

GENETHERA INC  
Form 10-K  
April 15, 2014

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the Fiscal Year Ended December 31, 2013**

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

**FOR THE TRANSITION PERIOD FROM 01/01/2013 TO 12/31/2013**

**Commission File Number:**

**000-27237**

**GeneThera, Inc.**

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(Exact name of registrant as Specified in its Charter)

**Nevada**

**65-0622463**

(State or Other Jurisdiction of

(Internal Revenue Service

Incorporation or Organization)

Employer Identification Number)

**7577 W. 103rd Ave. Suite 212 Westminster, CO**

**80021**

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code:

**(303) 439-2085**

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

**None**

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

**Common Stock, \$0.001 per share**

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



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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 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.

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, and 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   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

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

The issuer's revenues for the most recent fiscal year ended December 31, 2013 were \$0.

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$23,711.

State the number of shares of the issuer's common stock outstanding, as of the latest practicable date: 31,481,590 shares of common stock issued and outstanding as of January 17, 2014.

**FORM 10-K**

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013**

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### **PART I.**

#### **FORWARD-LOOKING AND CAUTIONARY STATEMENTS**

Sections of this Form 10-K, including Business and Management's Discussion and Analysis or Plan of Operation, contain "forward-looking statements". These forward-looking statements are subject to risks and uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the results, performance or achievements expressed or implied by the forward-looking statements. You should not unduly rely on these statements. Forward-looking statements involve assumptions and describe our plans, strategies, and expectations. You can generally identify a forward-looking statement by words such as may, will, should, would, could, plan, goal, potential, expect, anticipate, estimate, believe, intend, project, and similar words and variations thereof. This report contains forward-looking statements that address, among other things,

\* Our financing plans,

\* Regulatory environments in which we operate or plan to operate, and

\*Trends affecting our financial condition or results of operations, the impact of competition, the start-up of certain operations and acquisition opportunities.

Factors, risks, and uncertainties that could cause actual results to differ materially from those in the forward-looking statements ("Cautionary Statements") include, among others,

- \* Our ability to raise capital,
- \* Our ability to execute our business strategy in a very competitive environment,
- \* Our degree of financial leverage, risks associated with our acquiring and integrating companies into our own,
- \* Risks relating to rapidly developing technology, and regulatory considerations;
- \* Risks related to international economies,
- \* Risks related to market acceptance and demand for our products and services,
- \* The impact of competitive services and pricing, and
- \* Other risks referenced from time to time in our SEC filings.

All subsequent written and oral forward-looking statements attributable to us, or anyone acting on our behalf, are expressly qualified in their entirety by the cautionary statements. We do not undertake any obligations to publicly release any revisions to any forward-looking statements to reflect events or circumstances after the date of this report or to reflect unanticipated events that may occur.



## ITEM 1. BUSINESS

In November 2007, GeneThera, Inc. ( we , us , the Company or GeneThera ) reincorporated in the State of Nevada to the fact that a third party had acquired the Company 's prior Florida Corporate Charter and the fact that the Company was unable to regain the control of such Corporate Charter. We had a special meeting of shareholders where it was unanimously resolved for GeneThera to transfer its Charter to the State of Nevada as soon as possible in order to recognize our new incorporation on our next SEC filing. The reinstatement was completed by January 2008.

Our common stock currently trades on the OTC Over-The-Counter market under the symbol GTHR. Our executive offices are located at 7577 W. 103<sup>rd</sup> Ave. Suite 212 in Westminster, CO 80021 and our telephone number is 303-439-2085.

For the fiscal year 2013, and as of now, the Company had one subsidiary, GeneThera, Inc., a Colorado corporation. In addition, GeneThera holds a 90% ownership in Applied Genetics, a commercial diagnostics laboratory located in Monterrey, Mexico. On December 1, 2011, Dr. Antonio Milici, the Company 's Chief Executive Officer was appointed Interim President of Applied Genetics. Upon becoming President of the company, Dr. Milici started a reorganization plan of the Applied Genetics operations. The goal of this reorganization plan was to initiate revenues generating operations beginning in the third quarter of 2013. Due to lack of reliable funding, the reorganization plan has been delayed until dependable funding is secured in 2014.

## COMPANY PROFILE

GeneThera is a biotechnology company, dedicated to improving food safety by applying the latest molecular technologies to eradicate "cross-over"(zoonotic) diseases such as Johne's disease, Mad Cow Disease, Chronic Wasting Disease, and E.coli. Diseases of terrestrial, avian and aquatic life animals influence a number of economic and global security issues; food for an increasing world population, access to international trade, species conservation and protection of those endangered, and economic growth in developing and re-organizing nations. Because many animal disease agents are zoonotic (transmissible between humans and animals, causing infection in both species), their management and prevention are crucial to improving public health on a global scale. The Company focuses on developing molecular diagnostic tests, therapeutics, and vaccines in the belief that better technologies and methodology need to be implemented to help control emerging diseases in animals and in humans, and believes that, if not, these diseases in animals will likely continue to cause serious and growing problems in terms of economics, human health and biodiversity.

GeneThera has developed proprietary diagnostic assays for use in the agricultural and veterinary markets. Specific assays for Chronic Wasting Disease (among elk and deer) and Mad Cow Disease (among cattle) have been developed and are available currently on a limited basis. E. coli (predominantly cattle) and Johne's disease (predominantly dairy cattle and bison) diagnostics are in development. GeneThera is making a pivotal shift from a Research and Development organization into a product marketing and revenue



generating entity. The Company's previous strategy that we had maintained from inception to July 2008 had been one of research only. We focused all our energies, talent, and resources to the incubation and growth of new ideas in the realm of genetically engineered disease detection and vaccination. We feel that with recent announcements the Company is positioned to move from a developmental stage to a product oriented stage company, depending on reliable funding.

GeneThera provides genetics-based diagnostic and is currently working on vaccine solutions to meet the growing demands of today's veterinary industry and tomorrow's agriculture and healthcare industries. The Company is organized and operated both to continually apply its scientific research to more effective management of diseases and, in so doing, realize the commercial potential of molecular biotechnology.

The Company believes it will require significant additional funding in order to achieve its business plan. Over the next 12 months, in order to have the capability of achieving its business plan, the Company will require at least \$10,000,000 in additional funding. There are no guarantees that the Company will be able to secure such financing, and if the financing is secured, there are no guarantees whether the Company can fully achieve the goals laid out in its business plan.

### **Johne's Disease**

GeneThera's focus includes the diagnosis and treatment of Johne's disease.

Johne's disease is a worldwide problem of domestic animals primarily including dairy cattle, sheep and goats. A significant public health concern is associated with Johne's disease (JD), which results from an infection with bacteria called *Mycobacterium paratuberculosis*. This organism grows very slowly, causes a gradually worsening disease condition, and is highly resistant to the infected animal's immune defenses. Therefore, infected animals harbor the organism for years before they test positive or develop disease signs.

Major Factors related to Johne's disease:

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Worldwide Infection.

.

Reduction in milk production to 25%+.

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High culling rate which increases costs.

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JD affects trade and hinders exports.

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Link between JD and Crohn's disease.

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Reduction in quality wool production in sheep.

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Highest at risk animals are young calves or pre-born.

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Bacterium can survive in contaminated soil for over 1 year.

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Spread in herds can occur by fecal contamination, colostrum, milk, and transplacental.

.

Calves can become infected by suckling on dirty teats.

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For every one clinical stage in a herd there are 15-20 silently infected plus additional 6-8 carriers.

**Stage I:** Silent, subclinical, non-detectable infection. Typically this stage occurs in all calves, heifers, and young stock less than two years of age and many adult animals exposed to small doses of disease-causing organisms. Infected animals at this early stage are rarely detected with currently available diagnostic tests, including fecal culture or serologic tests (ELISA). This stage progresses slowly over many months or years to stage II.

**Stage II:** Subclinical infection. Typically this stage occurs in older heifers or adults. Animals at this stage appear healthy but are shedding adequate numbers of MAP organisms in their manure to be detected on fecal culture. Blood tests will detect some, but not all animals at this stage. Blood test (ELISA) positive animals should be confirmed positive by fecal culture.

**Stage III:** Clinical JD. It is categorized as any animal with advanced infection the onset which is often associated with a period of stress such as recent calving. Cattle at this stage have intermittent, watery pea-soup manure. Animals lose weight and gradually drop in milk production, but continue to have a good appetite. Some animals appear to recover but often relapse in the next stress period. Most of these animals are shedding billions of organisms and are positive on culture. Most are positive on serologic tests (ELISA & AGID). Clinical signs often last several weeks to months before the animals are sent to slaughter in a thin, emaciated condition. In the final and terminal aspects of stage III of the fatal disease, animals become emaciated with fluid diarrhea and develop bottle jaw. The carcass may not pass meat inspection for human consumption in the later phases of stage III.

