

[Below are extracts from a registration statement filed by Senestech with the U.S. Securities and Exchange Commission on September 21, 2016. This was in preparation for its IPO; the company started selling publicly traded stock on December 8, 2016.

https://www.sec.gov/Archives/edgar/data/1680378/000114420416124776/v446625_s1.htm]

OVERVIEW

We have developed and are seeking to commercialize globally a proprietary technology for managing animal pest populations through fertility control. We believe our innovative non-lethal approach, targeting reproduction, is more humane, less harmful to the environment, and more effective in providing a sustainable solution to pest infestations than traditional lethal pest management methods. Our approach is designed to promote food security and reduce infrastructure damage, disease outbreaks, environmental contamination and other costs associated with rodent infestations. Our first fertility control product candidate, ContraPest, will be marketed for use in controlling rat populations. We are pursuing regulatory approvals for ContraPest in various jurisdictions, including the U.S., India, Argentina and the European Union (EU). We submitted ContraPest for registration with the U.S. Environmental Protection Agency, or the EPA, on August 23, 2015, and the EPA granted registration approval for ContraPest effective August 2, 2016. We believe ContraPest is the first fertility control product approved by the EPA for the management of rodent populations. However, before we can begin selling ContraPest in the U.S., we must obtain registration from the various state regulatory agencies. To date, we have received registration for ContraPest in ten states, with additional applications pending. Other business initiatives include expanding our technology to other species and applications, and developing bio-synthetic sources of triptolide, an active ingredient in ContraPest that also has pharmaceutical applications. These and other initiatives may produce a less expensive source of triptolide for our own use, and provide us with the potential opportunity to earn revenue from the sale of such product to our licensees and other potential consumers of triptolide.

[...]

Current efforts to control rodent populations include the use of lethal chemical agents, also referred to as rodenticides, the sale of which constituted a \$900 million market worldwide in 2013.

[...]

Our fertility control product candidate, ContraPest, targets the reproductive capabilities of rodents by inducing the gradual loss of eggs in female rodents and disruption of sperm in male rodents, resulting in contraception that can progress to sterility in both females and males. By targeting rodent fertility, our solution is:

- Sustainably effective — ContraPest causes rodent populations to remain at a sustained low level, as demonstrated by studies in which we have observed decreases in wild rodent populations of more than 40% over a 12-week period. We believe this decrease in population will continue and, based on studies conducted by third parties, will stabilize at an approximately 70% reduction in 12 months without rebound (based on an initial population of approximately 10,000 rats). The rebound pattern is also significantly reduced in a rodent population treated with ContraPest because the non-reproductive rodents continue to defend their territory from invasion by other rodents.

- Targeted delivery — our proprietary formulation appears to be attractive to rodents, can be placed in strategic feeding locations in our proprietary bait station, and delivers active ingredients directly to targeted reproductive organs.
- Safe — studies of ContraPest have demonstrated that ContraPest is not lethal to rodents or harmful to people or other animals, nor does it accumulate in rodents or pose a risk of secondary exposure to predators of rodents.
- Environmentally friendly — ContraPest does not contain poisons, breaks down into inactive ingredients when it comes in contact with soil or water in the environment and utilizes a closed delivery system designed to prevent exposure to non-target species and the environment.
- Humane — our solution neither results in rodent death nor causes physical suffering in rodents.

[...]

Key elements of our strategy are:

- Obtain regulatory approval for our lead product candidate, ContraPest, throughout the U.S., and in Argentina, India, the EU and other parts of the world, and seek additional related regulatory approvals to support product evolution.

[...]

Our Third Party Relationships and Commercialization Plans

To date, we have entered into arrangements with the following manufacturing, marketing and distributions partners:

- Neogen — Under our agreement with Neogen Corporation, a developer, manufacturer and marketer of a diverse line of products dedicated to food and animal safety, we granted to Neogen an exclusive license in North America to manufacture, distribute and sell commercial rodent control products, which include ContraPest, for the later of 10 years or the expiration of the patent for ContraPest (if issued).
- NeoVenta — Pursuant to our agreement with NeoVenta Solutions, a sales and marketing company, we granted to NeoVenta an exclusive license for 10 years to represent us in the marketing, sales and distribution of ContraPest in India and certain surrounding Southeast Asian countries at such time, if any, that regulatory approval in these countries has been obtained.
- Bioceres — Under our agency agreement with INMET, the research and development subsidiary of Bioceres, Inc., a leading agricultural biotechnology company in Argentina, we have authorized INMET, which specializes in bacterial fermentation solutions, to seek regulatory approval for and conduct pre-sales marketing of ContraPest in Argentina. We intend to create a joint venture entity with INMET, which we will control. At such time, if any that regulatory approval in Argentina is obtained, this joint venture will manage all sales and marketing of ContraPest in Argentina. We also have a services agreement with INMET to provide research and development services to develop an efficient production method for a bio-synthetic version of triptolide.

