluted net loss per share	$ (0.74)	$ (0.78)	$ (0.66)	$ (0.71)

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

(a) Disclosure Controls and Procedures; Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial and accounting officers, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of December 31, 2015. Based on this evaluation, our principal executive and principal financial and accounting officers concluded that our disclosure controls and procedures were effective as of December 31, 2015.

There was no change in our internal control over financial reporting during the quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(b) Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework).

Based on our assessment, management concluded that, as of December 31, 2015, our internal control over financial reporting was effective based on those criteria.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting. The report appears below.

(c) Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

The Board of Directors and Stockholders of
Heron Therapeutics, Inc.

We have audited Heron Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Heron Therapeutics, Inc.'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 the accompanying *Management's Report on Internal Control Over Financial Reporting* included in Item 9A. 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 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, Heron Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Heron Therapeutics, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015, and our report dated February 18, 2016 expressed an unqualified opinion thereon.

/s/ OUM & CO. LLP
San Francisco, California
February 18, 2016

ITEM 9B. OTHER INFORMATION.

The following disclosure would have otherwise been filed on Form 8-K under the heading "Item 1.01 Entry into Material Definitive Agreement":

On December 18, 2015, Heron entered into a Commercial Supply Agreement (the "Agreement"), with*** (the "Counterparty"), effective as of December 8, 2015. Pursuant to the Agreement, the Counterparty will manufacture and supply*** (the "Excipient"), and certain other raw materials used to manufacture the Excipient to the Company in such quantities as the Company may order from time to time, subject to certain limitations. The Counterparty will manufacture the Excipient in accordance with certain specifications describing quality-related processes, systems and commitments. Subject to certain conditions, the Company will purchase from the Counterparty its worldwide requirements of the Excipient for use in SUSTOL for the prices set forth in Appendix 3 to the Agreement, which prices the Counterparty may adjust each year during the Agreement's term. Such adjustment may not exceed the percentage increase in the U.S. Producer Price Index, Pharmaceutical preparation manufacturing, reported by the U.S. Department of Labor Statistics. The initial term of the Agreement is five years from the effective date, subject to early termination under certain circumstances and renewal options.

The foregoing is a summary of the Agreement and does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, which is attached hereto as Exhibit 10.36 and is incorporated herein by reference.

*** Information omitted pursuant to a confidential treatment request filed with the SEC.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item will be contained in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2015. Such information is incorporated herein by reference.

We have adopted a Code of Ethics that applies to our Principal Executive Officer, Principal Financial and Accounting Officer, and to all of our other officers, directors and employees. The Code of Ethics is available in the Corporate Governance section of the Investor Resources page on our website at www.herontx.com. We intend to disclose future waivers or material amendments to certain provisions of our Code of Ethics on the above-referenced website within four business days following the date of such waiver or amendment.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this item will be contained in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2015. Such information is incorporated herein by reference.

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

Additional information required by this item will be contained in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2015. Such information is incorporated herein by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information regarding our equity compensation plans as of December 31, 2015.

	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 the First Column)
Equity compensation plans approved by security holders			
Stock option and awards plans (1)	5,109,468	$ 17.31	3,880,849
Employee stock purchase plan	—	—	99,532
Equity compensation plans not approved by security holders (2)	3,325,520	$ 7.99	—
Total	8,434,988	$ 13.64	3,980,381

(1) Consists of awards granted under the 2002 Plan and the 2007 Plan.
(2) Consists of non-plan grants made to certain employees in 2012, 2013 and 2014. These grants were made with the same terms as stock option grants made under the 2007 Plan.

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

Information required by this item will be contained in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2015. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information required by this item will be contained in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2015. Such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements.

   The consolidated financial statements and supplementary data set forth in Part II of the Annual Report on Form 10-K are included herein.

2. Consolidated Financial Statement Schedules.

   These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits.

   The Exhibit Index attached to this report is incorporated by reference herein.

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.

HERON THERAPEUTICS, INC.

BY: /s/ BARRY D. QUART
Barry D. Quart, Pharm.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Barry D. Quart and Brian G. Drazba as his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, with respect to this annual report and any and all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, 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 the said attorney-in-fact and agent or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ BARRY D. QUART Barry D. Quart, Pharm. D.	Chief Executive Officer and Director *(Principal Executive Officer)*	February 19, 2016
/s/ BRIAN G. DRAZBA Brian G. Drazba	Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 19, 2016
/s/ CRAIG A. JOHNSON Craig A. Johnson	Director	February 19, 2016
/s/ JOHN W. POYHONEN John W. Poyhonen	Director	February 19, 2016
/s/ ROBERT H. ROSEN Robert H. Rosen	President, Chief Commercial Officer and Director	February 19, 2016
/s/ KEVIN C. TANG Kevin C. Tang	Chairman of the Board of Directors	February 19, 2016

EXHIBIT INDEX

Exhibit	Document Description
3.1	Certificate of Incorporation, as amended through July 29, 2009 (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 3.1, filed on August 4, 2009)
3.2	Bylaws (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 22, 2016)
3.3	Certificate of Amendment of Certificate of Incorporation (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on June 30, 2011)
3.4	Certificate of Amendment of Certificate of Incorporation (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 13, 2014)
4.1	Common Stock Certificate (Incorporated by reference to our Registration on Form S-3 (Registration No. 333-162968), as Exhibit 4.1, filed on November 6, 2009)
4.2	Form of Warrant to Purchase Shares of Common Stock (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.3, filed on October 22, 2009)
4.3	Amended and Restated Certificate of Designation, Preferences, and Rights of Series A Preferred Stock (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.C, filed on December 19, 2006)
10.1*	1997 Employee Stock Purchase Plan, as amended to date (Incorporated by reference to our Definitive Proxy on Schedule 14A, as Exhibit B, filed on April 28, 2015)
10.2	Lease Agreement between Registrant and Metropolitan Life Insurance Company for lease of Registrant's offices in Redwood City dates as of November 17, 1997 (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1997, as Exhibit 10-E, filed on March 30, 1998)
10.3*	2002 Equity Incentive Plan dated June 13, 2002 (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-90428), as Exhibit 99.1, filed on June 13, 2002)
10.4*	Amended and Restated 2007 Equity Incentive Plan (Incorporated by reference to our Definitive Proxy on Schedule 14A, as Exhibit A, filed on April 28, 2015)
10.5*	Form of 2007 Equity Incentive Plan Stock Option Agreement (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-148660), as Exhibit 4.3, filed on January 14, 2008)
10.6*	Form of 2007 Equity Incentive Plan Restricted Stock Unit Agreement (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-148660), as Exhibit 4.4, filed on January 14, 2008)
10.7*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, as Exhibit 10-O, filed on March 31, 2008)
10.8*	Form of Indemnification Agreement (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, as Exhibit 10-S, filed on March 31, 2008)
10.9	Securities Purchase Agreement, dated as of October 19, 2009, by and among the Registrant and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on October 22, 2009)

Exhibit	Document Description
10.10	Registration Rights Agreement, dated as of October 22, 2009, by and among the Registrant and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on October 22, 2009)
10.11	Securities Purchase Agreement, dated as of April 24, 2011, by and among the Company and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on April 28, 2011)
10.12	Form of Senior Secured Convertible Note due 2021 (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on April 28, 2011)
10.13	Securities Agreement, dated as of April 24, 2011, by and between the Company and Tang Capital Partners, LP, as Agent for the Purchasers (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.3, filed on April 28, 2011)
10.14	Second Amendment to Lease, effective as of April 1, 2011, by and between the Company and Metropolitan Life Insurance Company (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.4, filed on April 28, 2011)
10.15*	Management Retention Agreement, dated as of April 25, 2011, by and between the Company and Michael A. Adam (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.6, filed on April 28, 2011)
10.16	Securities Purchase Agreement, dated June 29, 2011, by and between the Company and the purchasers listed on Schedule I thereto (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on June 30, 2011)
10.17	Amendment to Senior Secured Convertible Note Due 2021, dated June 29, 2011, by and between the Company and the purchasers named in the Securities Purchase Agreement, dated April 24, 2011, (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on June 30, 2011)
10 .18	Third Amendment to Lease, effective as of July 28, 2011, by and between the Company and Metropolitan Life Insurance Company (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on August 3, 2011)
10.19	Securities Purchase Agreement, dated July 25, 2012, by and between the Company and the purchasers named therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on July 25, 2012)
10.20	Registration Rights Agreement, dated July 25, 2012, by and between the Company and the purchasers named therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on July 25, 2012)
10.21*	Management Retention Agreement as of December 3, 2012, by and between the Company and Mark S. Gelder, M.D. (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2012, as Exhibit 10-AH, filed on March 1, 2013)
10.22*	Executive Employment Agreement, dated May 1, 2013, by and between the Company and Barry D. Quart, Pharm.D. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, as Exhibit 10-AI, filed on May 10, 2013)

Exhibit	Document Description
10.23*	Executive Employment Agreement, dated May 1, 2013, by and between the Company and Robert H. Rosen (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, as Exhibit 10-AJ filed on May 10, 2013)
10.24	Form of Non-Qualified Stock Option Agreement (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as Exhibit 10-AL, filed on August 8, 2013)
10.25*	Amendment to Management Retention Agreement, dated as of April 25, 2011, as amended May 29, 2013 (as amended, the Retention Agreement) (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as Exhibit 10-AM, filed on August 8, 2013)
10.26*	Offer Letter dated November 10, 2012 between the Company and Mark S. Gelder, M.D. (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AE, filed on March 7, 2014)
10.27*	Offer Letter dated October 16, 2013 between the Company and Brian G. Drazba (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AF, filed on March 7, 2014)
10.28*	Management Retention Agreement as of October 23, 2013, by and between the Company and Brian G. Drazba (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AG, filed on March 7, 2014)
10.29*	Executive Employment Agreement, dated November 1, 2013, by and between the Company and Paul Marshall (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AH, filed on March 7, 2014)
10.30*	Amendment to Executive Employment Agreement, dated May 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Dr. Barry Quart (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.1, filed on May 8, 2015)
10.31*	Amendment to Executive Employment Agreement, dated May 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Robert Rosen (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.2, filed on May 8, 2015)
10.32*	Amendment to Management Retention Agreement, dated October 23, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Brian G. Drazba (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.3, filed on May 8, 2015)
10.33*	Amendment to Executive Employment Agreement, dated November 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Paul Marshall (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.4, filed on May 8, 2015)
10.34+	SUSTOL® (granisetron, extended release) Injection Commercial Manufacturing Services Agreement – Finished Final Drug Product, dated May 27, 2015, by and between Heron Therapeutics, Inc. and Lifecore Biomedical, LLC) (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on May 29, 2015)

Exhibit	Document Description
10.35*	Executive Employment Agreement, dated October 12, 2015, by and between Heron Therapeutics, Inc. and Neil Clendeninn (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, as Exhibit 10.2, filed on November 6, 2015)
10.36+	Commercial Supply Agreement, dated December 8, 2015, by and between Heron Therapeutics, Inc. and ***.
23.1	Consent of Independent Registered Public Accounting Firm (OUM & Co. LLP)
24.1	Power of Attorney (included on the signature page hereto)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan, contract or arrangement.