### **Crohn's Disease**

Crohn's disease (also known as Crohn-Leśniowski Disease, or "Charlotte Forditis" morbus Leśniowski-Crohn, granulomatous and regional enteritis) is an inflammatory disease of the intestines that may affect any part of the gastrointestinal tract from anus to mouth, causing a wide variety of symptoms. It primarily causes abdominal pain, diarrhea (which may be bloody), vomiting, or weight loss, but may also cause complications outside of the gastrointestinal tract such as skin rashes, arthritis, and inflammation of the eye.

Crohn's disease is an autoimmune disease, in which the body's immune system attacks the gastrointestinal tract, causing inflammation; it is classified as a type of inflammatory bowel disease. There has been evidence of a genetic link to Crohn's disease, putting individuals with siblings afflicted with the disease at higher risk. It is understood to have a large environmental component as evidenced by the higher number of cases in western industrialized nations. Males and females are equally affected. Smokers are three times more likely to develop Crohn's disease than non-smokers. Crohn's disease affects between 400,000 and 600,000 people in North America. Prevalence estimates for Northern Europe have ranged from 27-48 per 100,000. Crohn's disease tends to present

initially in the teens and twenties, with another peak incidence in the fifties to seventies; although, the disease can occur at any age.

Similar to Johne's disease in cattle, no known pharmaceutical or surgical cure for Crohn's disease currently exists for humans. Furthermore, new discoveries of MAP have been found in human patients and we believe that individuals that are genetically predisposed could possibly be contracting the disease through digestion of Johne's disease - infected milk.

## **BUSINESS MODEL**

GeneThera has developed proprietary diagnostic assays for use in the agricultural and veterinary markets. Specific assays for Chronic Wasting Disease (among elk and deer) and Mad Cow Disease (among cattle) have been developed and are available currently on a limited basis. E. coli (predominantly cattle) and Johne's disease (predominantly dairy cattle and bison) diagnostics are in development. GeneThera is making a pivotal shift from a Research and Development organization into a product marketing and revenue generating entity, depending on reliable source of funding. The Company's previous strategy that we had maintained from inception to July, 2008 had been one of research only. We focused all our energies, talent, and resources to the incubation and growth of new ideas in the realm of genetically engineered disease detection and vaccination. We feel that with recent announcements the Company is positioned to move from a developmental stage to a product oriented stage company once funding is secured.

GeneThera provides genetics-based diagnostic and is currently working on vaccine solutions to meet the growing demands of today's veterinary industry and tomorrow's agriculture and healthcare industries. The Company is organized and operated both to continually apply its scientific research to more effective management of diseases and, in so doing, realize the commercial potential of molecular biotechnology.

GeneThera animal disease assay development business is based on its Integrated Technology Platform (ITP) that combines a proprietary diagnostic solution called Gene Expression System (GES) with PURIVAX™, its system for analyzing large-scale DNA sequencing. The first part of this platform is the ongoing development of molecular diagnostic assays solutions using real time Fluorogenic Polymerase Chain Reaction (F-PCR) technology to detect the presence of infectious disease from the blood of live animals. The second part of the ITP is the development of therapeutic vaccines using RNA interference technology. Interference RNA technology is a new technique that is based on the use of short RNA sequences complementary to a specific target gene. Once the RNA sequence binds to the gene, the gene is deactivated or "silenced" and no longer able to produce the specific protein. It also allows for the efficient, effective, and continuous testing, management and treatment of animal populations. These facts distinguish the technology from any alternative testing and management methodology available to agriculture today -- all of which require the destruction of individual animals and even entire herds. Our testing and data analysis processes also allow us not only to

separate infected from clean animals, but also to gain knowledge vital to development of preventative vaccines.

Each individual assay utilizes the proprietary Field Collection System (FCS) for the collection and transportation of blood samples to GeneThera laboratory. This system consists of two (2) tubes. A 5 milliliter (ml) red cap tube containing 1ml anticoagulant solution and a 10 ml white cap tube. One (1) ml of blood is collected from the animal and added to the red cap tube. Ten (10ml) of milk is collected into the white cap tube. The FCS allows GeneThera to maintain the integrity of each sample by the addition of specific reagents to test tubes contained in the system. GeneThera FCS is designed to be an easy-to-use method of gathering blood samples from harvested or domesticated animals. It ensures consistency of samples as well as increased assurance of each sample's integrity.

To date, GeneThera has successfully developed the ability to detect Chronic Wasting Disease, a disease affecting elk and deer in North America. The release of commercialized Field Collection Systems and laboratory diagnostic testing occurred in October of 2003 as a marketing trial. GeneThera has also successfully developed an assay for the detection of Mad Cow Disease, a disease recently found in the United States, but which has been in Europe for many years. The Field Collection Systems are available for purchase from the Company. Chronic Wasting Disease and Mad Cow Disease are both in the family of diseases called Transmissible Spongiform Encephalopathy (TSE). Diagnostic assays for E. coli O157:H7 and Johne's disease are in the final stages of development.

The Company, through GeneThera, is also developing vaccines for Chronic Wasting Disease and E. coli O157:H7. The Company will need the approval of the USDA before the vaccines can be manufactured or sold. The approval process for animal vaccines is time-consuming and expensive. We anticipate that such approval, if it is obtained, may require more than \$5 million and may require more than two years for each vaccine for which approval is sought. Currently, we do not have the capital necessary to seek approval of any of our candidate vaccines, and we cannot provide any assurance that we will be able to raise the capital necessary for such approval on terms that are acceptable to us, if at all. In addition, even if we are successful in raising the capital necessary to seek approval of any vaccine, there are no assurances that such an approval will be granted, or if granted, whether we will be able to produce and sell such vaccines following such an approval in commercial quantities or to make a profit from such production and sales.

Our recent developments, which were delayed due to lack of reliable funding, included the progress we made in regards to our Johne's disease validation trials, which was scheduled to begin in collaboration with the Universidad Nacional Autonoma de Mexico, a prominent state university in Mexico City. However, the lack of reliable funding and poor performance from Nutricion Avanzada, has substantially delayed this progress. Our joint venture with Nutricion Avanzada, created a new company Applied Genetics. Their poor marketing performance negatively affected our progress. Applied Genetics would have been the marketing arm of GeneThera for the Mexican marketing of our Johne's

disease testing service and subsequent Vaccine, (which has currently suspended our development), was never efficiently in contact with several major ranchers throughout Mexico, and the report from Nutricion Avanzada concerning the overwhelming response from the ranchers, was never validated even though, it was obvious their outcry for help in detecting and eliminating Johne's disease which is still running rampant in their herds. Government approval and recommendation was expected to occur quickly once the validation trials were completed. Unfortunately, our designated investor defaulted on their escrow investment agreement causing negative financial repercussions. The validation trials should have been completed within 3-4 months from start; now, the Company is eagerly awaiting for funding to complete such important task with our Company and Subsidiary. We were supposed to have been conducting paid testing on a limited basis during such validation trials, which were not completed.

We did not renew an agreement we had with STC.UNM (the technology development arm of The University of New Mexico) in connection with the genetic vaccine they developed and patented for E.coli 0157:h7 due to lack of validated collaboration from their part and our lack of funding. This is the one where the vaccine acts on a genetic level to inhibit the growth and shedding of the deadly E.coli 0157:h7 bacteria from cattle. The vaccine has already passed initial animal trials and is now set to enter the clinical trial phase, but without our reliable funding, we were unable to continue our collaboration. In the near future, we will once again seek partnerships for the completion of the clinical trials and subsequent taking of the finished vaccine to market. Once we secure funding, and also due to the specific genetic makeup of the vaccine, we will expect the clinical trials to be completed within 12-18 months from the date we start again with our collaboration. This is 3 to 5 times faster than a standard vaccine might take.

GeneThera's majority owned subsidiary, Applied Genetics, based in Monterrey Mexico was the Company's commercial molecular diagnostic laboratory. Applied Genetics' focus was and still is to test milk, feces, and blood samples from dairy cows, sheep and goats, exclusively in Mexico, employing GeneThera proprietary technology. Once our funding is secured, the reorganization plan will be in effect.