To date, we have not generated any revenue from product sales, but we currently expect to commercialize ContraPest and begin to generate revenue from the sale of products or through the payment of royalties by our strategic partners beginning in the fourth quarter of 2016. Specifically, we anticipate that sales of ContraPest will commence in North America in late 2016 through our distribution relationship with Neogen, and that we will begin receiving royalty payments from Neogen thereafter. Subject to obtaining necessary regulatory approvals, we also intend to market ContraPest in international jurisdictions, including India, Argentina and the EU, directly and through our existing and future strategic relationships. Target markets for ContraPest include municipalities (e.g., subways, transit systems and public housing agencies); agriculture (e.g., farms, storage facilities and protein production facilities (including cattle, sheep, pig and poultry facilities)); food production (e.g., factories, meat-packing facilities, dairy production plants and vegetable and fruit preparation facilities); and commercial (e.g., major restaurant chains, retail locations, casinos and hotels). In addition, we intend to approach large pest management companies to pursue potential partnerships for the distribution and sale of ContraPest.

[...]

Regulatory Strategy

While the EPA has granted us exclusive-use status for ContraPest, this approval was granted on a restricted-use basis, including indoor and limited outdoor use, and is based on a liquid formulation. We intend to diligently pursue additional related regulatory approvals from the EPA to support our product evolution, including seeking approval for full outdoor use, removal of the restricted-use status, alternative formulations and for additional species (utilizing approved active ingredients). In addition, we believe that the EPA will support us in facilitating regulatory reviews outside of the U.S., and we are exploring a relationship with the Danish Environmental Protection Agency to assist us with obtaining regulatory approvals in the EU. See “Business — Government Regulation and Product Approval” for additional information.

We have developed a pipeline of potential additional fertility control and animal health products, with diverse applications, as outlined in the following chart [N.B. –chart formatting is modified below]:

ContraPest

Environmental Protection Agency (EPA) granted registration approval for ContraPest effective August 2, 2016; to commercialize following approval

Population management: Rodents

Plant-based fertility control

Pilot studies have been completed; additional testing required for the use of this product to manage pest populations in select sites such as schools and hospitals

Population management: Rodents

Feral animal fertility control

Pilot studies are in process to show efficacy of this product candidate; to complete larger pivotal studies and regulatory submission

Population management: Feral dogs and hogs

Non-surgical spay and neutering

Pilot studies completed show encouraging signs of efficacy; to complete additional studies and regulatory submission

Companion animal health: Companion dogs and cats

Boar taint

Additional scientific and field studies and regulatory submission required

Food production and safety: Boars

Animal cancer treatment

Proof of concept study to be performed to determine whether proprietary formulation may provide - effective delivery of triptolide to dogs for cancer therapy

Companion animal health: Companion dogs

[...]

We are dependent on a key ingredient for ContraPest, triptolide, which has limited sources and must be in a very refined condition.

If we are unable to develop additional sources of triptolide, which is one of the key ingredients for ContraPest, the long term ability to produce ContraPest at a cost effective price could be in jeopardy; the limited sources could restrict our production if supplies were reduced; another use of the ingredient could cause the price to increase beyond our ability to market at a competitive price; and increased demand for the ingredient could cause the quality of the refined ingredient to be less than needed for our production.

[...]