\+ Confidential treatment has been requested with respect to certain portions of the exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

EXHIBIT 10.36

This Agreement includes Confidential Information

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

COMMERCIAL SUPPLY AGREEMENT

EXCIPIENT

This Commercial Supply Agreement (this "Agreement"), effective as of the 8th day of December, 2015 (the "Effective Date"), is entered into by and between:

HERON THERAPEUTICS, Inc., a company incorporated under the laws of Delaware, with its principal office located at 123 Saginaw Drive Redwood City, CA ("Company"); and

, a company incorporated under the laws of the ***, with its principal office located at ***, on behalf of itself and its Affiliates which provide products or services under this Agreement ("").

Company and *** are hereinafter sometimes referred to separately as a "Party" or together as the "Parties".

RECITALS

WHEREAS, Company is engaged in the research and development of pharmaceutical products;

WHEREAS, *** develops, manufactures and sells a broad range of biochemicals and organic chemicals globally for use in pharmaceutical development and as key components in pharmaceutical and other high technology manufacturing;

WHEREAS, Company uses the Excipient in the Finished Product, and desires to engage *** to manufacture the Excipient and supply the Excipient and also certain Raw Materials as requested during the term of this Agreement; and

WHEREAS, *** is willing to manufacture and supply to Company the Excipient and certain Raw Materials upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

1. Definitions and Interpretation

1.1 "Affiliate" means any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" shall mean ownership of over fifty percent (50%) of the equity capital, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" shall mean the power to control the distribution of profits.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

1.2 "Analytical Methods" means the set of validated analytical methods related to the Manufacturing of the Excipient as provided by Company to ***, and, if applicable, methods related to Raw Materials supplied by *** to the Company.

1.3 "Applicable Law(s)" means any domestic or foreign, supranational, regional, national, state and local laws and the rules, regulations, guidelines and requirements of all Regulatory Agencies in effect from time to time applicable to *** with respect to the Manufacturing Process of Raw Materials or the Excipient, including without limitation in the United States (U.S.) and the European Union (EU).

1.4 "Batch" means the Excipient or other material as defined in the relevant Batch Record that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of Manufacturing.

1.5 "Batch Record" shall mean the document, proposed by *** and approved by Company in writing that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the Manufacture and testing of Raw Materials and Excipient. The Batch Record shall also include or incorporate by reference such information as Raw Materials Specifications, in process and final or other Excipient sampling standards, test methods, specifications, equipment and instrumentation specifications and standard operating procedures, including standard operating procedures for in-process quality control testing.

1.6 "Biochronomer® Technology" means Heron's proprietary polymer-based bioerodible technology designed to release drugs over an extended, sustained period of time.

1.7 "Certificate of Analysis" means a document, which is dated and signed by a duly authorized representative of the Quality Control or Quality Assurance department of ***, certifying that a Batch of Excipient or an order of Raw Materials meets all Specifications.

1.8 "Certificate of Compliance" means a document, signed by an authorized representative of ***, attesting that a particular Batch of Excipient was manufactured in accordance with cGMP and Applicable Law.

1.9 "Commencement Date" means the date Company issues its initial binding written purchase order for the commercial supply of Excipient under Section 3.2 below.

1.10 "Commercial Forecast" shall have the meaning set forth in Section 3.1 hereof.

1.11 "Commercially Reasonable Efforts" means the carrying out of such obligations with a level of effort and resources consistent with those commercially reasonable efforts and industry standard practices of a company performing contract manufacturing of pharmaceutical products.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

1.12 "Compliance Level" shall have the meaning set forth in Section 2.11(b) hereof.

1.13 "Confidential Information" shall mean all the technical information, whether tangible or intangible, including (without limitation) any and all data, techniques, discoveries, inventions, processes, know-how, patent applications, inventor certificates, trade secrets, methods of production and other proprietary information, that either Party or any Affiliate of a Party has ownership rights to (as either owner, licensee or sub-licensee), or may hereafter obtain rights. In order for oral information to be considered to be Confidential Information hereunder, it must be identified as confidential and proprietary at the time of disclosure, or be of such type of information such that a reasonable person would believe that such information was confidential or proprietary. All written information must be conspicuously marked using words such as "confidential" or "proprietary" in order to be considered to be Confidential Information hereunder.

1.14 "Current Good Manufacturing Practices" or "cGMP" shall mean the standards relating to Manufacturing practices as required by the rules and regulations of Regulatory Agencies in compliance with ICH guidelines for active pharmaceutical ingredients, intermediates or bulk products as established by the principles detailed in the guidance document developed by the International Conference on Harmonization known as "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients".

1.15 "Deviation" shall mean excursions or nonconformity from processes, specifications, or quality systems that may affect the safety, identity, strength, purity, or quality of Excipient or any regulatory submissions for Excipient or any Raw Materials ordered by Company.

1.16 "EMA" means the European Medicines Agency of the European Union.

1.17 "Excipient" means ***, in all instances intended to meet the Specifications, manufactured in accord with cGMP and sold by *** to Company.

1.18 "Failure to Supply" shall have the meaning set forth in Section 2.9(a) hereof.

1.19 "FCA" shall have the meaning as set forth in the 2010 edition of the International Commercial terms published by the International Chamber of Commerce, as may be amended or modified from time to time.

1.20 "FDA" means the United States Food and Drug Administration, and any successor thereto.

1.21 "Finished Product" means the finished dosage form of a drug product that contains Excipient or Raw Material manufactured by ***.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

1.22 "For Cause Audit" means an audit of manufacturing records of the Parties by the other Party following: a) an unfavorable observations during regulatory inspections that are potentially material to the quality of the Excipient or b) a major or repeated quality excursion that may result in a failed manufacture Batch or product Recall.

1.23 "Forecast" shall have the meaning set forth in Section 3.1 hereof.

1.24 "Laboratory" shall have the meaning set forth in Section 4.2 hereof.

1.25 "Latent Defect" shall mean any nonconformity in any Batch of Excipient that was not, and could not reasonably be expected to have been, found by exercise of ordinary care in inspection and testing by the Company, provided, however, that a Latent Defect shall not include a noncomformity that could not have been avoided or prevented by *** by ordinary care and otherwise met all requirements for the Manufacture of Excipient. The Parties agree identification following delivery of the Excipient: (i) of a failure to follow cGMPs by ***, (ii) that the Certificate of Analysis is incorrect, (iii) that the Certificate of Compliance is incorrect, or (iv) a Batch record is incorrect, that results in Nonconforming Excipient is a Latent Defect.

1.26 "Manufacture, Manufacturing or Manufactured" means all activities related to the manufacturing of the Excipient, or any ingredient thereof in accordance with the terms and conditions of this Agreement and the Quality Agreement, which may include manufacturing the Excipient for development, or use in the manufacture of active pharmaceutical ingredients, in-process and final testing and release of the Excipient, or any component or ingredient thereof, quality assurance activities related to manufacturing and release of the Excipient and regulatory activities related to any of the foregoing.

1.27 "Manufacturing Process" shall mean the instructions, Specifications (as well as specifications for raw materials and packaging materials), formulae, procedures, tests and standards developed, established and described by Company for Manufacturing Excipient and/or Raw Materials.

1.28 "Marks" shall have the meaning set forth in Section 11.4 hereof.

1.29 "Minimum Lead Time" shall have the meaning set forth in Section 3.2(c) hereof.

1.30 "Nonconforming Excipient" shall mean any Excipient that does not meet the pre-approved release Specifications at the time of release and includes materials as to which any of the following apply: a) the materials have not been packaged for shipment in accordance with the instructions agreed to in writing by Company and ***; b) the materials do not meet Specification upon delivery to the carrier approved by Company; c) the materials shipped do not have an accurate Certificate of Compliance and/or Certificate of Analysis d) the materials were not manufactured in accord with cGMP, the Batch Record, the Specifications and the Quality Agreement or e) contains a Latent Defect. For the avoidance of doubt Nonconforming Excipient cannot be as a result of any action or inaction that occurs following delivery of Excipient or Raw Materials to Company.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

1.31 "Nonconforming Raw Materials" shall mean any Raw Materials that do not meet the pre-approved release at the time of release and includes materials as to which any of the following apply: a) material that does not have an accurate Certificate of Analysis, or b) the material was not manufactured in accord with the Specifications and the Quality Agreement or c) the material contains a Latent Defect.

1.32 "Out of Specification" or "OOS" shall mean all test results that fall outside the Specifications.

1.33 "Qualified Alternate Facility" shall have the meaning set forth in Section 2.11(a) hereof.

1.34 "Quality Agreement" means that separate document between Company and *** referenced herein and attached hereto as Appendix 1 describing quality related processes, systems and commitments associated with the manufacturing and supply of the Excipient.

1.35 "Raw Materials" means all reagents, solvents and critical raw materials which have Specifications, and which are used in the Manufacture of the Excipient.