## **INTEGRATED TECHNOLOGY PLATFORM (ITP)**

GeneThera's Integrated Technology Platform (ITP) is the foundation for fast-track rDNA vaccine development. We are currently working on the development of a recombinant DNA vaccine for Johne's disease. Johne's disease is a chronic debilitating infectious disease of ruminants, characterized by weight loss and, particularly in cattle, by profuse diarrhea. The casual agent is a bacterium, Mycobacterium avium subspecies paratuberculosis. Infected animals may show no sign of the disease until years after the initial infection. Johne's is a slow, progressive disease with worldwide distribution.

The vaccine development is in the in vitro or pre-clinical stage. We expect to initiate experimental animal studies for Johne's disease in the next 18-24 months. ITP combines the following technologies: 1) gene expression system technology or "GES"; 2) viral DNA purification technology or PURIVAX™ technology; 3) genetically engineered





Adenovirus (rAD) and recombinant Adeno Associate Virus (rAAV) systems (vectors). This integrated technology platform yields fast-track vaccine development. Leveraging its ITP, GeneThera believes that it can develop a prototype vaccine within 12 months versus the current standard of 18 to 24. We estimate that the cost to bring these vaccines to market is \$5-7 million. There is no assurance that we will be able to raise the capital necessary to bring a vaccine to market and if the capital is raised, that we will be able to comply with the government regulations involved in bringing such a product to market. The GES applied modular unit system utilizes robotics and is based on nucleic acid extraction in conjunction with F-PCR technology to develop gene expression assays. Using GES assays, vaccine efficacy can be measured quickly because it will be unnecessary to wait for the antibody response to measure how well the vaccine is working. F-PCR will allow effective quantification of the precise number of viral or bacterial genetic particles before, during and after vaccine injection(s). We anticipate that the more effective the vaccine is, the stronger the decrease of the infectious disease particles will be.

## **GES SYSTEM**

GES is a proprietary assay development system. To date, the system has been used to develop our TSE and Johnes disease molecular assay. GES is a gene expression system to be used in our laboratory and will be marketed for commercial sale under the trade name HERDCHECK. The core of GES is Fluorogenic Polymerase Chain Reaction technology (F-PCR). GeneThera approaches the technical problems related to the use of conventional PCR in molecular diagnostics via our modular unit concept. Specifically, the modular unit consists of an Automated Nucleic Acid Workstation (ANAW) and a Sequence Detection System (SDS) that are integrated, allowing an operator to perform the entire procedure of DNA extraction and F-PCR analysis within a closed computerized system. This system results in minimal intervention and non post-PCR manipulation. GES is a molecular genetic base system that utilizes Fluorogenic Polymerase Chain Reaction (F-PCR). Fluorogenic PCR (F-PCR) is a technology based on sequence specific hybridization between a nucleic acid target and a fluorogenic probe, a short sequence of DNA chemically treated to generate light at a specific wavelength, complementary to the target sequence. The probe consists of an oligonucleotide, a short synthetic DNA molecule, with two fluorescent molecules (a reporter and quencher dye) attached to both ends of the oligonucleotide. Due to the unique design of the Fluorogenic probe, the activity of the Taq Polymerase enzyme allows direct detection of PCR products by the release of the fluorogenic reporter during PCR. The reporter and the quencher dye are linked at the end of the probe. When the probe is intact, the proximity of the reporter dye to the quencher dye results in a suppression of the reporter fluorescence. During PCR, if the target of interest is present, the probe specifically anneals between the forward and the reverse primer site. The nuclease activity of the Taq DNA Polymerase cleaves the probe between the reporter and the quencher only if the region binds to the target. If the probe is not bound then no cleavage occurs. After cleavage, the shortened probe dissociates from the target and the polymerization of the DNA strand continues. This process occurs in every cycle and does not interfere with the exponential accumulation of the product. The cleavage of the oligonucleotide between

the reporter and the quencher dye results in an increase of fluorescence of the reporter that is directly proportional to the amount of the product accumulated. The specificity of this 5' nuclease assay results from the requirement of sequence complementary between probe and template in order for cleavage to occur. Thus, the fluorogenic signal is generated only if the target sequence of the probe is generated by PCR. No signal is generated by non-specific amplification.

To perform GES, specific laboratory equipment is needed. This involves some substantial initial costs to set up the laboratory operations. We have performed this substantial set up and are fully operational to perform GES. We currently have all the specific equipment necessary to further development. However, the use of F-PCR represents a great advantage over other available systems because of its greater sensitivity, speed, and accuracy.

The Automated Nucleic Acid Workstation is a highly flexible robotic system that extracts and purifies acids from a variety of complex samples, preparing them for F-PCR analysis. Data management system software includes a database to manage all run phases and record sample processing.

The Sequence Detection System detects the fluorescent signal generated by the cleavage of the reporter dye during each PCR cycle. This process confers specificity without the need of post-PCR hybridization. Most importantly, the SDS offers the advantage of monitoring real-time increases in fluorescence during PCR processing. Specifically, monitoring real-time progress of the PCR completely changes the approach to PCR-based quantitation of DNA and RNA, most particularly, in improving the precision in both detection and quantitation of DNA and RNA targets.

GeneThera currently faces limited competition in the use of F-PCR technology and the modular unit concept for commercial testing of either infectious disease in animals or food pathogen contamination. Currently, most labs utilize conventional microbiology, immunological or conventional PCR methods for either veterinary diseases or food pathogen contamination detection. Specific to microbiology and immunological techniques, the drawbacks of these approaches are:

1.

The antibodies-based culture media used to detect the presence of infectious diseases has a low level of sensitivity; and

2. High background due to non-specific binding of antibodies and/or culture

contamination; sample preparation and storage creates artifacts; and long, cumbersome protocols necessary to perform these tests.

A major technical limitation of conventional PCR is the risk of contaminating a specimen with the products of previously amplified sequences. Known as cross-contamination, this phenomenon represents a constant challenge to any lab using conventional PCR. Managing these challenges is cumbersome and difficult to streamline. Fluorogenic PCR (F-PCR) attempts to overcome these drawbacks by making it possible for PCR to efficiently test large numbers of samples even when major laboratory facilities are not

readily available. A novel methodology, F-PCR allows quantitative and qualitative detection of specific nucleic acid sequences in a sensitive, accurate, and rapid fashion.

## **PURIVAX™ TECHNOLOGY**

GeneThera has developed a large-scale process for highly purified and high viral titer (viral concentration) Adenovirus and AAV genetically engineered viruses. This technology enables GeneThera to develop Adenovirus and AAV-based recombinant DNA vaccines for veterinary diseases and food pathogens. GeneThera's PURIVAX™ is a purification system that dramatically improves biological purity and viral titer of recombinant Adenovirus and AAV vectors. PURIVAX™ is intended to completely eliminate toxic side effects associated with Adenoviruses and AAV vectors, thereby making it possible to develop highly immunogenic and safe recombinant DNA vaccines. Importantly, recombinant DNA (rDNA) vaccine technology represents a powerful tool for an innovative vaccine design process known as genetic immunization.

Recombinant Adenovirus (rAD) and AAV (rAAV) vectors are the ideal candidates for a gene delivery system. These viruses can efficiently deliver genetic material to both dividing and non-dividing cells, thereby overcoming some of the obstacles encountered with first generation retroviral vectors.

Equally important, rAD and rAAV are engineered virus genomes that contain no viral gene. One of the key features for rAD and rAAV is their ability to infect a large variety of cells. However, two technical challenges had to be overcome to fully utilize rAD and rAAV in the development of rDNA vaccines:

1.

Lack of large scale purification system; and

2. Low viral titer.

Traditional technologies and first generation chromatography processes are limited both in terms of purity and yield. And, due to the limitation of these purification technologies, adequate viral titers cannot be achieved. We believe that the result is that there is currently no efficient system to deliver immunogenic genetic sequences into cells.

This is the significance of GeneThera's PURIVAX™, rAD and rAAV system for rDNA vaccine development. Succinctly stated, it is designed to be able to achieve both high purity and high viral titer (up to 10e16 viral particles/eulate) based on its propriety multi-resin anion exchange chromatography system. GeneThera believes that biological contaminants such as endogenous retrovirus, bacterial, mycoplasma, non-specific nucleic acids, lipids, proteins, carbohydrates and endotoxins are eliminated during the purification process.

## **PRODUCT DEVELOPMENT**

GeneThera provides a comprehensive Johne's solution that allows diagnosing, treating and managing herds at risk or already infected with Johne's disease.

Our proprietary Integrated Product Development Platform (IPDP) is design to prevent the spread of Johne's disease to healthy animals and at the same time allow to better control the disease in those herds where the disease is already present.

More importantly we believe that the GeneThera platform can prevent the spread of the Mycobacterium into the food chain. An important part of this strategy is GeneThera's ability to detect the presence of a low number of infected particles in milk tested for the presence of the Mycobacterium Paratuberculosis. Therefore, our IPDP not only is able to detect Johne's infected animals, but can also prevent potential human infections.