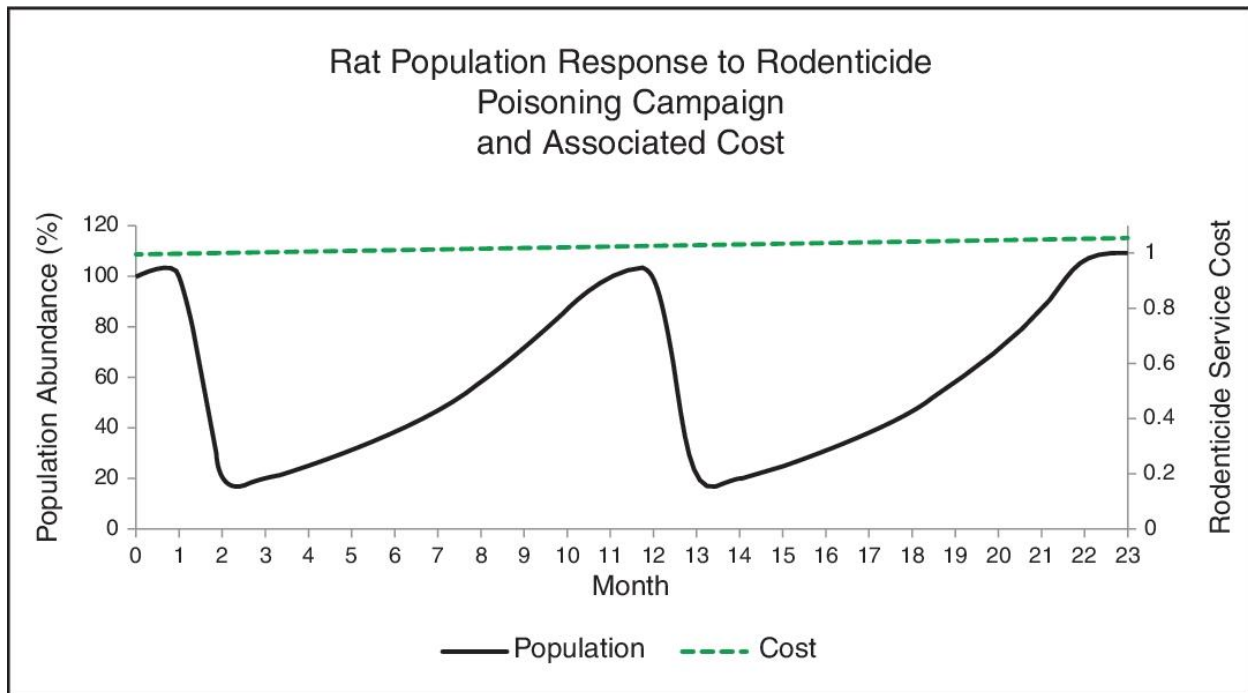
Current Problem

[...]

Rodenticides are not a long-term solution.

[...]

Due to rebounding rodent populations exposed to rodenticides, property owners and pest management operators must continuously apply rodenticides in an effort to control these populations. This creates an ongoing cycle of rodenticide treatment, with the costs of rodenticides remaining constant. Moreover, rodenticides are often distributed indiscriminately, on a non-targeted basis, which likely decreases their effectiveness in controlling rat infestations. The following chart, which is based on data derived from our population models and current market pricing for rodenticides, demonstrates that the use of rodenticides does not sustainably reduce rat populations in the long term, while the cost of using rodenticides remains relatively constant over that same period.



Rodenticides are an ineffective delivery method for rodents

Due to their understanding of cause and effect, studies have shown that rodents will generally not consume food that they have seen adversely affect other rodents. When the adverse effects of rodenticides are displayed by other rodents, other rodents in the vicinity typically avoid the areas where the rodenticides were located.

Rodenticides are unsafe

Rodenticides contain lethal chemicals that can be toxic to humans and other animals. The EPA has observed that between 1993 and 2008, the American Association of Poison Control Centers logged between 12,000 and 15,000 reports of rat and mouse poison exposures each year in children under the age of six. These numbers and other concerns about pet and non-target wildlife exposures have spurred the EPA and similar authorities to renew its efforts to establish better protections for children and the environment. For example, the EPA and similar authorities in other jurisdictions have established stronger restrictions on the sale and use of ten active ingredients found in various registered rodenticide products. These restrictions prohibit the sale of “loose” rodenticide bait, such as pellets, powders, and liquids and require all such consumer-use baits be sold with protective bait stations. They also prohibited the use of second-generation anticoagulants, or SGARs, in any consumer-use product. In May 2014, the EPA and Reckitt Benckiser Group plc (a large manufacturer of rodenticides, including d-CON) reached an agreement to cancel 12 of their mouse and rat poisons that do not comply with the new EPA safety standards.

Rodenticides are harmful to the environment

Rodenticides are designed to cause the rodent pest to die over five or more days, permitting the target animal to continue to consume the rodenticide during that period. Since the target animal may consume significantly higher doses than are needed to be lethal, the lethal chemicals can accumulate in the target animal. This process is known as bio-accumulation. If the target animal is consumed by other animals (such as predators), other animals can become sick or die from the lethal chemicals remaining in the deceased animal. In addition, deceased animals contaminated by rodenticides can spread the lethal chemicals to the surrounding area.

Rodenticides are inhumane

The most common type of rodenticide prevents blood from clotting. Once the rodent has consumed the rodenticide, lethal chemicals cause the rodent to bleed internally and through its eyes, nose and ears, gradually culminating in death over 10 to 14 days from exposure. Therefore, rodenticides result in a long, painful death. This raises moral concerns, particularly in regions such as India, among people who do not want to cause unnecessary pain in animals.