1.36 "Recall" means any action: (a) by the Company to recover title to, or possession of, quantities of Finished Product shipped to third parties or shipped to intermediates on the Company's behalf (including, without limitation, the voluntary withdrawal of the Finished Product from the market or clinical use), or (b) by the Company to effect a field correction, or (c) by any Regulatory Authority to detain or destroy any of the Finished Product.

1.37 "Regulatory Agency" means any and all bodies and organizations, including, without limitation, the FDA and EMA, regulating the manufacture, importation, distribution, use and sale of the, Finished Product, Excipient or Raw Materials used therein.

1.38 "Specifications" means the Excipient Specifications in Appendix 2, Raw Material specifications, packaging component specifications, or process intermediate specifications, as the context requires. Specifications include a list of tests, pertaining to analytical procedures, and appropriate acceptance criteria including, but not limited to, numerical limits, ranges, and qualitative analysis that establish the set of criteria to which a test article must conform to be considered acceptable for use in the manufacture of Raw Materials or Excipient. These Specifications can only be modified by agreement in writing between the Parties and in accord with the terms of the Quality Agreement

1.39 "SUSTOL" means Sustol® (granisetron) Injection, extended release, as a Finished Product under this Agreement.

1.40 "Technology Transfer" means the transfer from *** or its Affiliates to Company or any third party designated by Company of the full and complete standard

operating procedures and tangible and intangible information that is reasonably necessary to the process of manufacturing the Excipient and/or Raw Materials, inclusive of, documents, manufacturing instructions, communications from Regulatory Authorities, know-how, licenses, stability samples, retention samples and materials (including Raw Materials Specifications) that are reasonably necessary to manufacture Excipient or Raw Materials to meet all Specifications and to comply with all Applicable Laws in connections with such transfer. This should include all information required by Regulatory Agencies that requires *** assistance to provide.

1.41 "Term" shall have the meaning set forth in Section 9.1 hereof.

1.42 "Third Party Supplier" means a manufacturer of Excipient other than ***.

2. Manufacture and Supply of Excipient and Raw Materials

2.1 General Conditions of Supply. During the Term, *** and its Affiliates shall Manufacture and supply Excipient and/or Raw Materials to Company, and Company shall purchase Excipient and/or Raw Materials from *** and its Affiliates in such quantities as Company may order from time to time, subject to the limitations and requirements set forth herein. Raw materials will be supplied in accord with the conditions below for Excipient except as stated in Appendix 4.

2.2 Specifications. At all times during the Term, *** shall Manufacture the Excipient in accordance with cGMP, the Specifications and the Quality Agreement. At all times during the Term, *** shall Manufacture Raw Materials in accordance with the Raw Materials Specifications and the Quality Agreement.

2.3 Person in the Plant. *** and/or its Affiliates shall permit Company employees, consultants and/or representatives (excluding agents of third parties which are competitors of ***) to be admitted to the Facility, subject to the safety and security policies of ***, during the Manufacturing of the Excipient and/or Raw Materials for the purposes of (i) observing the manufacturing process and (ii) reviewing all Batch Records and other documents, including, without limitation, all production logs, reagent preparation records, Deviation reports, Raw Materials testing and release data, *** procedures, and the like. Heron employees, consultants and/or representatives shall not be auditing the operations but shall merely observe the Manufacturing activities. All such Company employees, consultants and/or representatives pursuant to this Section 2.3 will be bound by a confidentiality agreement that is at least as stringent as the confidentiality terms set forth herein. *** shall consider, in good faith, any suggestions that Company or its onsite, consultants and/or representatives have regarding the design or operation of the Facility for Manufacturing and will promptly respond to Company regarding such suggestions.

2.4 Quality Control and Release. The quality control(s) and the release(s) of Excipient (including documentation) shall be done by *** in accordance with cGMP, the Specifications and the Quality Agreement. The quality control(s) and the release(s) of

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

Raw Materials (including documentation) shall be done by *** in accordance with the Specifications and the Quality Agreement. Company, subject to the provisions of Section 4 of this Agreement, shall have the right to reject Excipient or Raw Materials that are Non-conforming Excipient or Raw Materials. *** shall retain and store remaining samples of the Excipient and critical Raw Materials as required by Applicable Law.

2.5 Inspections. Inspections of *** facilities and/or its Affiliates' facilities used in the Manufacture of the Excipient and/or Raw Materials shall be conducted as specified in the Quality Agreement. Subject to the limitations and qualifications set forth in the Quality Agreement, upon prior notice of at least thirty (30) days, *** or its Affiliates shall permit Company's representatives (excluding agents of third parties which are competitors of ***) once per year, or more frequently if deemed warranted as a For Cause Audit as specified in the Quality Agreement, to visit and audit *** facilities used in the Manufacture of the Excipient or Raw Materials to observe the Manufacturing thereof, to discuss with appropriate officials of *** and to inspect and audit records relevant to the Manufacturing of the Excipient and Raw Materials.

2.6 Changes to Specifications and Process. The Specifications shall be amended only as agreed upon in writing by Company and ***; provided, however, that the Parties agree to cooperate to amend or supplement the Specifications to the extent reasonably necessary to comply with changes in Applicable Laws and/or regulations or the requirements of applicable Regulatory Agencies or as Company may reasonably request from time to time (provided such request is made in good faith). *** shall follow the change control procedures set forth in the Quality Agreement for any proposed changes in the Manufacturing process. *** acknowledges that any such change(s) shall, in each case, comply with cGMP (if required), this Agreement and the Quality Agreement. In the event such amendment (whether as a result of changes in Applicable Laws or the requirements of applicable Regulatory Agencies or at Company's reasonable and good faith request or otherwise) requires additional cost or schedule adjustments for the Manufacture of the Excipient or Raw Materials hereunder, Company and *** shall agree in good faith on an equitable adjustment to price and/or schedule, as appropriate. Any such amended Specifications shall be reflected in and attached hereto as an amended and restated Appendix 2.

2.7 Documentation.

(a) General. Upon completion of Manufacture of each batch of Excipient, *** shall provide to Company the following documentation related to the Manufacturing of Excipient: copy of executed Batch Records, a Certificate of Analysis, Certificate of Compliance, Deviations, and any other information specified in the Quality Agreement. Upon completion of Manufacture of each order of Raw Materials, *** shall provide to Company the following documentation: copy of executed Batch Records, a Certificate of Analysis, notation of any Deviations and any other information specified in the Quality Agreement.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

(b) Batch Records and Order Documents. The Batch Records and documents related to orders of Raw Materials shall be treated as Confidential Information of Company and shall not be used or disclosed by *** other than for the purposes of permitting *** to exercise its rights or fulfil its obligations under this Agreement (including but not limited to, the provision of the Batch Record of Manufacture of Raw Materials to Company for quality review) and, where necessary, for disclosure to the relevant Regulatory Agencies in order to comply with regulatory requirements relating to the Manufacturing of Excipient or Raw Materials by *** or its Affiliates.

(c) Retention of Documentation. All documentation related to the Manufacturing of Excipient or Raw Materials shall be archived with *** or its Affiliates after Manufacturing in accordance with *** document retention policies and Applicable Law. Company shall be contacted at least ninety (90) days before destruction of any Excipient or Raw Materials specific records and shall be given the option to retain such documents.

2.8 Safety. Each Party shall immediately notify the other Party of any unusual health or environmental occurrence relating to Excipient or Raw Materials. Each Party shall advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding Excipient or Raw Materials.

2.9 Proprietary Rights. All inventions related specifically to (i) the Excipient or (ii) those Raw Materials proprietary to Company listed and identified as proprietary on Appendix 4. ("Proprietary Raw Materials"), pursuant to the services provided under this Agreement by *** or its Affiliates to Company, conceived or reduced to practice during the Term, and as a result of this Agreement, whether or not patentable, and whether or not invented solely by or on behalf of Company or jointly by or on behalf of Company and *** shall be owned solely by the Company. All know-how related specifically to the Excipient or Proprietary Raw Materials Manufactured and supplied by *** or its Affiliates to Company, arising during the Term, and as a result of this Agreement, whether arising as a result of the activities by or on behalf of Company alone or by or on behalf of Company and *** jointly, shall be owned solely by Company. *** shall cooperate in vesting ownership of the foregoing inventions and know-how in Company including, but not limited to, delivering such acknowledgements, assignments, and conveyance documents as Company shall request.

2.10 Process Improvements. Upon request from either Party, *** shall prepare, from time to time, a plan which details the agreed services necessary to implement improvements or changes to the processes involved in the Manufacture of Excipient or Raw Materials Manufactured and supplied by *** or its Affiliates to Company, or where new or additional equipment is being used in such Processing. The scope and price of any such a work plan should be agreed in writing by the Parties and set forth in a separate statement of work referring to and falling under the terms of this Agreement. The Price of such additional work shall be consistent with similar previously performed work and/or industry standards. Should the parties make process improvements that result in a

reduction in the cost of the Excipient or Raw Materials ordered by Company from *** or its Affiliates, the Parties will share equally in such savings after the cost of the implementation has been credited to the Party or Parties that paid for such process improvement.

2.11 Purchase Commitment.

(a) During the Term and upon the terms and subject to the conditions of this Agreement and as long as *** can demonstrate to Company's reasonable satisfaction, based on capacity availability, Batch size and other commercially reasonable requirements, that *** has in place an acceptable alternate Manufacturing facility at which *** is capable of manufacturing the Excipient and/or necessary Raw Materials for the Manufacture of the Excipient in compliance with this Agreement and the Quality Agreement ("Qualified Alternate Facility"), Company agrees to purchase from ***, its and its Affiliate's annual worldwide requirements of the Excipient for use in SUSTOL. If *** does not have a Qualified Alternate Facility, then during the Term and upon the terms and subject to the conditions of this Agreement, Company agrees to purchase from ***, not less than *** of its and its Affiliate's annual worldwide requirements of the Excipient for use in SUSTOL unless there is a Failure to Supply pursuant to Section 2.12(a).