## **HERD GUARD**

Herd Guard™ is our comprehensive Johne's management solution that includes a diagnostic (HerdCheck™), a therapeutic (HerdSafe™), and a management system (HerdSoft™) to eradicate or mitigate Johne's disease.

### **HERDCHECK™ (Molecular Test)**

HerdCheck is our diagnostic product. Samples are collected using a Field Collection System with includes specific collection tubes and ship to a GeneThera laboratory for processing.

The major features of the testing system are:

High throughput system.

Capable of more than 20,000 tests per month.

Highly defined and structured testing system.

Proprietary Real Time PCR technology.

### **HERDSAFE™ (Genetic Therapy)**

HerdSafe is our therapeutic product. HerdSafe is the large-scale purification and recombinant based DNA vaccine using Adenovirus and AVV genetically engineered viruses. (PURIVAX™)

### **HERDSOFT™ (Software Management)**

HerdSoft™ is our comprehensive Johne's disease management solution which is a web-based product connected to our data center. The management system will deliver results, collect data and incorporate environmental analysis to guide the client on therapy and management of their herd to control Johne's disease in their facility.

## **DEVELOPMENTS TO DATE**

### **HerdCheck**

GeneThera has developed a molecular system for the detection of Johne's disease in milk, blood and feces of dairy cows infected with the Mycobacterium paratuberculosis sub. Avium. (MAP). Samples from milk obtained from supermarket shelves were either



spiked with different concentrations of MAP or naturally processed. The bacterial DNA was isolated using both, manual and robotic- based DNA extraction procedures and analyzed using The Real Time PCR technology. Using this methodology we can detect between two (2) and twenty (20) bacterial particles from 10 ml of milk. We believe that our test will be very useful for early detection of MAP both in milk samples and infected cows.

We are currently evaluating several robotic systems for DNA extraction. We believe that we can further increase the sensitivity of the molecular assay by using robotic driven DNA extraction methods.

GeneThera set up a molecular diagnostic laboratory in Monterrey Mexico, which will be operated by Applied Genetics, our majority owned subsidiary. Once we secure funding, the laboratory will be scheduled to initiate commercial activity during the third part of 2014.

### **HerdSoft**

To date we have developed a prototype computer program to track samples that will be received and processed in our commercial laboratory in Mexico. This program will initially be used to track samples that will be sent out and received to our laboratory. We had to stop our timeline waiting for secured funding. We will then work on improving the system in order to track samples during the different phases of DNA extraction procedures. In addition we will continue to develop a data base system to store and analyze data collected during sample analysis.

### **HerdSafe**

We are currently developing a vaccine for Johne's disease. GeneThera approach for developing this vaccine is based on the use of PURIVAX technology, genetically engineered Adenoviral and AVV, and silencing RNA technology (iRNA). To date we have modified the Adenovirus by inserting a gene of the MAP bacterium responsible for triggering the infection in blood cell.

However at the present time we do not have the financial resources to implement further development work; therefore, we will need to secure substantial funding to continue the development of the Johne's vaccine.

### **Disease and FUTURE DEVELOPMENT PLANS**

We anticipate that research and development (R&D) will be the source for both assay development and vaccine design/development. If we are able to develop assays for different diseases, we intend to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by GeneThera. To date, we have introduced our diagnostic solution for Chronic Wasting Mad Cow Disease on a very limited basis. We anticipate that R&D will be ongoing during the life of the Company, as

this is the source for new products to be introduced to the market. Our plan is to seek new innovations in the biotechnology field. We cannot assure you that we will be successful in developing or validating any new assays or, if we are successful in developing and validating any such assays, that we can successfully commercialize them or earn profits from sales of those assays. Furthermore, we cannot assure you that we will be able to design, develop, or successfully commercialize any vaccines as a result of our research and development efforts.

It is GeneThera intention to continue with the research and development and validation of the molecular tests and DNA vaccines. Future plans comprises in initiating validation procedures for Johnes disease molecular test. These validation protocols will be performed in Mexico. At the present time, we do not plan to initiate any validation protocol in the United States.

In parallel, we will continue R&D phases for the Johnes disease vaccine. We plan initiating an experimental animal protocol to determine the safety of our vaccines. We estimate that the experimental animal protocol may take up to a year. We project to initiate the experimental animal studies within 24-36 months.

## **R&D SERVICES**

**Molecular, Cellular, Viral Biology Research and Consulting Services:** We provide independent research services to scientists in academia, the pharmaceutical industry, and the biotechnology industry. Primarily, GeneThera expertise focuses on technology relevant to animal and human immunotherapy. These services are backed by the cumulative experiences of greater than 50 years of research and development in both government and industry by GeneThera senior scientists. GeneThera intends to develop a commercial-scale implementation of Adenovector Purification Process to support R&D material production. Furthermore, GeneThera intends to evaluate and test commercially available expression vectors and incorporate them into its vector repertoire. These technologies are well established within the repertoire of GeneThera scientific staff. We cannot provide any assurance, however, that we will be able to successfully offer these services or that, if offered, we can provide them profitably.

### **Research & Development Services:**

#### **Molecular Biology:**

Synthetic cDNA Construction

Prokaryotic Expression Vector Construction & Development

E. coli Expression Strain Evaluation

Pilot Scale Fermentation

Mammalian Expression Vector Construction & Development

Baculovirus Expression

Protein Isolation

Protein Engineering: Complement Determining Region Conjugated Proteins

Monoclonal Antibody Production Chimerization & Humanization

Vector design for Prokaryotic Expression of Antibody Fragments (Fab) and Single Chain Antibody (ScFv)

Pilot Scale-up Development

Process Purification & Characterization

Assay Development & Quality Control Pharmaceutical Dosage and Formulation

**Gene Therapy Testing Services:** GeneThera offers GLP (Good Laboratory Procedure) testing programs for somatic cell, viral and naked DNA-based gene therapies. Our scientists have over ten years of experience in providing fully integrated bio-safety testing programs for the cell and gene therapy fields. To date, the Company has not generated any revenues with regard to these services, and there is no assurance that we will generate any revenues from such services.

**Replication-Competent Viral Vector Testing:** Sensitive in vitro cell culture assays are used to detect replication-competent retroviruses or adenoviruses. GeneThera can work with clients to provide custom replication-competent virus detection assays for the particular vector construct.

**Complete Somatic Cell and Viral Vector Packaging and Producer Cell Line Characterization:** GeneThera offers all of the assays mandated by regulatory authorities worldwide for the bio-safety analysis and characterization of cells and cell lines used in gene therapy products.

**Vector Stock Characterization:** Custom purity and potency testing is available for gene therapy viral vector stocks.

**Vector Purification Process Validation for Viral Clearance:** Most biopharmaceuticals require viral clearance studies to validate the removal of potential contaminants, such as those from bovine components or from helper viruses (adenovirus in AAV production). GeneThera can provide custom design and performance of viral studies for various vector purification processes.

**Custom Bio-safety Testing Programs for Somatic Cell, Ex Vivo Cell, and Tissue Therapies:** GeneThera can guide our clients through the unique process of designing and implementing a bio-safety testing program that meets the needs of each specific project.

GeneThera is currently seeking contracts for these services to be performed on an annual basis. There is no assurance that any contracts will be signed or that the Company will generate significant revenues or profits from any such contracts.

## **MARKETING STRATEGY**

GeneThera goal is to focus on the international markets, primarily South America, for the commercialization of its animal testing platform. The company has no plans to offer any veterinary services in the United States.

We established our first molecular diagnostic laboratory in Mexico. It is our intention to secure funding in order to set up a network of laboratories in Northern, Central and Southern Mexico, funding permitting.

Our marketing approach is to align ourselves with both, the private sector and government agencies.

Applied Genetics, a majority owned subsidiary of GeneThera is a molecular diagnostic company located in Monterrey Mexico. Applied Genetics focuses on the commercialization of molecular testing for Johne's disease. The company is located in a 2500 sq feet laboratory facility in San Pedro Garza. We have delayed our close working relationship with the largest Mexican University, the National University of Mexico, on validating Johne's disease molecular testing until we secure funding. The goal of this validation study is to obtain Mexican Government approval of the Johne's molecular test.

\*

Applied Genetics laboratory is outfitted with state of the art technology to ensure the validity of results.

\*

Sample collection, delivery procedure sets, and laboratory procedures are stringently implemented.

Applied Genetics employs GeneThera HERDCHECK™ proprietary technology for the molecular testing of Johne's disease.