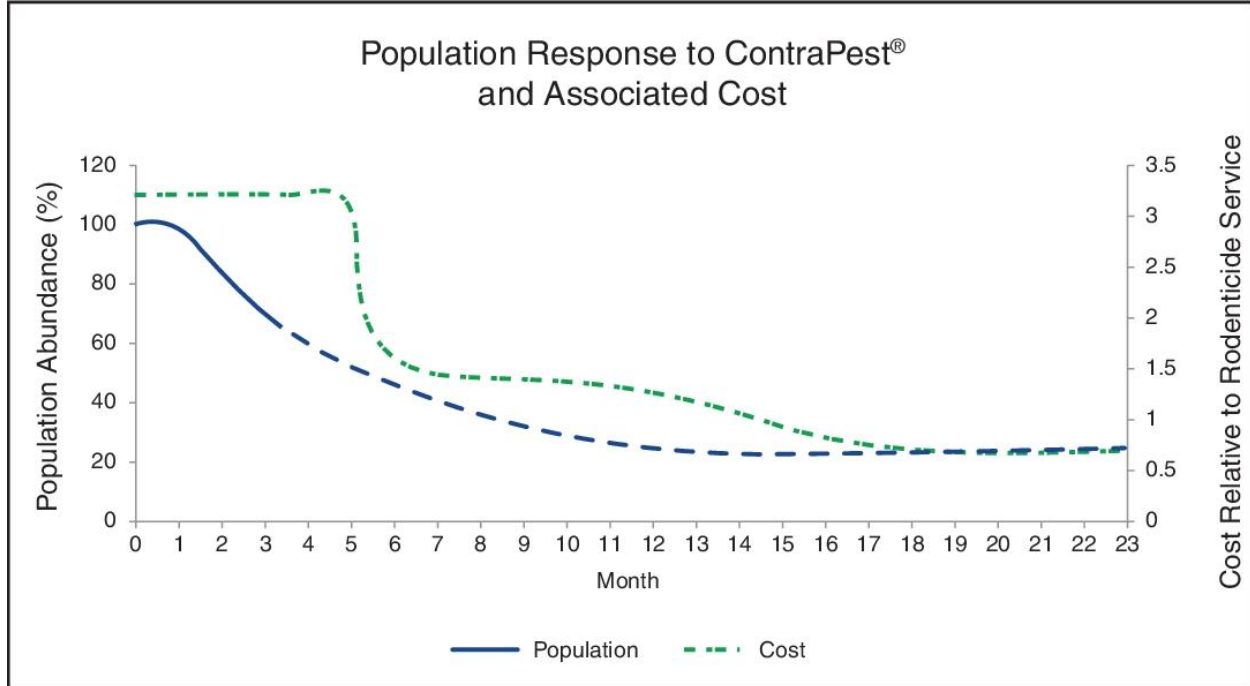
Our Solution — Fertility Control

Our first fertility control product candidate, ContraPest, targets the reproductive capabilities of rodents by inducing the gradual loss of eggs in female rodents and disruption of sperm in male rodents, resulting in contraception that can progress to sterility in both females and males. By targeting rodent fertility, our solution is sustainably effective, directed, safe, environmentally friendly and humane.

Our solution is sustainable over the long term

ContraPest causes rodent populations to remain at a sustained low level. A third-party laboratory study in partnership with the United States Department of Agriculture National Wildlife Research Center, or NWRC, completed in December 2014 observed that 50 wild-caught rats treated with ContraPest resulted in a 95% reduction in litter sizes. A follow-up USDA study completed in June 2015 involving 50 wild-caught rats demonstrated a 96% reduction in litter size in female and male rats treated with ContraPest in an open arena study. We have also conducted open population studies, including in trash rooms in the New York City subway completed August 2013 and with the largest hog producer in the United States completed in March 2015, in which we have observed decreases in wild rodent populations of more than 40% over a 12-week period. We believe this decrease in population will continue and, based on studies conducted by third parties, will stabilize at an approximately 70% reduction in 12 months without rebound (based on an initial population of approximately 10,000 rats).

Consequently, rat populations treated with ContraPest do not experience the same “population rebound” effect as those treated with rodenticides. The rebound pattern is also significantly reduced in a rodent population treated with ContraPest because the non-reproductive rodents continue to defend their territory from invasion by other rodents. As a result, property owners and pest management operators may be able to substantially decrease the amount of ContraPest used over time, thus reducing the total cost of rodent population control in the long term. The following chart, which is based on data derived from our population models and field studies, predicts that as the use of ContraPest sustainably reduces rat populations over time and on an ongoing basis, the cost of ContraPest would be lower in the long term as compared to rodenticides.



Our solution involves a targeted delivery

Our proprietary formulation appears to be attractive to rodents. To maintain proper hydration, rats drink 10% of their body weight in water each day; our product is a liquid bait and comprised mostly of water. Moreover, studies show that rats prefer eating sweet and fatty foods. ContraPest incorporates these elements, and our studies demonstrate

that rats prefer ContraPest even when other familiar food and water sources were abundant, such as in indoor garbage collection areas of urban, industrial facilities. Once consumed, our product is designed to avoid first pass through the liver to deliver active ingredients directly to targeted reproductive organs, thus increasing its effectiveness and minimizing harm to the animal.