(b) If during the Term *** reasonably believes that Company is not purchasing Excipient at the level required by this Section 2.11 (the "Compliance Level"), it will provide Company with written notice requesting that Company provide sufficient documentation demonstrating compliance with the Compliance Level. Company shall have sixty (60) days after such notice to provide documentation responsive to the request, and which illustrates solely the Company's annual requirements for Excipient, and that amount purchased from ***. If Company provides such documentation and such documentation does not demonstrate, to *** reasonable satisfaction Company's compliance with the Compliance Level, then, in the event that Company does not agree with *** findings, Company and *** shall mutually agree on an acceptable independent third party auditor to review Company's books and records solely to determine whether Company met the Compliance Level. Such third-party auditor will be required to sign a standard form of confidentiality agreement for the benefit of Company. The cost of the independent third party shall be borne by Company if the independent third party determines reasonably that Company was out of compliance with the Compliance Level, otherwise by ***. If pursuant to this Section 2.11(b) Company is deemed or determined to be out of compliance with the Compliance Level, then *** may adjust pricing by not more than the per cent (%) shortfall in the Compliance Level as determined by the independent third party. Any adjusted pricing hereunder would remain in effect until such time as Company demonstrates compliance with the Compliance Level.

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2.12 Delay; Third Party Supplier.

(a) If *** is or will be unable, for any reason (including an event of Force Majeure under Section 11.17 hereof), to supply the Excipient in accordance with the quantities and/or delivery dates specified by Company in a purchase order received by *** (provided that such quantities are within the Forecast and such delivery dates meet the Minimum Lead Time requirements herein) ("Failure to Supply"), *** shall promptly notify Company in writing of such circumstance. Within thirty (30) days of such Failure to Supply, *** shall notify Company of the cause of such failure and shall propose a plan of remediation. Further, *** will use commercially reasonable efforts to initiate a Technology Transfer to support the manufacture of Excipient by a Third Party Supplier. Each company will bear its own costs related to such Technology Transfer.

(b) If such Failure to Supply will continue or does continue for a period of ninety (90) or more consecutive days, and *** is unable in its then current facility or any Qualified Alternate Facility to Manufacture the Excipient in quantities necessary to cure the Failure to Supply, then Company may, at its discretion and upon written notice to *** and without being deemed to be in breach of Section 2.8 of this Agreement, Manufacture or have Manufactured by a Third Party Supplier that quantity of Excipient required by Company that *** is or may be unable to supply. In such event, *** will use commercially reasonable efforts to complete a Technology Transfer to support the manufacture of Excipient by a Third Party Supplier or the Company, which shall mean providing all documentation, access to records, and other necessary support, provided any additional third-party costs incurred by *** to support such Technology Transfer will be at the Company's cost. Further, if Company at such time is receiving its annual worldwide commitment from ***, then following the Failure to Supply Company will only be required to purchase *** of its annual supply of the Excipient for use in the Finished Product from *** following the Failure to Supply.

(c) *** shall promptly notify Company when *** can resume supply of Excipient in accordance with this Agreement and provide Company with a firm date for delivery of the Excipient in accordance with Company's needs. Upon receipt of notice the annual commitment will return to at least fifty-five (55%) per cent of the Company's annual worldwide requirements for the Excipient for the Finished Product.

2.13 Exclusivity.

During the Term and for an additional period of either:

(i) *** years if:

(1) *** terminates this Agreement; or

(2) Company terminates this Agreement for material breach in accordance with Section 9.2(a);

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

(ii) *** years if the Company terminates this Agreement for reasons unrelated to *** performance or nonperformance;

without considering other limitations with respect to the use of Heron's proprietary technology, *** shall not Manufacture any product that uses or relies on Heron's proprietary Biochronomer Technology for itself or for or on behalf of any Third Party.

3. Forecasts, Release, Purchase Orders, Delivery and Storage

3.1 Forecasts. Within (30) thirty days following the Effective Date Company shall determine its initial estimated purchases of the Excipient from *** under this Agreement and shall deliver to *** a written, rolling twelve (12) month forecast (the "Forecast") of such estimated quantities. The Forecast shall cover each of the next succeeding four (4) calendar quarters. The first calendar quarter shall be binding on Company, the second calendar quarter is also binding, but can be increased or decreased by up to two (2) Batches from the preceding forecast for such quarter, and the following two calendar quarters shall be non-binding. After delivery of the initial Forecast, the Forecast shall be updated by Company on a calendar quarterly basis, which update shall include the next successive calendar quarter added to the last period of the previous Forecast. Although the third and fourth calendar quarters of the Forecast are non-binding, Company understands that *** shall use the Forecast for planning purposes (including scheduling of production campaigns, Raw Material acquisitions and investment in equipment and other resources) in order to make available the production capacity required to Manufacture and supply the forecasted amounts and provide replacement Batches of the Excipient, if required, within the time frames specified therein.

3.2 Commercial Supply; Purchase Orders.

(a) To initiate *** Manufacture and supply of commercial quantities of the Excipient under this Agreement, Company must issue a binding written purchase order for its initial purchase of Excipient at least ninety (90) days prior to the first scheduled shipment of Excipient thereunder or such shorter time as may be agreed upon by the Parties in writing.

(b) All purchase orders for Excipient hereunder shall be in complete Batches equal to the size of the current manufacturing batch size agreed between the Parties in Appendix 3.

(c) All purchase orders subsequent to the initial purchase order for commercial supply must be issued at least ninety (90) days prior to the scheduled shipment of Excipient thereunder or such shorter time as may be agreed upon by the Parties in writing. The minimum number of days between the date of a purchase order and the shipment of Excipient under this Section 3.2(c) and Section 3.2(a) above shall be referred to hereinafter as the "Minimum Lead Time".

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(d) Within fourteen (14) days of receipt of a purchase order, *** shall notify Company in writing of its acceptance of the purchase order. If *** fails to respond within fourteen (14) days of receipt of the purchase order, the purchase order shall be deemed accepted, but only to the extent that any amount ordered is not in excess of the Forecast and that the requested delivery date satisfies the Minimum Lead Time.

(e) If a purchase order exceeds the Forecast or does not meet the Minimum Lead Time, *** may accept such purchase order, but will be required only to use Commercially Reasonable Efforts to fill such excess or accommodate such shorter lead-time.

(f) For each such purchase of Excipient, the purchase order shall specify: (i) an identification of the Excipient ordered; (ii) quantity requested; (iii) the requested delivery date; and (iv) shipping instructions and address.

(g) Each purchase order is a contract for the purchase of such Excipient under the terms and conditions set forth in this Agreement, to the exclusion of any additional or contrary terms set forth in any purchase order, unless otherwise explicitly agreed to in writing by the Parties.

3.3 Release of Excipient. *** shall notify the Company when (i) the Manufacture of Excipient is complete, (ii) all Manufacturing records have been reviewed, (iii) all testing is completed, reviewed, and Excipient meets Specifications (as evidenced by a Certificate of Analysis), (iv) all Deviations, if any, have been adequately reviewed and approved by the Company, and (v) Excipient has been released by *** in accordance with the Quality Agreement, and a Certificate of Compliance is issued. *** shall make efforts to ensure that release is targeted for four (4) weeks after Manufacturing is complete. If this target release date cannot be achieved for a Batch, *** shall notify Company of the reason. In the event the target release date cannot be achieved for reasons that are outside of *** or its Affiliates' control (e.g. a Force Majeure event), and the target release date for a Batch of Excipient is late by thirty-five (35) days: (a) on the first occurrence of such late release during a calendar year, there shall be no late penalty; (b) on the second occurrence of such late release during a calendar year, there will be a reduction in the purchase price for such late Batch of five per cent (5%) of the purchase price; and (c) on the third and following occurrences of such late release during a calendar year, there will be a reduction in the purchase price for such Batch of ten per cent (10%) of the purchase price. The Company will be responsible for dispositioning product in accordance with procedures detailed in the Quality Agreement.

3.4 Delivery, Title and Risk of Loss. All Excipient supplied by *** or its Affiliates hereunder shall be supplied FCA *** shipping point. Delivery of the Excipient to the carrier at such *** shipping point shall constitute delivery to Company. Title to and risk of loss for the Excipient sold hereunder shall pass to the Company or its designee when the Excipient is delivered to the carrier at *** shipping point. *** and its Affiliates reserve the right to make delivery in instalments of multiple Batches, all such instalments to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries.

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3.5 Packaging. *** and its Affiliates will preserve, package, handle, and pack all Excipient and Raw Materials so as to protect the Excipient and Raw Materials from loss or damage, in conformance with standard commercial practices, the Specifications, the Quality Agreement, government regulations and other applicable standards.

3.6 Raw Material Inventory. Prior to receipt of the first Forecast, the Parties shall meet and agree upon the quantities of Raw Materials *** shall have in inventory, in order to ensure that Forecast is delivered and maintain continuity supply during the applicable time frames. Thereafter, the parties shall engage at least quarterly to review Raw Materials requirements and inventory on hand, as well as the status of those suppliers from which Raw Materials are obtained, or, if manufactured by *** or its Affiliates the status of the relationship with respect thereto. Company agrees to reimburse *** for all costs related to any Raw Materials that expire or are otherwise unusable due to Company not ordering the quantities of Excipient in the Forecast, provided *** shall use Commercially Reasonable Efforts to ensure that any such excess Materials do not expire or become unusable (e.g., through the appropriate rotation of its Raw Materials inventory and reprocessing of Raw Material).

3.7 Purchase of Raw Materials. Company may also purchase Raw Materials from *** or its Affiliates as required for *** Manufacture of Excipient at the Price in Exhibit 3 under the terms of the Agreement.

3.8 Storage. *** and its Affiliates shall hold all Excipient and Raw Materials under the storage conditions established pursuant to the Quality Agreement and, with respect to Excipient, in accordance with cGMP.

4. Rejection, Defects and Non-Conforming Goods

4.1 Nonconforming Goods. Within thirty (30) days from the date *** delivers Excipient to Company (or to a third party designated by Company) after Excipient release, Company shall have the right to determine whether such Excipient is Nonconforming Excipient. Any claim by Company that Excipient is Nonconforming Excipient shall be made in writing to *** or its Affiliates as applicable within such thirty (30) day period and shall be accompanied by a detailed report of analysis prepared by or on behalf of Company. If the Excipient contains a Latent Defect, then the thirty (30) day time period referred to herein shall not apply; provided that (i) Company notifies *** or its Affiliate promptly upon having reason to know of such Latent Defect (but in any event no later than ninety (90) days prior to the expiration of the Batch and (ii) the limitation on remedy and liability set out in Section 4.3 below shall apply with respect thereto.