Samples are normally collected by using a field collection system (FCS), which includes specific collection tubes, and ship to Applied Genetics laboratory. The major features of the testing system are:

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High throughput system.

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Highly defined and structured testing system.

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Proprietary Real Time PCR technology.

## **SALES AND MARKETING**

We did not renew a marketing agreement with Nutricion Avanzada S.A. due to lack of performance. Nutricion Avanzada is the largest Mexican distributor of animal feed and has an extensive distribution network, but not in biotechnology. Under the preliminary terms of the agreement Nutricion Avanzada had 1) exclusive rights to market, sell and distribute GeneThera FCS in Mexico; 2) would have purchased products from GeneThera and resell it to third parties; 3) would have purchased the products at a 30% discounted rate; 4) was supposed to have covered expenses related to market, sell and distribute the products, but they failed to do so. This agreement had an initial one-year term renewable upon mutual agreement. We opted not to renew our agreement with the President of Nutricion Avanzada. We believe this agreement was not performed properly. Instead of giving us substantial market introduction, we had none. Moreover, we were unable to avoid expending significant funds to develop a sales and marketing organization because the marketer was unable to provide written contract agreements detailing such important and accurate scientific work. The CEO and also Chief Scientific Officer discussed this with Nutricion Avanzada's president to no avail since this marketer had no knowledge of biotechnology. The Company is continuing to interview prospective marketers for our commercial laboratory.



## **COMMERCIAL DIAGNOSTIC TESTING**

In the event that we are able to develop assays for the detection of diseases in animals, we intend to establish a series of diagnostic testing laboratories geographically proximate to the primary sources of individual diseases and/or according to specific available operating efficiencies. The specific number of labs to be built and operated will be based on assay demand (demand facilitated by the number of specific disease assays GeneThera develops), our ability to obtain the capital to build the labs, and our ability to successfully manage them from our principal office. As of the date of this filing, we are in negotiations to establish one diagnostic testing laboratory outside of our Colorado facility.

## **LICENSING**

Through our licensing division, we intend to manage the marketing and sale of the vaccines developed by our R&D. As GeneThera does not intend to be a vaccine manufacturer, we plan to use our licensing division to license the technology related to any vaccines that may be developed and to manage the revenue potential available from the successful development and validation of specific vaccines. We cannot provide any assurance that we will develop any vaccines or that, if they are developed, we will be able to license them successfully or that any such license will produce significant revenues.

## **INTELLECTUAL PROPERTY**

We do not own any patents on any of our technology and have not filed any applications for patents in any country. We cannot give any assurance that we will be able to file any patent applications or that, if we file one or more applications for patents, any patents will issue or that, if issued, the claims granted in any such patents will afford us adequate protection against competitors with similar technology.

We also depend upon the skills, knowledge, and experience of our scientific and technical personnel, none of which is patentable. To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to endorse, we rely on trade secret protection to protect our interests.

## **COMPETITION**

We face competition from many companies, universities, and research institutions in the United States and abroad. Virtually all of our competitors have substantially greater resources, experience in product commercialization, and obtaining regulatory approvals for their products, operating experience, research and development, marketing capabilities, and manufacturing capabilities that we do. We will face competition from companies marketing existing

products or developing new products for diseases targeted by our technologies. The development of new products for those diseases for which we are attempting to develop products could render our product candidates noncompetitive and obsolete.

Our current competitors include primarily, IDEXX Laboratories, Inc., Academic and government institutions are also carrying out a significant amount of research in the field of veterinary health, particularly in the field of Johne's disease. We anticipate that these institutions will become more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed and to market commercial products similar to those that we seek to develop, either on their own or in collaboration with competitors.

Any resulting increase in the cost or decrease in the availability of technology or product candidates from these institutions may affect our business.

Competition with respect to our veterinary technologies and potential products is and will be based, among other things, on effectiveness, safety, reliability, availability, price, and patent protection. Another important factor will be the timing of market introduction of products that we may develop and for which we may receive regulatory approval. Accordingly, the speed with which we can develop products, complete the required animal studies or trials and approval processes and ultimately supply commercial quantities of the products to the market is expected to be an important competitive factor. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and to secure sufficient capital resources for the often-substantial period between technological conception and commercial sales.

Several attempts have been made to develop technologies that compete with F-PCR. To our knowledge none of these technologies have resulted to date in any product available on the market. The field of biotechnology is very dynamic.

The possibility that more advanced technologies could be developed into products that may compete with ours is very strong. However, it is very difficult to predict the length of time necessary for this scenario to take place.

## **MANUFACTURING**

We do not manufacture any products in Mexico. We do not rely on Nutricion Avanzada facilities in Apodaca, Mexico for manufacturing and assembling of our Field Collection System due to their poor performance during the past year. We do not intend to establish a manufacturing facility to manufacture any products that we may develop in Mexico. We do not intend to manufacture, sell, and distribute any diagnostic or therapeutic product in the United States in the foreseeable future.

## **PRODUCT LIABILITY**

The testing, manufacturing, and marketing of the Company's proposed products involves an inherent risk of product liability attributable to unwanted and potentially serious health effects in animals that may receive any vaccines that we may develop and market. To the extent we elect to test, manufacture, or market veterinary vaccines and other products, we will bear the risk of product liability directly. We do not currently have product liability



insurance. There is no guarantee that we can obtain product liability insurance at a reasonable cost, or at all, or that the amount of such insurance will be adequate to cover any liability that we may be exposed to. In the absence of such insurance, one or more product liability lawsuits against us can be expected to have a material adverse effect on our business and could result in our ceasing operations.

## **GOVERNMENT REGULATION**

Our unique approach to the testing for various animal diseases allows us to begin commercialization of its diagnostic tests without the need for a long and enduring approval process from the USDA. However, it is our intention not to seek, in the foreseeable future, any approval either from the USDA or the FDA for any of the products we develop both, diagnostic or therapeutic. It is our intention to perform any validation or clinical trials of our product abroad and primarily in Mexico where our commercial operation is located. SAGARPA is the Mexican Government Agency that regulates and approves animal tests and vaccines; we have initiated the formal approval process for our HerdCheck molecular system. SAGARPA will require a validation study to be performed to demonstrate the effectiveness of the system. Validation studies will be performed according to SAGARPA guidelines. We have submitted an application outlining a protocol for animal studies. Validation studies will be conducted in collaboration with The Center of Training, Research, and Expansion of High Plateau Animal Production of the School of Veterinary Medicine (C.E.I.E.P.A.A) of the Universidad Nacional Autonoma de Mexico (UNAM). UNAM is a federal institution credited with SAGARPA. We expect the validation study to commence and be finally completed within the next 12-18 month period.

## **ITEM 1A:RISK FACTORS**

We encounter various risks related to our business and our industry. While the Company is optimistic about its long term prospects, the following risk factors should be considered in evaluating its outlook.

**There is a substantial doubt about GeneThera's ability to continue as an on-going concern.**

GeneThera has had negligible revenues since inception, had a negative working capital deficit and an accumulated deficit of \$23,388,434 and \$22,346,418, respectively as of December 31, 2013 and 2012, and had a net loss of \$1,045,003 for the year ended December 31, 2013. Because of these circumstances, GeneThera will require additional working capital to develop business operations. There is no assurance that GeneThera will reach a level of revenues adequate to generate sufficient cash flow from operation or obtain additional financing necessary to support GeneThera operating expense requirements. If financing is available, it may involve issuing securities senior to our common stock. In addition, in the event we do not raise additional capital from conventional sources, such as our existing investors or commercial banks, there is a

likelihood that our growth will be restricted and we may be forced to scale back or curtail implementing our business plan.

**If a Loss of Key Personnel Will Occur This Event Could Adversely Affect the Company.**

The Company depends to a large part on the efforts and continued employment of Antonio Milici, M.D., Ph.D., our President, Chairman and Chief Executive Officer. The loss of Dr. Milici will have a material adverse effect on the business, results of operations (if any) and financial condition of the Company. In addition, the loss of Dr. Milici may force the Company to seek a replacement who may have less experience, fewer contacts, or less understanding of the business. Further, we may be unable to find a suitable replacement for Dr. Milici, which could force the Company to curtail its operations and/or cause any investment in the Company to become worthless. The Company has an employment agreement with Dr. Milici, which ends on January 7, 2017.

**If the Company fails to attract and retain additional highly skilled personnel, operations will suffer.**

Finding qualified personnel in the biotechnology industry is very challenging. Smaller biotechnology companies are always at a disadvantage because of its limited financial resources. The Company has been unable at this time to hire any additional qualified personnel. If the Company is unable to hire additional personnel this may result in a substantial delay of its R&D and commercial operations.