In addition, our solution utilizes a unique delivery system in the field that not only allows us to evaluate the effectiveness of our fertility control products, but also enables us to observe rodent pest behavior and determine the optimal locations for our proprietary bait stations. We also are able to customize the specific concentration of our product candidate to address the target pest.

Our solution is safe

Studies of ContraPest have demonstrated that doses of ContraPest are not lethal to rodents or harmful to people or other animals. The active ingredients in ContraPest are included at very low concentrations (together totaling less than 0.1% of the formulation) and have short half-lives of less than 20 minutes in the blood of rodents. Therefore, the active ingredients in ContraPest do not accumulate in tissues or organs of the rat (as poisons do) and thus do not sicken or kill predators or scavengers that eat a rat that has consumed ContraPest.

In addition, at the concentrations of active ingredients in our product, there is no potential for reproductive disruption in humans. A human would have to consume impossibly large amounts of the active ingredients in our product to have any effect. Further, the man-made chemical that is one of our active ingredients (4-vinylcyclohexene diepoxide, or VCD) has been used in manufacturing settings, and no toxic effects have been demonstrated in humans. The other active ingredient (triptolide) is a plant-derived ingredient used in traditional Chinese medicine to treat symptoms of rheumatoid arthritis.

Moreover, ContraPest is delivered in a ready-to-use and pre-packaged plastic container which is inserted into a tamper-resistant rodent bait station. As the container is inserted into the station, a spike punctures the foil-covered opening, allowing the liquid bait to flow into a tray within the bait station. The tank is a non-refillable container, which is recapped and disposed of when empty. Thus, as a “closed system,” there is little opportunity for handler exposure and virtually no opportunity for bystander exposure.

Our solution is environmentally friendly

ContraPest does not contain poisons, and the ingredients in ContraPest target the reproductive organs of the rodent and do not accumulate in other tissues or organs of the rat. As a result, the ingredients in ContraPest do not cause illness or death in other animals that come into contact with or eat the rat that has consumed ContraPest, and there is no risk of secondary exposure expected from the use of ContraPest as a contraceptive. Also, the active ingredients in ContraPest are present in our product in very low concentrations, and break down into inactive, or inert, ingredients when they come into contact with soil or water in the environment. Moreover, ContraPest is packaged in a delivery system that dispenses the liquid bait directly into a tamper-resistant rodent bait station. These bait stations are limited to use only indoors and in the immediate perimeter of structures (no more than one foot from the exterior walls). As a result, ecological exposure of the liquid product will be limited to animals that directly contact or consume the bait, and there is little risk of exposure to non-target species or to the surrounding environment.

Our solution is humane

ContraPest does not cause rodent death and we have not observed any physical suffering in rodents exposed to ContraPest. ContraPest allows rodent pests to live out the course of their natural lives, while defending their territory and keeping out other invading rodents. By reducing rodents’ ability to reproduce, but keeping them alive, our product has the effect of humanely reducing rodent populations in the long-term.

Recent Research Regarding the Effectiveness of ContraPest

The majority of our research efforts have been focused on developing our lead product, ContraPest. We have completed studies regarding the effectiveness of our product, which were funded by and in cooperation with the NIH, the United States Department of Agriculture, or USDA, the NWRC, and the New York Metropolitan Transit Authority, or MTA, and other third parties. The following summarizes the results of these recent studies:

- A NWRC study involving approximately 50 rats completed in June 2015 demonstrated a 96% reduction in litter size in female and male rats treated with ContraPest in a laboratory setting;

- A January 2015 study in Rose Hill, North Carolina resulted in a 30% reduction in rodent activity over 12 weeks after being exposed to ContraPest, as compared to the use of rodenticide alone;
- A NIH-funded study in February 2013 in the subway trash rooms of the MTA in New York City observed that there was a 43% reduction in the rodent population in the trash rooms that were baited with ContraPest; and
- Internal laboratory studies involving 32 rats have shown zero pups born to any rat groups provided with ContraPest along with food and water, while rats given the control bait with no active ingredients had on average 11 pups per litter.

In September 2015 we initiated a research study with the Chicago Transit Authority, or CTA, to begin a field trial of our bait station. That study is now complete. While the observations and results are subject to a confidentiality agreement, the performance of the bait stations met expectations. We have additional field trials underway in Hawaii and Massachusetts (Somerville), and are contemplating further research trials in a variety of applications.