4.2 Disagreement Concerning Fulfilment of Requirements. In the event of a disagreement concerning Nonconforming Excipient, Company and *** shall agree on an independent testing laboratory or quality expert on matters of compliance with cGMP, if applicable or Applicable Law of recognized standing in the industry selected by Company

and approved by both Parties ("Laboratory") to determine whether any such Excipient was Nonconforming Excipient. The findings of the Laboratory shall be binding. The expenses related to such testing shall be borne by *** only if the testing confirms that the material is Nonconforming Excipient (unless the nonconformity was attributable to Company's negligence or wilful misconduct) and otherwise by Company. During any period that the Parties are in dispute regarding the conformity of the Excipient, ***, or as applicable its Affiliates shall, if requested by Company, replace such quantity of Excipient. Company shall pay for the original shipment of Excipient within thirty (30) days of requesting a replacement batch and shall pay for the replacement shipment of Excipient unless the Laboratory confirms the nonconformity of the original shipment, provided, however, that the Company is only obligated to pay for Excipient that is Non-conforming Excipient if the reason for the nonconformity is undetermined or is determined to be due to the fault of the Company or its contractors or licensees.

4.3 Remedies for Non-Conforming Product. If *** is notified within the notice period set forth in Section 4.1 that any Excipient delivered to Company is Nonconforming Excipient, *** or its Affiliates shall replace, at its own cost, the nonconforming Excipient with substitute Excipient that conforms to the Excipient Requirements within a commercially reasonable period not to exceed ninety (90) days from the date that Company notifies *** or its Affiliates of such non-conformity (unless the nonconformity is attributable to Company's negligence or wilful misconduct). Pursuant to written directions from *** or its Affiliates, Company shall either return the Non-conforming Excipient to *** or its Affiliates or destroy it, in each case, at *** or its Affiliates' expense. If Company is directed, and agrees, to destroy Nonconforming Excipient, *** or its Affiliates shall pay to Company the documented out-of-pocket cost (without mark-up) of such destruction within thirty (30) days of such request following which Company will follow *** or its Affiliates instructions regarding destruction. Company shall provide *** or its Affiliates, if requested a certificate certifying such destruction following completion. Except as provided for under Section 6.6 hereof regarding *** indemnification obligations for third party claims, the remedy described in this Section 4.3 shall be Company's sole remedy and *** and its Affiliates only liability for Nonconforming Excipient.

4.4 Deviations and OOS. At the request of either Party, the other Party and its Affiliates shall cooperate in the investigation and response to any Excipient complaints concerning Deviations and OOS, which may relate to *** or its Affiliates role in the Manufacture of Excipient (in addition to complying with the corresponding provisions in the Quality Agreement).

5. Sales Prices and Terms of Payment

5.1 Currency. Except as otherwise expressly indicated, all references to "$" or to "dollars" in this Agreement shall be read as referring to the legal tender of the United States of America.

5.2 Sales Prices. The sales prices for Excipient Manufactured under this Agreement and released by *** quality assurance department shall be the sales price

designated on Appendix 3, after taking into account the credit for previous purchases of Raw Materials as detailed on Appendix 3. The sales prices are to be understood as packaged and ready for further processing at the facility of Company or of a third party designated in writing by Company, excluding costs of shipping, insurance and freight and further excluding applicable sales or other taxes (which will be applied as set forth in Section 5.6 hereof). All prices are quoted in United States Dollars.

5.3 Invoices and Payments. *** shall invoice Company after final release by the Company of the Excipient. Following final release of the Excipient, or request for shipment by Company, *** shall have not more than thirty (30) days to ship the Excipient unless Company has requested *** to store such Excipient. The Company shall have up to the time of final release to request either the shipment of the Excipient to Company or for storage by ***. Company shall make all payments in accordance with the invoices and Appendix 3. Further, all payments made hereunder are due within thirty (30) days from the date of the invoice. Payments shall be made in accordance with the instructions on the invoice. All payments hereunder shall be made in United States Dollars. If the Company requests that *** not ship Excipient upon release by Company, then *** shall store the Excipient for Company, and Company shall execute *** standard Bill and Hold Letter Agreement passing title to and risk of loss of the Excipient to Company and authorizing *** to invoice Company for the Excipient upon final release by Company. In addition, if Company does not request shipment of stored Excipient within ninety (90) days of final release, then Company agrees to pay *** its standard storage fee for customer product stored on site at an *** facility. Unless *** is notified sooner of the final release or withholding of final release by Company of any Batch of Excipient, such Batch shall be deemed for purposes of invoicing and shipment to be finally released by Company thirty (30) days after *** delivery of the completed Batch Records and other documents specified in the Quality Agreement for such Batch to Company. If Company withholds final release of any Batch of Excipient, Company shall provide in its notice to *** a written description of the specific defects in the Batch Record which caused Company to withhold final release of such Batch.

5.4 Overdue Payments. Company shall pay interest on all past-due amounts at a rate of interest equal to the lesser of 1.0% per month or the maximum rate permitted by Applicable Law.

5.5 Price Adjustment.

(a) Notwithstanding any other provision of this Agreement to the contrary, each year of the Term following the first year of the Term, with sixty (60) days prior written notice to Company, and in addition to any other price adjustment that may be permitted by this Agreement or otherwise agreed to by the Parties, *** may adjust the pricing applicable to Company's purchases of the Excipient for such year by an amount not to exceed the percentage increase in the U.S. Producer Price Index, PCU325412325412, Industry: Pharmaceutical preparation manufacturing, Product: Pharmaceutical preparation manufacturing, Base Date: 198106 (or any similar successor index) as reported by the U.S. Department of Labor Bureau of

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Labor Statistics from the Effective Date to the time of such written notice to Company reflecting such price increase. *** may also adjust the pricing applicable to the Company's purchases of Excipient hereunder by the documented increase in the price of raw materials received by *** from unrelated third parties and not manufactured by *** or its Affiliates for the Company.

5.6 Taxes.

(a) If Company must withhold from any payment to *** or its Affiliates under this Agreement any taxes required to be withheld by Company under the Applicable Laws of any country, state, territory or jurisdiction, such amount shall be paid to the appropriate taxing authorities. Upon request, Company shall provide *** and its Affiliates with documentation of such withholding as is reasonably available to allow *** and its Affiliates to document such tax withholdings for purposes of claiming tax credits and similar benefits.

(b) Any use tax, sales tax, excise tax, duty, custom, inspection or testing for, or any other tax, fee or charge of any nature whatsoever imposed by, any governmental authority, on or measured by the transaction between Company and *** or its Affiliates shall be paid by Company in addition to any other amounts due hereunder.

6. Recall, Warranties, Indemnification and Insurance

6.1 Recall.

(a) Company shall be responsible for conducting any Recall arising out of or related to this Agreement (including without limitation any Recall of any Finished Product). *** and its Affiliates shall fully cooperate with and give all reasonable assistance to the Company to the extent the Recall relates to the Excipient, or as necessary to respond to inquiries from Regulatory Agencies. Further, *** and/or its Affiliates shall be responsible for the direct costs associated therewith to the extent that such recall is a result of *** or its Affiliates failure to manufacture the Excipient or Raw Materials to its Specifications, or if such Recall directly results from a material breach of *** or its Affiliates obligations hereunder, and/or of the Quality Agreement and/or from its gross negligence or wilful misconduct (in which case *** and/or its Affiliates shall be responsible for the direct costs and expenses associated with such Recall); provided, however, that to the extent such Recall or similar action is also due to Company's breach of its representations, warranties or obligations hereunder or under the Quality Agreement or from Company's or its Affiliates' or licensees' (if any) negligence or wilful misconduct, then *** and its Affiliates liability for such Recall shall be reduced proportionately by the damages or losses attributable to Company. Otherwise, Company shall bear all expenses associated with any Recall. In the event of such Recall or similar action, each Party shall use commercially reasonable efforts to mitigate the costs associated therewith.

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(b) In the case of a disagreement as to the existence or level of Nonconforming Excipient or Nonconforming Raw Materials in connection with a Recall under Section 6.1(a) above, then the matter shall be referred to the Laboratory in accordance with Section 4.2 above. The decision of the Laboratory shall be final and binding on the Parties.

6.2 Adverse Event Reporting. Company shall be responsible for all reporting to Regulatory Authorities of Adverse Events. If *** becomes aware of any Adverse Events, it shall report all information in its possession regarding such event to Company as soon as practicable in order to allow Company to fulfil its regulatory reporting obligations within the time frames required by the Regulatory Agency(ies) and Applicable Laws after becoming aware of such information, and shall cooperate with Company as necessary to report such event to the Regulatory Agency(ies).

6.3 *** Representations, Warranties and Covenants. *** hereby represents and warrants on behalf of itself and its Affiliates as follows:

(a) (i) The execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which *** or its Affiliates is a party or *** or its Affiliates constituent documents, (ii) *** and its Affiliates are not prohibited or limited by any law or agreement (to which it is a party) from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by *** or its Affiliates as applicable;

(b) The Excipient shall be Manufactured and shipped in compliance with cGMP, the Specifications, and all other Applicable Laws, rules and regulations;

(c) All Excipient delivered by *** hereunder will conform to the Quality Agreement and the Specifications; and

(d) It is not debarred and has not and will not use, in performing its obligations under this Agreement in any capacity, the services of any person debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992.

(e) The Batch Records, executed Batch Records and written procedures maintained by *** will accurately reflect in all material regards the processes and procedures followed by it in the Manufacturing of the Excipient, and the records and written procedures maintained by its Affiliates will accurately reflect in all material regards the processes and procedures followed by it in the Manufacturing of the Raw Materials.

(f) Each Certificate of Analysis will reflect the results of the tests conducted on the sample of Excipient or Raw Materials to which it relates.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

(g) *** and/or its Affiliates as applicable will have obtained and maintained in effect all such approvals and permits as may be required under Applicable Laws, rules, regulations and requirements to operate the Manufacturing facility for the Excipient or the Raw Materials for the purposes of Manufacturing Excipient and Raw Materials under the Quality Agreement and under this Agreement.