**If the Company fails to attract significant additional capital, the Company may be unable to continue developing its products.**

From the beginning of its operation, GeneThera has obtained limited funding to implement its business strategy. The Company believes it will require significant additional funding in order to achieve its business plan. Over the next 12 months, in order to have the capability of achieving its business plan, the Company will require at least \$10,000,000 in additional funding. There are no guarantees that the Company will be able to secure such financing, and if the financing is secured, there are no guarantees whether the Company can fully achieve the goals laid out in its business plan. If financing is available, it may involve issuing securities senior to our common stock. In addition, in the event we do not raise additional capital from conventional sources, such as our existing investors or commercial banks, there is a likelihood that our growth will be restricted and we may be forced to scale back or curtail implementing our business plan.

**Rapid growth may place significant demands on our resources.**

We expect significant expansion of our operations, funding permitting, moving forward. Our anticipated future growth will place a significant demand on our managerial, operational and financial resources due to:

- \* The need to manage relationships with various strategic partners and other third parties.
  
- \* Difficulties in hiring and retaining skilled personnel necessary to support our business.
  
- \* The need to train and manage a growing employee base.
  
- \* Pressures for the continued development of our financial and information management systems.

If we have not made adequate allowances for the costs and risks associated with this expansion or if our systems, procedures, or controls are not adequate to support our operations, our business could be harmed.

**The Company may not be able to comply with Government regulations.**

The Company is subject to or affected by laws and regulations that govern, for example: the vaccination of animals for certain diseases. The failure to comply with these laws and regulations, or to obtain applicable governmental approvals, could result in the imposition of penalties, cause delays in, or make impossible, the marketing of our products and services.

**The Company may be unable to compete against other more established biotech or pharmaceutical companies.**

The Company operates in a very competitive and difficult area. Biotechnology business is notoriously difficult and risky. The Company competes with other more established and better funded companies in the United States and overseas that are involved in the development of similar products. Several of these companies have significantly greater financial resources as well as greater production and marketing capabilities. The field of Biotechnology requires extensive research and development. Better funded competitors may be able to develop and market superior or less expensive products which will make the Company's products less valuable or unmarketable.

**The Company has limited Government Regulatory Experience.**



The Company has never successfully undertaken a clinical trial for animal testing. Our experience in this area is limited. The Company has never obtained regulatory approvals for any of its products. As such, the Company may be unable to ever successfully undertake a clinical trial of its products, and may be forced to curtail or abandon its current business plan.

**The Company has a history of operating losses.**

We have generated no revenues to date from our operations. Historically we have had net operating losses each year since our inception. Additionally even if we are able to

commercialize our technology or any products it is not certain that will result in revenues or profitability.

**The Company relies on third parties for sale, distribution and manufacturing.**

We do not have any in house sale, distribution or manufacturing capabilities. The success of our operations depended entirely by the ability of our marketing partner Nutricion Avanzada who failed to sell our tests and products to the dairy and cattle industry.

**The Company has a limited operating history on which investors may evaluate our operation and prospects for profitable operations**

If we continue to suffer losses as we have in the past, investors may not receive any return on their investments. Our prospects must be consider speculative in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development. A substantial risk is involved in investing in the company because we have fewer resources than established companies.

**The company depends on new and rapidly evolving technologies**

We are engaged in activities in the biotechnology field, which is characterized by extensive research effort and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. We cannot assure that research and discoveries by other biotechnology, agriculture, pharmaceutical or other companies will not render our technologies or products uneconomical or result in products superior to those we develop, depend on new and evolving technologies. If these technologies do not produce satisfactory results our business maybe harmed.

**Over the last year we have narrowed our potential product development to focus on the molecular testing of Johnes disease.**

Due to the increase cost of R&D and the very challenging economic environment we have decided to concentrate our efforts in the development of a commercial platform for the diagnostic of Johnes disease. As a result, the success of the company depends entirely on being able to commercialize our product. If we are unable to achieve this goal, the Company s operations could greatly suffer and any investment in the Company could be lost.

**The Company may not obtain foreign regulatory approval to market any of our products.**

If we fail to obtain regulatory approval of any of our products, we will not be permitted to market our products and may be forced to cease operations.

**Our technology is not protected by patents.**

Our technology and know-out is not patented. We rely on trade secrets to protect our intellectual property. We cannot assure, however, that these trade secrets will provide meaningful protection for our intellectual property. Furthermore, in absence of patent protection, competitors who independently develop substantially equivalent technology may harm our business.

**The Company may not be able to raise the required capital to conduct our operations and develop and commercialize our products.**

We require substantial additional resources in order to conduct our operations and develop and commercialize our products and run our facilities. We will need significant additional funds or a collaborative partner, or both, finance research and development activities of our potential products. Accordingly we are continuing to pursue additional sources of financing. Additional financing through strategic collaborations, public or private equity financing sources may not be available on accepted terms. Additionally equity financing could result in significant dilution to our shareholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, or products that we would otherwise seek to develop and commercialize on our own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs or potential products any of which could have a material adverse affect on our financial condition or business prospect

**We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company.**

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC. Changes in the laws and regulations affecting public companies, including the provisions of SOX and rules adopted by the SEC, have resulted in, and will continue to result in, increased costs to us as we respond to these requirements. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may determine that our internal control over financial reporting was not effective. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy

limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees, and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

**Compliance with Section 404 of the Sarbanes-Oxley Act will continue to strain our limited financial and management resources.**

We incur significant legal, accounting and other expenses in connection with our status as a fully reporting public company. The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have imposed various new requirements on public companies, including requiring changes in corporate governance practices. As such, our management and other personnel need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure of controls and procedures. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

**Investors May Face Significant Restrictions On The Resale Of Our Common Stock Due To Federal Regulations Of Penny Stocks.**

Our common stock will be subject to the requirements of Rule 15c-9, promulgated under the Securities Exchange Act as long as the price of our common stock is below \$5.00 per share. Under such rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements, including a requirement that they make an individualized written suitability determination for the purchaser and receive the purchaser's consent prior to the transaction. The Securities Enforcement Remedies and Penny Stock Reform Act of 1990, also requires additional disclosure in connection with any trades involving a stock defined as a penny stock. Generally, the Commission defines a penny stock as any equity security not traded on an exchange or quoted on NASDAQ that has a market price of less than \$5.00 per share. The required penny stock disclosures include the delivery, prior to any transaction, of a disclosure schedule explaining the penny stock market and the risks

associated with it. Such requirements could severely limit the market liquidity of the securities and the ability of purchasers to sell their securities in the secondary market.

In addition, various state securities laws impose restrictions on transferring "penny stocks" and as a result, investors in the common stock may have their ability to sell their shares of the common stock impaired.

**Shareholders May Be Diluted Significantly Through Our Efforts To Obtain Financing And Satisfy Obligations Through The Issuance Of Additional Shares Of Our Common Stock.**

We have no committed source of financing. Wherever possible, our Board of Directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock. Our Board of Directors has authority, without action or vote of the shareholders, to issue all or part of the authorized but unissued shares of common stock. In addition, if a trading market develops for our common stock, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market. These actions will result in dilution of the ownership interests of existing shareholders, may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of the Company because the shares may be issued to parties or entities committed to supporting existing management.

**The market price of our common stock historically has been volatile.**

The market price of our common stock historically has fluctuated significantly based on, but not limited to, such factors as general stock market trends, announcements of developments related to our business, actual or anticipated variations in our operating results, and our ability or inability to generate new revenues.

Our common stock is traded on the OTC market under the symbol GTHR. In recent years, the stock market in general has experienced extreme price fluctuations that have oftentimes been unrelated to the operating performance of the affected companies. Similarly, the market price of our common stock may fluctuate significantly based upon factors unrelated or disproportionate to our operating performance. These market fluctuations, as well as general economic, political and market conditions, such as recessions, interest rates or international currency fluctuations may adversely affect the market price of our common stock.

**We currently have a sporadic, illiquid, volatile market for our common stock, and the market for our common stock may remain sporadic, illiquid, and volatile in the future.**

We currently have a highly sporadic, illiquid and volatile market for our common stock, which market is anticipated to remain sporadic, illiquid and volatile in the future and will

likely be subject to wide fluctuations in response to several factors, including, but not limited to:

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actual or anticipated variations in our results of operations;

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our ability or inability to generate revenues;

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the number of shares in our public float;

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increased competition; and

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conditions and trends in the market for our services.