We have also begun exploring diverse applications with a variety of collaborators. We have conducted proof of concept studies with feral dogs on the Navajo Reservation in New Mexico with a grant from the USDA, and we have collected rabies and geographic data on stray dogs in the Tibetan refugee camps of Mainpat, India. We are currently collaborating with Texas A&M University to test the potential of our product candidates to manage feral pigs. Studies have also been conducted for proof of concept in Australia with wallaby, rat, and mouse populations and in New Zealand with brushtail possums. We have also conducted early trials with cats in collaboration with the University of Florida. These diverse studies seek to provide evidence of the potential for ContraPest and the continued development of fertility control technology in general.

[...]

Scientific Background Regarding our Product

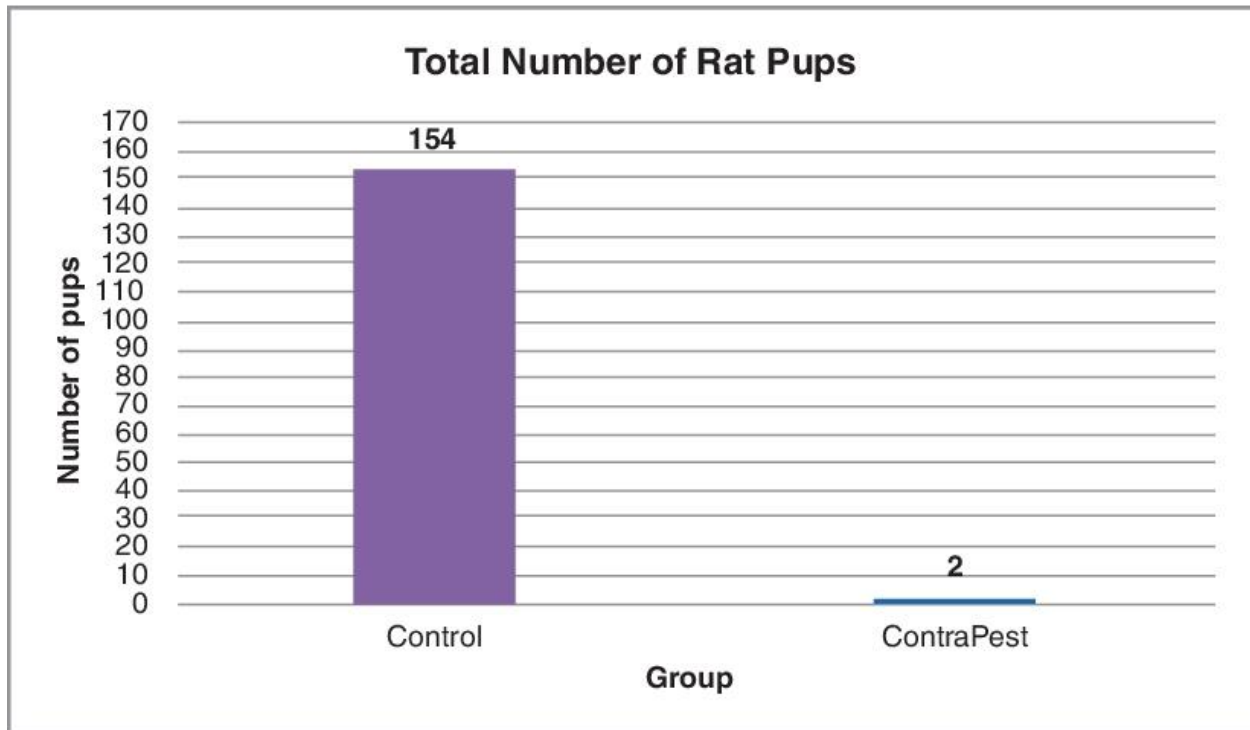
ContraPest is a liquid bait containing the active ingredients VCD and triptolide. When consumed, ContraPest causes contraception that can progress to sterility in male and female rats beginning with the first breeding cycle following consumption.

The female rat is born with a finite number of eggs, also called oocytes, and she remains fertile and will reproduce until the day she dies. Within the ovary, eggs are contained in structures called follicles. The non-regenerating and most immature stage of follicles is called primordial. The primordial follicles mature through several stages from primary to secondary to antral follicles and ultimately ovulate. Once the primordial follicles have become depleted, ovarian failure occurs, which terminates reproductive capability.

VCD has been well studied and causes specific loss of ovarian small follicles (both primordial and primary); because oocytes do not regenerate, loss of these follicles leads to ovarian failure. Following repeated dosing, VCD causes ovarian failure in rats. However, daily dosing of mice and rats with VCD does not produce generalized toxicity nor does it affect other tissues. A VCD-dosed rat will continue to reproduce until the pool of secondary and antral follicles are depleted through ovulation or atresia, which is the natural death of the follicle, which can take up to three months.