6.4 Company Representations, Warranties and Covenants. Company represents and warrants that (i) the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which Company is a party or Company's constituent documents, (ii) Company is not prohibited or limited by any law or agreement to which it is a party from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by Company.

6.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT.

6.6 Company Indemnification. Company shall indemnify, defend and hold harmless ***, its Affiliates and its or their directors, officers and employees from all actions, losses, demands, damages, fines, penalties, costs and liabilities arising from any third party claim (including reasonable attorneys' fees) to which *** is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:

(a) any breach by Company of any of its obligations or representations and warranties under this Agreement;

(b) any negligent act or omission or willful misconduct by Company, its Affiliates or its or their directors, officers, employees, agents or subcontractors;

(c) *** following any of Company's procedures as described in the Analytical Methods, the Manufacturing Process or the Specifications;

(d) Company's incorporation of the Excipient or the Raw Materials into the Finished Product;

(e) the labeling, marketing, distribution or sale by Company of the Finished Product;

(f) the use of the Excipient in a use other than that for which it is described in a regulatory filing by Company, or of the Finished Product; or

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

(g) the infringement by the Finished Product and/or the Excipient of any intellectual property or other proprietary rights of any third party.

6.7 *** Indemnification. *** shall indemnify, defend and hold harmless Company, its Affiliates and its or their directors, officers and employees from all actions, losses, demands, costs and liabilities arising from any third party claim (including reasonable attorney's fees) to which Company is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:

(a) any breach by *** of any of its obligations or representations and warranties under this Agreement or the Quality Agreement; or

(b) any negligent act or omission or willful misconduct by ***, its Affiliates or its or their directors, officers, employees, agents or subcontractors.

6.8 Limitation on Indemnification. Provided, however, that neither Party shall have the obligation to indemnify, defend, and/or hold harmless the other Party, its Affiliates and its or their directors, officers and employees for any and all actions, losses, demands, damages, fines, penalties, costs and liabilities to the extent that such Party has an obligation to indemnify the other Party with respect to such actions, losses, demands, damages, fines, penalties, costs and/or liabilities pursuant to Section 6.6 or Section 6.7 above.

6.9 Indemnification Procedure. Either Party intending to seek indemnification from the other Party under Sections 6.5 or 6.6 above, as the case may be, shall give the other Party prompt notice of any such claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the other Party and its legal representatives in the investigation of any matter which is the subject of indemnification. Such Party seeking indemnification shall not unreasonably withhold its approval of the settlement of any claim, liability or action covered by the above indemnification provisions. Notwithstanding the foregoing, the failure to give timely notice to the indemnifying Party shall not release the indemnifying Party from any liability to the Party seeking indemnification to the extent the indemnifying Party is not prejudiced thereby.

6.10 Company Insurance. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for five (5) years after the expiration or termination of this Agreement, Company shall obtain and maintain commercial product liability insurance with limits of not less than $10,000,000 per occurrence for product liability. With respect to all insurance coverage required under this Section 6.8, (i) Company shall, promptly upon *** request, furnish *** with certificates of insurance evidencing such insurance and (ii) in the event of any reduction in coverage, termination or cancellation of any such policy shall provide no less than thirty (30) days' prior written notice of reduction in coverage, termination or cancellation.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

6.11 *** Insurance. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for five (5) years after the expiration or termination of this Agreement, *** shall obtain and maintain product liability insurance (including through self-insurance) with limits of not less than $10,000,000 per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.9, *** shall, promptly upon Company's request, furnish Company with certificates of insurance evidencing such insurance or other similar evidence if self-insured.

7. Regulatory Matters; Quality; Compliance with Laws

7.1 Regulation of Manufacturing Process. If *** or its Affiliates are required by the FDA, EMA, or any other Regulatory Agency to validate or re-validate Manufacturing processes that will impact the Manufacturing of Excipient or Raw Materials as the case may be, *** or its Affiliates shall notify Company and consult with Company regarding the required activities, provided, however, that if such requested changes are solely related to the Excipient, *** shall inform the Company promptly and the requested changes will be discussed and agreed to between the parties. *** or its Affiliates shall be responsible for the costs of any such validation or re-validation that is required due to the non-compliance of the *** Manufacturing facility with cGMPs or Applicable Law applicable generally to manufacturing in *** facility; otherwise any such costs that are specific to the Manufacturing of the Excipient or Raw Materials shall be borne by Company.

7.2 Correspondence. *** and its Affiliates will notify Company (pursuant to the Quality Agreement) promptly upon receipt of any correspondence from a Regulatory Agency, which relates to the Excipient or Raw Materials. In addition, *** shall provide to the Regulatory Agencies all documents and information requested by such authority, and shall submit to all inquiries, audits and inspections by the Regulatory Agencies.

7.3 Quality Agreement. Within one (1) month following the execution of this Agreement, the Parties shall execute a revised Quality Agreement in substantially the form attached to this Agreement as Appendix 1. In the event of a conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall control except with respect to matters relating to compliance with cGMPs as specified in the responsibility matrix and related regulations, in which case, the Quality Agreement will control.

7.4 Records. *** and its Affiliates shall maintain all quality assurance manufacturing records, Batch Records, executed Batch Records and other records directly related to the Manufacture of Excipient or Raw Materials required by any applicable Regulatory Agency, in a secure area reasonably protected from fire, theft and destruction.

7.5 Regulatory Documents and Support. *** and its Affiliates shall provide to Company such documentation as may be requested by a Regulatory Agency and necessary support, including copies of documents, required for regulatory filings by Company.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

7.6 Regulatory Inspections. *** and its Affiliates shall reasonably accommodate requests made on behalf of Company by a Regulatory Agency to inspect the Manufacturing facility and or any Qualified Alternate Facility. *** and its Affiliates shall reasonably accommodate GMP audits or other required audits by Company in preparation for such inspections if necessary. *** and its Affiliates shall use commercially reasonable efforts to support such audits. To the extent practicable, *** and its Affiliates shall inform Company of such any inspections directly or indirectly related to the Excipient or Raw Materials and shall permit two (2) representatives to be present during those portions of such inspections that relate to the Excipient or Raw Materials. *** and its Affiliates shall promptly provide the Company with information reasonably requested by Company and information requested by a governmental or Regulatory Agency in the course of an inspection related to or affecting the Excipient or Raw Materials. *** and its Affiliates shall provide Company with a summary of the observations made by Regulatory Agencies and the plan to correct any deficiencies related to the Excipient or Raw Materials and those areas of the Facility that are directly related to the manufacture of the Excipient or Raw Materials following each inspection.

7.7 Access to Facilities. Company and/or its' designees will have routine access (subject to *** standard safety, security and confidentiality policies and procedures) on no more than three months' prior written notice, to *** and its Affiliates manufacturing facilities at mutually agreeable times for the purpose of auditing *** and its Affiliates compliance with cGMP regulations as defined and/or Applicable Law, and for overall compliance with the relevant legislation, and with respect to the manufacture of Excipient or Raw Materials on Company's behalf; provided, however, if a For Cause Audit, is required by Company, *** or its Affiliates as applicable will allow Company or its designees to access *** and its Affiliates manufacturing facilities with ten (10) days notice at no cost. Except with respect to For Cause Audits, routine audits will be limited to one (1) audit every calendar year at no cost and will be conducted by a reasonable number of employees or representatives of Company or its designees who are subject to the same requirements of confidentiality as Company.

7.8 Compliance with Laws; Authorizations. In performing this Agreement, each Party shall (i) comply with all Applicable Law and regulations and (ii) obtain all releases, licenses, permits or other authorization required by any governmental body or authority.

8. Confidentiality; Intellectual Property License

8.1 Confidentiality Obligations of ***. In the course of the performance of this Agreement, Company may, from time to time, disclose Confidential Information of Company to *** or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, *** and its Affiliates shall: (i) maintain in confidence and not disclose the Confidential Information of Company to any third party, except on a need-to-know basis to *** (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with *** (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of Company for any purpose other than the performance of *** and/or its Affiliates' obligations hereunder.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

8.2 Confidentiality Obligations of Company. In the course of the performance of this Agreement, *** and its Affiliates may, from time to time, disclose Confidential Information of *** to Company or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, Company shall: (i) maintain in confidence and not disclose the Confidential Information of *** and its Affiliates to any third party, except on a need-to-know basis to Company's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with Company's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of *** and its Affiliates for any purpose other than the performance of Company's obligations hereunder.

8.3 Exceptions. The provisions of Sections 8.1 and 8.2 above shall not apply to any Confidential Information of the disclosing Party that can be shown by competent evidence by the receiving Party:

(a) To have been known to or in the possession of the receiving Party without any separate obligation of confidentiality before the date of its actual receipt from the disclosing Party;

(b) To be or to have become readily available to the public other than through any act or omission of any Party in breach of any confidentiality obligations owed to the disclosing Party;

(c) To have been disclosed to the receiving Party, other than under an obligation of confidentiality, by a third party which is not known to the receiving Party to have had an obligation to the disclosing Party not to disclose such information to others; or

(d) To have been subsequently independently developed by the receiving Party without use of or reference or access to the disclosing Party's Confidential Information.

8.4 License. During the Term, Company hereby grants to *** a royalty-free, non-exclusive license under any know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the Excipient or the Manufacture of the Excipient that are owned or controlled by Company and that are necessary for *** performance of its obligations under this Agreement, but only for such purposes and only to the extent useful for *** to perform its obligations under this Agreement. During the Term, Company hereby grants to Affiliates of ***, as applicable, a royalty-free, non-exclusive license under any know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the Manufacture of the Raw Materials that are owned or

controlled by Company and that are necessary for such party's performance of its obligations under this Agreement, but only for such purposes and only to the extent useful for such party to perform its obligations under this Agreement.