Furthermore, because our common stock is traded on the OTC market, our stock price may be impacted by factors that are unrelated or disproportionate to our operating performance. These market fluctuations, as well as general economic, political and market conditions, such as recessions, interest rates or international currency fluctuations may adversely affect the market price of our common stock. Shareholders and potential investors in our common stock should exercise caution before making an investment in our Company, and should not rely on the publicly quoted or traded stock prices in determining our common stock value, but should instead determine the value of our common stock based on the information contained in our public reports, industry information, and those business valuation methods commonly used to value private companies.

## **ITEM 2:**

### **DESCRIPTION OF PROPERTY**

We lease approximately 9,600 square feet for our biotechnology laboratory located at 7577 W. 103<sup>rd</sup> Ave. in Westminster, Colorado 80021. The lease terminates January 31, 2014 with expectancy of renewal. The rent is \$7,000 per month for the first 14 months, \$10,970 per month for months 15 through 26 and \$12,584 per month for the remainder of the lease. We sub-lease 700 square feet of office space to GTI Corporate Transfer Agents, LLC, a related party, located in Suite 209. The lease is on a three-year basis and the rent is \$1,000 per month until January 31, 2017. We sub-lease laboratory and office space for several biotechnology and holdings companies. These lessees have their



lab equipment in our laboratory spaces for their research and development work. The Company is permitted to utilize their lab equipment, which enhances the R&D collaboration among scientific peers. We do not own any real estate property. If we are able to develop assays for different diseases, we intend to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by GeneThera. Currently, we do not have the funds to purchase or construct any such laboratories and do not have commitment from any party to provide the funds for a laboratory.

Applied Genetics, our Mexico subsidiary leases approximately 2,500 square feet of office and laboratory space located at 1007 Avenida Lazaro Cardenas, San Pedro Garza, in Nuevo Leon, Mexico. The lease terminates in June 2016. The rent is \$4,300 per month.

**ITEM 3:**

**LEGAL PROCEEDINGS**

On June 6, 2006, the Internal Revenue Service filed a Federal Tax Lien at the Jefferson County Recorder in the State of Colorado in the amount of \$29,321. The Company has not satisfied the judgment.

On June 29, 2007, the Internal Revenue Service filed a Federal Tax Lien at the Jefferson County Recorder in the State of Colorado the amount of \$1,983. The Company has not satisfied the judgment.

On June 6, 2008, M.A.G. Capital, LLC; Mercator Momentum Fund III, LP; Mercator Momentum Fund, LP; and Monarch Pointe Fund, Ltd. filed a Judgment at the Orange County Recorder in the amount of \$37,721. The Company has not satisfied the judgment.

On June 6, 2008, Mark A. Shoemaker filed a Civil Judgment at the LA County/Recorder of Deeds Court in the amount of \$37,721. This lawyer has been disbarred and incarcerated. The Company will not satisfy the judgment.

In June 2009, James Tufts filed a complaint at the Small Claims Court in Jefferson County CO in the amount of \$4,000 plus expenses from a London trip. The Company has not satisfied the judgment.

On June 26, 2009, Enterprise Leasing Company of Denver filed a Civil Judgment at the Jefferson County District Court in the State of Colorado in the amount of \$78,178. The Company has not satisfied the judgment.

On August 17, 2010, Banc of America Leasing filed a Civil Judgment at the Oakland County District in Troy, Michigan in the amount of \$24,002. The Company has not satisfied the judgment.

On September 23, 2010, Liberty Acquisitions filed a Civil Judgment at the Jefferson County Court in the State of Colorado in the amount of \$3,300. The Company has not satisfied the judgment.

On February 10, 2009, Centennial Credit Corporation filed a Civil Judgment at the Jefferson County Court in the amount of \$967. The Company has not satisfied the judgment.

On August 29, 2011, GeneThera had a court hearing concerning a litigation filed by The Park III related to unpaid rent according to our lease agreement. The District Court of Boulder entered a judgment against the Company in the amount of \$77,000. The Company has not satisfied the judgment.

On November 8, 2012, GeneThera apparently had litigation with Mark Gohr, a consultant the CEO hired when Gohr was laid off from Qwest in 2009. The Company was not aware of such litigation. The legal documentation was not served to the

Registered Agent. Gohr had a judgment by default in the amount of \$19,000. According to the Company's financial records reflecting whatever invoices, receipts, and/or credit card method of payment supposedly provided by Mark Gohr, this consultant financially assisted the Company for less than \$10,000. Litigation is pending.

On November 26, 2012, the Internal Revenue Service filed a Federal Tax Lien in the amount of \$1,275. The Company has not satisfied the lien.

**ITEM 4:**

**MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5:**

**MARKET FOR COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock currently trades on the OTC Market under the symbol **GTHR** . The following sets forth the rank of high and low bid quotations for the periods indicated. Such quotations reflect prices between dealers, without retail markup, markdown or commission, and may not represent actual transactions.

<b>Year</b>	<b>Quarter</b>	<b>High</b>	<b>Low</b>
<b>2013</b>	Fourth	\$	\$
		0.30	0.03
	Third	0.08	0.08
	Second	0.01	0.005
	First	0.01	0.003
<b>2012</b>	Fourth	\$	\$
		0.07	0.008
	Third	0.03	0.004
	Second	0.01	0.005
	First	0.01	0.003

**ITEM 6:**

**SELECTED FINANCIAL DATA**

Not applicable for smaller reporting companies.

**ITEM 7:**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

Sections of this Form 10-K, including the Management's Discussion and Analysis or Plan of Operation, contain forward-looking statements. These forward-looking statements are subject to risks and uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the results, performance or achievements expressed or implied by the forward-looking statements. You should not unduly rely on these statements. Forward-looking statements involve assumptions and describe our plans, strategies, and expectations. You can generally identify a forward-looking statement by words such as may, will, should, would, could, plans, goal, potential, expect, anticipate, estimate, believe, intent, project, and similar thereof. This report contains forward-looking statements that address, among other things,

- \* Our financing plans
- \* Regulatory environments in which we operate or plan to operate
- \* Trends affecting our financial condition or results of operations
- \* The impact of competition, the start-up of certain operations and acquisition opportunities.

Factors, risks, and uncertainties that could cause actual results to differ materially from those in the forward-looking statements ( Cautionary Statements ) include, among others,

- \* Our ability to raise capital
- \* Our ability to execute our business strategy in a very competitive environment
- \* Our degree of financial leverage
- \* Risks associated with our acquiring and integrating companies into our own
- \* Risks relating to rapidly developing technology
- \* Regulatory considerations
- \* Risks related to international economies
- \* Risks related to market acceptance and demand for our products and services
- \* The impact of competitive services and pricing
- \* Other risks referenced from time to time in our SEC filings

All subsequent written and oral forward-looking statements attributable to us, or anyone acting on our behalf, are expressly qualified in their entirety by the cautionary statements. We do not undertake any obligations to publicly release any revisions to any forward-looking statements to reflect events or circumstances after the date of this report

or to reflect unanticipated events that may occur.

You should read the following discussion of our results and plan of operation in conjunction with the consolidated financial statements and the notes thereto appearing elsewhere in this Form 10-K. Statements in this Management's Discussion and Analysis or Plan of Operation that are not statements of historical or current objective fact are forward-looking statements.

## **OVERVIEW**

We have developed proprietary diagnostic assays for use in the agricultural and veterinary markets. Specific assays for Chronic Wasting Disease (CWD) (among elk and deer) and Mad Cow Disease (among cattle) have been developed and are available currently on a limited basis. E. coli (predominantly cattle) and Johne's disease (predominantly cattle and bison) diagnostics are in development. We are also working on vaccine solutions to meet the growing demands of today's veterinary industry and tomorrow's agriculture and healthcare industries. The Company is organized and operated both to continually apply its scientific research to more effective management of diseases and, in so doing, realize the commercial potential of molecular biotechnology.

We have not generated significant operating revenue as of December 31, 2013. Our ability to generate substantial operating revenue will depend on our ability to develop and obtain approval for molecular assays and developing therapeutic vaccines for the detection and prevention of food contaminating pathogens, veterinary diseases, and diseases affecting human health.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern in their report on our consolidated financial statements for 2013. For 2013 and 2012, our operating losses were \$1,045,003 and \$1,811,792, respectively. Our current liabilities exceeded current assets by \$5,316,065 and \$4,618,570 as of December 31, 2013 and 2012, respectively.