The second active ingredient, triptolide, targets growing follicles and exerts a significant suppression of male fertility by disrupting sperm maturation and stopping the movement of sperm. Female rats treated with triptolide ovulate fewer eggs because the follicles stop growing. Triptolide does not affect primordial follicles, but when used in combination with VCD, the result is contraception that can progress to sterility in female rats.

Both VCD and triptolide are supported by evidence regarding their safety and mechanism of action. Additionally, recent studies, both in the lab and in the field, have documented their effect in fertility reduction and therefore reduction in rat populations. The graph below displays the total numbers of pups after two breeding rounds in one study.



[...]

Government Regulation and Product Approval

Federal, state and local government authorities in the United States regulate, among other things, the testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, distribution and marketing of the products we develop. Our wildlife and pest fertility control products must be approved by the EPA Office of Pesticide Programs, or OPP, before they can be legally marketed and sold in the United States. The process for obtaining regulatory approval and compliance with appropriate federal, state and local regulations is rigorous and requires the expenditure of substantial time and financial resources.

Additional product candidates in our pipeline may require approval from other government agencies, namely the USDA and FDA. In 2015, the FDA and EPA entered into a “data sharing” agreement to streamline data review and speed the regulatory process avoiding redundancy where possible.

United States Review and Approval Processes

In the United States, the EPA regulates the sale, distribution and use of any pesticide under the Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA. The EPA defines a pesticide as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” FIFRA defines a pest as “any insect, rodent, nematode, fungus, or weed.” To register a new product, all active ingredients within the product must be registered with the EPA.

On August 23, 2015, we submitted a set of registration applications for two active ingredients and ContraPest for EPA review and approval. Our application for ContraPest was submitted as a restricted use, indoor only, application. A restricted use product can only be handled by a certified pest control

operator. The requirements for an application are specified in detail by EPA regulations. These include requirements for data on which the EPA can evaluate the environmental effects, health effects, and safety of the product. The environmental effects data is reviewed by the Environmental Fate and Effects Division, or EFED. The health effects data is reviewed by the Health Effects Division, or HED.

Prior to submission, our active ingredients and product information was reviewed by the Hazard and Science Policy Council, or HASPOC, which includes HED members, and data waiver requests were granted for all of the required toxicology studies. EFED also reviewed the applications, and provided certain recommendations for testing, which were incorporated into our filing.

Upon filing an application with the OPP Registration Division (RD), there was a preliminary screen, where the application was initially reviewed for all required sections regarding chemistry, toxicity and environmental fate. Following this preliminary screen, the review period begins. Under the timelines set forth by the Pesticide Registration Improvement Extension Act (PRIA 3), RD has 20 months to review the application and reach a registration decision. Once the review period begins, RD will disperse the application to all the applicable science departments for an in depth review. For an application with an official review period greater than six months, OPP has 90 days in which it may identify any substantive science omissions and may reject the application unless the applicant can correct the omissions within 10 business days. This technical screening review period passed without EPA raising any issue. After completing the science reviews, each department will make its recommendations to RD. Based on these science recommendations, RD may decide it needs additional data and will contact the applicant with options for proceeding, which may include extending the review period until requisite data or other information can be developed and submitted for review. If RD has sufficient information, it will develop its initial risk and registration decisions, which it will articulate and publish in a document for public comment. RD has decided that it had sufficient data from the application and published the document for public comment on June 24, 2016. After the 30-day public comment period, OPP reviewed the public comments to address any additional concerns. This is considered one of the final steps prior to approval of a registration.

The EPA also requires that the following be submitted for review, in addition to data: a complete copy of the label proposed for the product, instructions for use and any claims that will be made by us, as well as, the complete formulation. We are also required to submit documentation describing the chemistry, manufacturing process and quality control parameters. This is done to ensure the product can be produced consistently. The entire submission must be reviewed and approved prior to any legal sales and distribution of the product. The EPA granted registration approval for ContraPest effective August 2, 2016. This EPA approval was granted on a restricted-use basis, including indoor and limited outdoor use, and is based on a liquid formulation. We intend to diligently pursue additional related regulatory approvals from the EPA to support our product evolution, including seeking approval for full outdoor use, removal of the restricted-use status, alternative formulations and for additional species (utilizing approved active ingredients). In addition, we believe that the EPA will support us in facilitating regulatory reviews outside of the U.S., and we are exploring a relationship with the Danish Environmental Protection Agency to assist us with obtaining regulatory approvals in the EU.