9. Term and Termination

9.1 Term. The initial period of this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the fifth (5th) yearly anniversary of the Commencement Date, unless earlier terminated as provided in Sections 9.2 and 9.3 below. Thereafter the Agreement shall be renewed automatically for additional three (3) year periods, unless cancelled by one of the Parties upon at least twelve (12) months prior written notice. Such initial period and any renewal period shall be referred to herein as the "Term".

9.2 Termination. Notwithstanding the provisions of Section 9.1 above, the Parties may terminate this Agreement in the event of either of the following:

(a) Termination for Material Breach. Either Party may terminate this Agreement by written notice at a date set in the notice (allowing at least one hundred and twenty (120) days for cure, except for default in payment obligations that are the subject of a good faith dispute for which the cure period is sixty (60) days) in the event of a material breach of this Agreement by the other Party; provided that the breaching Party fails to cure such breach within one hundred and twenty (120) days from the date of such notice; and further provided that the cure period for failure to pay an invoice when due (which is a material breach of this Agreement) is sixty (60) days.

(b) Termination by Company. The Company may terminate this Agreement, upon ninety (90) days' notice, under the following circumstances: (i) *** delivers two Batches that are determined to be Non-conforming Excipient during any twelve (12) month period, which are not replaced by *** with conforming Batches of Excipient within sixty (60) days following notification from the Company that such Batches are Non-conforming Excipient; (ii) three (3) or more Batches of Excipient, which are conforming Excipient, are delivered within any twelve (12) month period more than sixty (60) days after the delivery date established for the order (excluding Batches covered under (i) above, which are replacement Batches); or (iii) *** rejects any validly placed order for reasons other than Force Majeure.

(c) Insolvency. If either Party shall become insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of or against such Party, or if a receiver or trustee of such Party's assets shall be appointed, or bankruptcy proceedings begin, the other Party may terminate this Agreement, as may be permitted by the Applicable Laws, with immediate effect.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

9.3 Rights and Obligations Upon Termination.

(a) Technology Transfer; Return of Inventory and Confidential Information. In the event of any termination, *** and its Affiliates as applicable shall return to Company: (i) all Company property at Company's expense, unless such termination shall have been as a result of a breach of this Agreement by *** or its Affiliates in accordance with Section 9.2(a), in which case such property shall be returned at *** or its Affiliates' expense, except and solely to the extent required to be retained by law or to comply with such Party's continuing obligations hereunder or for purposes of dispute resolution or litigation; (ii) all Confidential Information of Company (except and solely to the extent required to by retained by law or to comply with *** continuing obligations hereunder or for purposes of dispute resolution or litigation) and shall make no further use of such Confidential Information without the prior written consent of Company and (iii) shall reasonably cooperate with the Company in supporting a Technology Transfer to a Third Party supplier, provided, however, that in the event termination is due to a default by the Company, *** obligations shall be solely to provide all records and other data related to the Manufacturing or Excipient or Raw Materials in its possession.

(b) Payments. Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then or thereafter due and payable. Upon termination of this Agreement by *** pursuant to Section 9.2(a), Company shall take delivery and pay for all Excipient or Raw Materials that is subject to an open purchase order, pay all monies due and owing pursuant to this Agreement and reimburse *** and its Affiliates for its costs for all material, work in process, finished Excipient or Raw Materials and all other outstanding inventory (meaning all raw materials that are specifically required and purchased by *** for the manufacture of the Excipient) to the extent that such items were reasonably acquired by *** or its Affiliates to meet its obligations hereunder in a timely manner, and make such other payments to *** or its Affiliates as may be set forth in Appendix 3 hereto.

9.4 Surviving obligations. Termination or expiration of this Agreement shall not affect any accrued rights or obligations of either Party. The terms of Sections 2.7(b), 2.7(c), 2.13, all of 4, 5.3, 5.4, 5.6, 6.1, 6.3 through 6.11, 8.1 through 8.3, 9.3, 9.4, all of 10 and all of 11 of this Agreement shall survive termination of this Agreement.

10. Governing Law; Dispute Resolution

10.1 Governing Law. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of New York, USA, without regard to its conflict of law provisions. The U.N. Convention on International Sales of Goods shall not apply to this Agreement.

10.2 Good Faith Meeting. In the event of any dispute arising between the Parties concerning this Agreement, Company and *** and its Affiliates agree that in the first place they shall meet for good faith discussions in an attempt to negotiate an amicable solution.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

10.3 Arbitration.

(a) Any dispute arising between the Parties out of or in connection with this Agreement, or the interpretation, breach or enforcement thereof that cannot be amicably resolved pursuant to Section 10.2 above within two (2) months as from the first appearance of such dispute shall be finally settled by arbitration as set forth in this Section 10.3.

(b) The arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that both Parties are domestic United States companies or in accordance with the International Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that one of the Parties is not a domestic United States company, except, in each instance, as such rules may be modified herein or by mutual agreement of the Parties.

(c) The seat of the arbitration shall be New York City, New York, USA, and it shall be conducted in the English language.

(d) The arbitration shall be conducted by three arbitrators. The Party initiating arbitration ("Claimant") shall appoint an arbitrator in its request for arbitration ("Request"). The other Party ("Respondent") shall appoint an arbitrator within thirty (30) days of receipt of the Request and shall notify the Claimant of such appointment in writing. If within thirty (30) days of receipt of the Request by the Respondent, either Party has not appointed an arbitrator, then that arbitrator shall be appointed by the American Arbitration Association. The first two arbitrators appointed in accord with this provision shall appoint a third arbitrator within thirty (30) days after the Respondent has notified Claimant of the appointment of the Respondent's arbitrator or, in the event of a failure by a Party to appoint, within thirty (30) days after the American Arbitration Association has notified the Parties and any arbitrator already appointed of its appointment of an arbitrator on behalf of the Party failing to appoint. When the third arbitrator has accepted the appointment, the two arbitrators making the appointment shall promptly notify the Parties of the appointment. If the first two arbitrators appointed fail to appoint a third arbitrator or so to notify the Parties within the time period prescribed above, then the American Arbitration Association shall appoint the third arbitrator and shall promptly notify the Parties of the appointment. The third arbitrator shall act as Chair of the tribunal.

(e) The arbitral award shall be in writing, state the reasons for the award, and be final and binding on the Parties. The award may include an award of costs, including reasonable attorneys' fees and disbursements. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

(f) Notwithstanding Section 10.1 hereof, the arbitration and this Section 10.3 shall be governed by Title 9 (Arbitration) of the United States Code.

(g) The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the American Arbitration Association, the Parties, their counsel and any person necessary to the conduct of the proceeding, except as may be lawfully required in judicial proceedings relating to the arbitration or otherwise.

11. Miscellaneous

11.1 Conditional Effectiveness. The effectiveness of this Agreement is conditioned upon Company and *** duly executing and delivering the Quality Agreement.

11.2 Publicity. Any public announcement or similar publicity with respect to this Agreement will be issued, if at all, at such times and in such manner as shall be mutually agreed in writing by the Parties. Notwithstanding the foregoing, any disclosure of this Agreement required by Applicable Law shall not be prohibited.

11.3 Use of Names. *** and its Affiliates shall not use the name of Company or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of Company. Company shall not use the name of *** or its Affiliates or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of ***. Notwithstanding the foregoing, Company shall be entitled to identify *** and its Affiliates as the source of the Excipient in any regulatory submission without *** prior written consent, and either Party may provide such disclosure as may be required by Applicable Law.

11.4 Marks. Each Party reserves all rights to any name, trademark, service mark or logo ("Marks") it may have or hereafter acquire. Neither Party shall by this Agreement obtain any right, title or interest in or to any Marks of the other Party or its Affiliates. Accordingly, neither Party shall use any Marks confusingly similar to or likely to cause confusion with the Marks of the other or of any other person or entity. Each use by a Party of any Marks of the other Party, whether in advertising or marketing materials, websites, company announcements or offering circulars, informational materials, public events, or otherwise, shall be subject to the prior written approval of the other Party.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

11.5 Limitation of Liability.

(a) NOTWITHSTANDING ANYTHING HEREIN (OR IN ANY RELATED AGREEMENT OTHER THAN A PROPERLY EXECUTED AMENDMENT) TO THE CONTRARY, EXCEPT WITH RESPECT TO A BREACH OF ARTICLE 8 OR FRAUD BY A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (SUCH AS LOST PROFITS) OR ANY SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, WHETHER BASED ON CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE AND REGARDLESS OF WHETHER ANY PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(b) NOTWITHSTANDING ANYTHING HEREIN (OR IN ANY RELATED AGREEMENT OTHER THAN A PROPERLY EXECUTED AMENDMENT) TO THE CONTRARY, EXCEPT IN THE CASE OF THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF ***, THE MAXIMUM AGGREGATE LIABILITY OF *** TO COMPANY FOR ANY CAUSE OF ACTION (OR RELATED CAUSES OF ACTION) ARISING OUT OF OR RELATED TO THIS AGREEMENT AND/OR THE DELIVERY OF THE EXCIPIENT SHALL NOT EXCEED THE AMOUNT ACTUALLY PAID BY COMPANY TO *** PURSUANT TO THIS AGREEMENT FOR THE EXCIPIENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE CLAIM GIVING RISE TO THE LIABILITY.

(c) The foregoing limitations in Section 11.5(a) and (b) above shall survive notwithstanding any failure of essential purpose of a limited remedy.

11.6 Assignment; Successors; Subcontractors; Third-Party Beneficiaries.

(a) Neither Party may assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other Party, which will not be unreasonably withheld, except that (i) either Party may assign, in whole or in part, without such consent any of its rights or obligations under this Agreement to any Affiliate of such Party, provided that any such assignment to an Affiliate shall not relieve the assignor as the primary obligor hereunder and/or (ii) either Party may assign in connection with the merger, consolidation or sale of the stock or substantially all of the assets of the business responsible for the performance of this Agreement, other than to a competitor of the other Party hereto with respect to the Finished Product, in which case such Party in question shall have the right to withhold consent to such assignment.

(b) Subject to the preceding subsection (a), this Agreement will apply to, be binding in all respects upon, and inure to the benefit of the successors and permitted assigns of the Parties.