We expect to pursue registration in each state, since product registration is required for every state in which the product will be distributed or sold. Each state has its own registration filing requirements. These registration programs are managed by state agricultural and/or environmental regulatory

agencies. For some state registration applications, all that is required is the EPA stamped-approved label, a completed application form, and a fee payment. Other states, notably California, New York, and several others, require more robust registration applications and may require data not required by EPA. ContraPest has received state registration from Georgia, Illinois, Louisiana, Maryland, Minnesota, New Jersey, North Carolina, Virginia, West Virginia and Utah. Registrations in additional states are currently pending. States vary in the expected timing of approval, from a few weeks to several months or more.

International Review and Approval Processes

Canada — Canada also has a product registration program similar to the U.S. program. Canada has entered into a data and review agreement with EPA intended to expedite the approval process.

European Union — The European Chemicals Agency (ECHA) is a decentralized agency of the European Union, or EU. The agency is responsible for the scientific evaluation of chemicals intended for use in human health and the environment developed by companies for use in the EU. The agency has a biocidal product committee that is responsible for the review of any biocidal product and active substances. A biocidal product is used to control unwanted organisms that are harmful to human or animal health, or that cause damage to human activities. These harmful organisms include pests (e.g. insects, rats or mice) and microorganisms (e.g. molds or bacteria). Biocidal products include; insecticides, insect repellents, disinfectants, preservatives for materials, and anti-fouling paints. The biocidal product committee has similar requirements to those in the United States, requiring that evidence of purity, safety, efficacy, and consistency of manufacturing processes all be demonstrated.

The member state where the biocidal product will be placed on the market is responsible for authorizing the product. This is referred to as the 'National authorization'. The process of national authorization relies however on the process of mutual recognition. Once a biocidal product is authorized by a first EU country (the 'Reference Member State'), the other EU countries must, if requested to do so, authorize the biocidal products under the same terms and conditions. Some products can also be authorized at EU level, allowing the companies to place these on the entire EU market. In these cases, it is the European Commission that authorizes the products. This is referred to as the 'Union authorization'.

In March 2016, ECHA decided to move toward a comparative assessment for rodenticides registered as a biocide. A comparative assessment will evaluate the risks and benefits of each rodenticide and a standard will be set for rodenticides based on this information. When a new rodenticide files for registration, it must meet this standard or best this standard to be accepted. This comparative assessment will be carried out by the Reference Member State. Representatives from various member states met in Helsinki the second week of June 2016 to determine which products or active ingredients will be used to set the standard for rodenticides. ECHA has moved to support the 5-year renewal, not the traditional 10-year renewal, of 8 anticoagulant rodenticides.

On July 4, 2016, we met with the Danish Environmental Protection Agency (DEPA) for a pre-meeting to discuss the registration of ContraPest in the EU. This meeting was to determine if DEPA was willing and capable to review and support a ContraPest dossier. DEPA agreed they would have the capacity to support a ContraPest dossier and they have executed their commitment as the competent authority to carry our EU registration application forward. We are engaged in ongoing discussions with DEPA to establish the application content.

United Kingdom — In addition to registration routes listed above, the UK has a data sharing agreement with the United States, Australia, and New Zealand for any wildlife fertility management product, allowing for a potentially expedited registration process.

Australia — The Australian Pesticides and Veterinary Medicines Authority, or APVMA, is an Australian government statutory authority established in 1993 to centralize the registration of all agricultural and veterinary products into the Australian marketplace. Previously each State and Territory government had its own system of registration. The APVMA assesses applications from companies and individuals seeking registration so they can supply their product to the marketplace. Applications undergo rigorous assessment using the expertise of the APVMA's scientific staff and drawing on the technical knowledge of other relevant scientific organizations, Commonwealth government departments and state agriculture departments. If the product works as intended and the scientific data confirms that when used as directed on the product label it will have no harmful or unintended effects on people, animals, the environment or international trade, the APVMA will register the product. As well as registering new agricultural and veterinary products, the APVMA reviews older products that have been on the market for a substantial period of time to ensure they still do the job users expect and are safe to use. The APVMA also reviews registered products when particular concerns are raised about their safety and effectiveness. The review of a product may result in confirmation of its registration, or it may see registration continue with some changes to the way the product can be used. In some cases the review may result in the registration of a product being cancelled and the product taken off the market.

Rest of the World — Country-specific regulatory laws have provisions that include requirements for certain labeling, safety, efficacy and manufacturers' quality control procedures to assure the consistency of the products, as well as company records and reports. With the exception of the EU, most other countries' regulatory agencies will generally defer to the EPA in establishing standards and regulations for pest management products.

Import Permits — Field and laboratory proof of principle studies have been conducted in other countries. In each country, import regulations have been met for the shipment of active ingredients. To date we have received import permits from Australia, New Zealand, Indonesia, Laos, and the Philippines. We expect that additional import permits will be obtained for various field trials in countries prior to registration.