(c) Notwithstanding any other provisions of this Agreement to the contrary, *** or its Affiliates may use one or more subcontractors (including, without limitation, any Affiliate of ***) in the performance of its obligations hereunder with written permission of Company, such approval not to be

unreasonably withheld, as long as it exercises appropriate diligence in the selection of such subcontractors and remains primarily liable for the performance of its obligations hereunder. With respect to any work performed by any Affiliate of *** in connection with this Agreement, the Parties agree and acknowledge that *** shall include the work performed by its Affiliate and the related charges, with reasonable accompanying detail, on those invoices submitted to the Company by *** in the regular course. Such work will be subject to the terms and conditions of this Agreement irrespective of the source of the invoice.

(d) Nothing expressed or referred to in this Agreement will be construed to give any person other than the Parties any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement. This Agreement and all of its provisions and conditions are for the sole and exclusive benefit of the Parties to this Agreement and their successors and assigns.

11.7 Transactions Outside Scope of Agreement. Other than as expressly provided for otherwise in this Agreement, this Agreement shall in no way limit or restrict the ability of either Party or any Affiliate of such Party to offer its products or services to any other person.

11.8 No Transfer of Rights. No transfer, grant or license of rights under any patent or copyright or to any intellectual property, proprietary information and/or trade secret is made or is to be implied by this Agreement except as may be expressly stated otherwise herein.

11.9 Independent Contractors. The Parties undertake to carry out this Agreement as independent contractors. No franchise, partnership, joint venture or relationship of principal and agent is intended by this Agreement. Neither Party is authorized, in the name of or on behalf of the other Party, to incur any obligation, receive any benefit or right or otherwise bind the other Party. All employees, agents, representatives and contractors of a Party are solely those of such Party and no acts thereof will be binding upon the other Party.

11.10 Waiver. The failure or the delay of any Party hereto to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach of this Agreement.

11.11 Severability. Should any provision of this Agreement become void or be cancelled, then the other provisions shall remain in full force and effect. If a provision of this Agreement should be void or should be declared void, then the Parties will attempt to replace it by another valid provision or will leave the provision unreplaced by mutual consent. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

11.12 Appendices. All appendices attached hereto are hereby incorporated in and made a part of this Agreement as if fully set forth herein.

11.13 Entire Agreement. This Agreement, including all appendices hereto, contains the final, complete and exclusive agreement of the Parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter.

11.14 Amendment. This Agreement shall not be deemed or construed to be modified, amended, rescinded, cancelled or waived, in whole or in part, except by written amendment signed by the Parties hereto.

11.15 Notices. All notices, consents, waivers and other communications under this Agreement must be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by facsimile (with written confirmation of transmission), (iii) when received by the addressee if sent by registered or certified mail (return receipt requested) or if sent by an internationally recognized overnight delivery service, in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a Party may designate by notice to the other Party):

If to Company:
Heron Therapeutics, Inc.
Attention: SVP, Technical Operations
123 Saginaw Drive
Redwood City, California 94063
Telephone: 650-366-2626
Fax: 650-365-6490

With a copy to:
Heron Therapeutics, Inc.
Attention: General Counsel:
123 Saginaw Drive
Redwood City, California 94063
Fax: 650-365-6490
Facsimile No.: 650-365-6490

If to ***:
***
Attention: Site Director
Facsimile No.: ***

With a copy to:
***
Attention: Legal Department
Facsimile No.: ***

11.16 Section Headings; Construction. The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

11.17 Force Majeure. Any events that cannot be prevented by *** or its Affiliates, such as fire, flood, war, strike, civil unrest, terrorism, natural catastrophes, government acts and regulations, and other events beyond *** or its Affiliates reasonable control, will free *** and its Affiliates for the duration of the event from its obligations under this Agreement. As soon as there is an indication of an event of force majeure, *** or its Affiliates will advise Company within ten (10) days or as soon as practical of the effect of such event on this Agreement and about the measures to be taken to mitigate such effect. The Parties are obligated to mitigate damages and to resume the fulfilment of the contractual obligations as quickly as possible.

11.18 Expenses. Except as otherwise expressly provided in this Agreement, in the appendices hereto or in any agreement or other document expressly referenced herein and forming a part hereof, including the Quality Agreement, each Party to this Agreement will bear its respective expenses incurred in connection the performance of its obligations hereunder. In the event of termination of this Agreement, the obligation of each Party to pay its own expenses will be subject to any rights of a Party arising from a breach of this Agreement by the other.

11.19 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

11.20 Governing Language. The validity, interpretation, construction and performance of this Agreement shall be in accordance with the English language. If this Agreement is translated into another language and there is a conflict between the non-English version and the English version, then the English version shall control.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

IN WITNESS WHEREOF, the Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed effective as of the Effective Date by their duly authorized representatives.

***	**HERON THERAPEUTICS, INC.**
By: ***	By: /s/ Paul Marshall
Name: ***	Name: Paul Marshall
Title: ***	Title: SVP Tech Ops

12/18/15

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

APPENDIX 1

QUALITY AGREEMENT

Quality Agreement between Company and *** and its Affiliates, as amended, supplemented or restated from time to time (actual version).

***

[*Redacted in its entirety*]

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

APPENDIX 2

SPECIFICATIONS

The Specifications for the Excipient with be as per the then current version of the controlled document: FPS 200-658 (SPEC-MAD-FPS-005916) or successor document agreed in writing by the Parties.

***

[*Redacted in its entirety*]

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

APPENDIX 3

PRICING

Annual Commitment (Batches)*	*Price per Kg of ***	Estimated Price/Batch (***)
1-4 Batches	$ ***	$ ***
5-15 Batches	$ ***	$ ***
>15 Batches	$ ***	$ ***

* Assumes batch sizes between *** kgs.

Pricing is per kg predicated on targeted Batch size of approximately *** of Excipient. Only full Batches may be ordered, not increments. If an approved process change results in a different target Batch size, the per unit prices will be recalculated and negotiated in good faith.

Volume pricing will apply based on the Contract Year's four-quarters forecast as of Jan 1st of each year, beginning January 1st 2016 ("Contract Year"). In the event the Forecast changes during the Contract Year whether by increase or decrease, the per kg pricing will be recalculated at the end of the year as of December 31st, applicable to all Excipient to have been delivered and accepted during the Contract Year, as follows:

(a) In the event the actual number of Batches purchased was less than the forecast for the Contract Year, Heron will pay to *** the difference between the price per unit paid, and the applicable per unit price based on actual Batches purchased. Such invoice and payments will be per the terms of the Agreement.

(b) In the event the actual number of Batches purchased for the Contract Year exceeds the forecast, *** will either refund to Heron, or credit to outstanding Firm Orders, at *** option, the difference between the price per unit paid by Heron, and the applicable per unit price based on actual Batches purchased unless it is the final year of the contact in which case *** will refund to Heron such amount.

Pre-purchased Raw Materials

Heron has purchased inventories of the Proprietary Raw Materials *** and *** that are presently stored at *** as agreed between the parties 23rd October 2013.

*** will provide a credit off the commercial price per kg of the price sated above when the purchased inventory is used. The amount of such credit is outlined in the table below. When these inventories are consumed or their usefulness has been excluded due to quality requirements necessary to make *** to established specifications, the pricing for *** will revert to the established per kg price outlined above.

Item	Credit/kg of ***
***	$ ***
***	$ ***

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

APPENDIX 4

PROPRIETARY RAW MATERIALS

All defined terms have the meaning assigned to them in the Supply Agreement.

List of Proprietary Raw Materials

***
Chemical Name: ***
Structure:
***

Specification: ***

***
Name: ***
Structure:
***

Specification: ***

Purchase and Delivery of Proprietary Raw Materials

Raw Materials can be purchased at the Price indicated below and the Price adjusted per Section 5.5. Orders should be placed for the standard batch sizes indicated below at least ninety (90) days prior to delivery. The Raw Material will be shipped in accord with shipment instructions provided in writing by the Company at the time of order placement. The Raw Materials will be delivered matching the Specifications indicated above along with a Certificate of Analysis, executed Batch Records, analytical test results, and copies of Raw Material Specifications for such Batch of Raw Materials.

All other terms will be as per the appropriate Section of this Agreement.

***
Price: $***
Standard batch size: ***

***
Price: $***
Standard batch size: ***

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-190550, 333-195928 and 333-198862) and Form S-8 (Nos. 333-35151, 333-90428, 333-118546, 333-127574, 333-137954, 333-148660, 333-162610, 333-167515, 333-176365, 333-176366, 333-190549, 333-198853, 333-202588 and 333-206165) of Heron Therapeutics, Inc. of our reports dated February 18, 2016 relating to the consolidated financial statements and the effectiveness of Heron Therapeutics, Inc.'s internal control over financial reporting, which appear in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP

San Francisco, California
February 18, 2016

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Barry D. Quart, certify that:

1. I have reviewed this Annual Report on Form 10-K of Heron Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) 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(s) 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: February 19, 2016

/s/ Barry D. Quart

Barry D. Quart, Pharm.D.
Chief Executive Officer
(As Principal Executive Officer)

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Annual Report on Form 10-K of Heron Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) 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(s) 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: February 19, 2016

/s/ Brian G. Drazba
Brian G. Drazba
Vice President, Finance and Chief Financial Officer
(As Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

Each of the undersigned, in his capacity as Chief Executive Officer and Chief Financial Officer, as applicable, of Heron Therapeutics, Inc. (the "Registrant"), hereby certifies, for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge that:

- the Annual Report of the Registrant on Form 10-K for the year ended December 31, 2015 (the "Report"), which accompanies this certification, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition of the Registrant at the end of such year and the results of operations of the Registrant for such year.

Dated: February 19, 2016

/s/ Barry D. Quart
Barry D. Quart, Pharm.D.
Chief Executive Officer
(As Principal Executive Officer)

/s/ Brian G. Drazba
Brian G. Drazba
Vice President, Finance and
Chief Financial Officer
(As Principal Financial and Accounting Officer)

This certification accompanies the Report to which it relates, is not deemed to be filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Heron Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Note: A signed original of this written statement required by Section 906 has been provided to Heron Therapeutics, Inc. and will be retained by Heron Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.