Although, we completed an equity financing with gross proceeds of approximately \$1.1 million in 2005, we will require significant additional funding in order to achieve our business plan. Over the next 12 months, in order to have the capability of achieving our business plan, we believe that we will require at least \$10,000,000 in additional funding. We will attempt to raise these funds by both means of one or more private offerings of debt or equity securities and revenues generated by our Project in Mexico. At this time, we have commitments for additional capital funds. This amount may exceed an additional \$2,500,000 depending on cost involved in the further development and commercialization of our products. In such event, we may need immediate additional funding. Our capital requirements will depend on many factors including, but not limited to, the timing of further development of assays to detect the presence of infectious disease from the blood of live animals, our hiring of additional personnel, the applications for, and receipt of, regulatory approvals for any veterinary vaccines that we may develop, and other factors. Our ability to raise capital will increase our ability to implement our business plan.

Over the next 12 months, we expect significant purchases and/or sales of plant or equipment and significant changes in the number of our employees for any off-balance sheet arrangements that will have current and future effect on our financial condition.

We also expect to spend a significant amount of our capital on research and development activities for commercialization relating to development and vaccine design/development. When we are able to develop assays for different diseases, we





intend to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by GeneThera. To date, we have introduced our diagnostic solution for Chronic Wasting Disease (CWD) and Mad Cow Disease on a very limited basis. We anticipate that significant funds will be spent on research and development throughout the life of the Company, as this is the source for new products to be introduced to the market.

Our plan is to seek new innovations in the biotechnology field. We may be successful in developing or validating any new assays and, when we are successful in developing and validating any such assays, we may be able to successfully commercialize them or earn profits from sales of those assays. Furthermore, we may be able to design, develop, or successfully commercialize vaccines as a result of our research and development efforts.

On January 16, 2013, the Company entered into an agreement with Caro Capital, LLC, for investor relations services. The Company issued 1,000,000 shares of common stock to Caro Capital for consideration of \$20. The Company was also to pay Caro \$5,000 per month for six months, payable when \$500,000 qualified capital which was supposed to have been raised for the Company by Caro Capital. Unfortunately, Caro Capital failed to perform. The Company waited for Caro Capital to provide their Consultant Report but they fail to provide it. Caro Capital had until 12-31-2013 to do so. Therefore, the 1,000,000 restricted shares were not process for legend removal and is in the process of cancellation.

On March 26, 2013, the Company entered into an agreement with Southridge Partners II, LP, under which Southridge agreed to assume up to \$3,788,419 of the Company's liabilities. The liabilities will be divided into tranches, which will be settled by issuances of the Company's common stock to Southridge. Common stock will be valued at 75% of the low closing bid price during the minimum period of consecutive trading days previous to settlement over which the dollar trading volume of the Company's common stock exceeds 300% of the purchase price. Shares issued to Southridge are not to exceed 9.99% of the Company's outstanding shares.

## **RELATED PARTY TRANSACTIONS**

The Company has an outstanding loan payable to Antonio Milici, its President and shareholder amounting to \$645,419 as of December 31, 2013 and 2012, respectively. This outstanding loan to the Company is unsecured and non-interest bearing.

GTI Corporate Transfer Agents, LLC is the Company's transfer agent. Ms. Michelle Torres became the Board Member of GTI Corporate Transfer Agents, LLC with a one-third ownership and/or interest. Ms. Tannya Irizarry has a one-third ownership and/or interest; the remaining one-third ownership belongs to Ms. Daisy Garcia.

## **RESULTS OF OPERATIONS**

**Year Ended December 31, 2013 Compared to Year Ended December 31, 2012**

For 2013, the Company has a net loss of \$1,059,848 or net loss per share of \$0.04, and \$0 of revenue as compared with a net loss of \$1,181,792, or \$0.07 per share, and revenue of \$0 for 2012.

**General and Administrative Expenses:** General and administrative expenses increased to \$682,686 for 2013 compared to \$670,331 for 2012.

**Consulting Expenses:** Consulting expenses decreased to \$0 for 2013 compared to \$240,000 for 2012.

**Depreciation and Amortization Expense:** Depreciation and amortization expenses decreased to \$15,538 for 2013 compared to \$36,288 for 2012.

## **LIQUIDITY AND CAPITAL RESOURCES**

We had a cash balance of \$1,331 as of December 31, 2013 and a cash balance of \$1,055 as of December 31, 2012. Our current cash balance is not sufficient to fund our business objectives and we will need significant additional capital over the next 12-18 months in order to fund our planned operations. We may be unable to secure any additional financing on terms that are acceptable to us, if at all.

We will require significant additional funding in order to achieve our business plan. Specifically, we intend to spend significant funds on validating and testing our products, seeking necessary regulatory approvals and focusing on international expansion. Over the next 12 month, in order to have the capability of achieving our business plan, we believe that we will require at least \$10,000,000. We will attempt to raise these funds by means of one or more private offerings of debt or equity securities or both. We may not be able to secure the financing that we believe is necessary to implement our strategic objectives and, even if additional financing is secured, we may not achieve our strategic objectives. As of the date of this Report, we do not have any firm commitments from any investors for any additional funding.

Our longer-term working capital and capital requirements will depend upon numerous factors, including revenue and profit generation, pre-clinical studies and clinical trials, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, competing technological and market developments, collaborative arrangements. Additional capital will be required in order to attain such goals. Such additional funds may not become available on acceptable terms and we cannot give any assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term.



## **CRITICAL ACCOUNTING POLICIES**

In December 2001, the SEC requested that all registrants discuss their most critical accounting policies in Management's Discussion and Analysis of Financial Condition or Plan of Operation. The SEC indicated that a critical account policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our significant accounting policies are described in Note 1 to our consolidated financial statements included in this Report.

## **RECENTLY ISSUED ACCOUNTING STANDARDS**

The Company does not expect the adoption of any recently issued accounting pronouncements to have a significant effect on its consolidated financial position or results of operations.

## **EMPLOYEES**

As of December 31, 2013, we had a total of two full-time employees who devoted substantial effort on our behalf. None of our employees are represented by a collective bargaining unit. We entered into an employment agreement with Antonio Milici, M.D., Ph.D., to serve as our Chief Executive Officer and Chief Scientific Officer through January 7, 2017. In consideration for his services, Dr. Milici will receive a base salary of \$216,000 per annum plus bonuses as may be determined by the Board of Directors in its sole discretion. As part of his employment agreement, Dr. Milici is subject to non-disclosure and non-competition obligations and has transferred to the Company all of his interests in any idea, concept, technique, invention or written work. We also entered into an employment agreement with Tannya L. Irizarry to serve as our Chief Administrative Officer through January 7, 2017. Ms. Irizarry's base salary is \$168,000 per annum. The above salaries have been accrued to be paid in common stock shares from the Company. There are no employee issues at this time.

## **RESEARCH AND DEVELOPMENT**

We anticipate that R&D will be the source for both assay development and vaccine design/development. If we are able to develop assays for different diseases, we intend to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by us. To date, we have introduced our diagnostic solution for Chronic Wasting Disease and Mad Cow Disease on a very limited basis. We anticipate that R&D will be ongoing during the life of the Company, as this is the source for new products to be introduced to the market. Our plan is to seek new innovations in the biotechnology field. We cannot assure you that we will be successful in developing or validating any new assays or, if we are successful in developing and validating any such assays, that we can successfully commercialize them or earn profits from sales of those assays. Furthermore, we cannot assure you that

we will be able to design, develop, or

successfully commercialize any vaccines as a result of our research and development efforts.

## **COMMERCIAL DIAGNOSTIC TESTING**

In the event that we are able to develop assays for the detection of diseases in animals, we intend to establish a series of diagnostic testing laboratories geographically proximate to the primary sources of individual diseases and/or according to specific available operating efficiencies. The specific number of labs to be built and operated will be based on assay demand (demand facilitated by the number of specific disease assays GeneThera develops), our ability to obtain the capital to build the labs, and our ability to successfully manage them from our principal office.

## **PROPERTIES**

We lease approximately 9,600 square feet for our biotechnology laboratory located at 7577 W. 103<sup>rd</sup> Ave. in Westminster, Colorado 80021. The lease terminates January 31, 2014. The rent is \$7,000 per month for the first 14 months, \$10,970 per month for months 15 through 26 and \$12,584 per month for the remainder of the lease. We sub-lease 700 square feet of office space to GTI Corporate Transfer Agents, LLC; a related party, located in Suite 209. The lease is \$1,000 per month until January 31, 2017. The Company is in negotiations with the landlord to renew the lease for another six years. The Company also sub-leases laboratory and office spaces to several biotechnology and holdings companies. These entities also have their laboratory equipment located at our premises for their R&D scientific work. If we are able to develop assays for different diseases, we intend to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by GeneThera. Currently, we do not have the funds to purchase or construct any such laboratories and do not have a commitment from any party to provide the funds for a laboratory.

## **ITEM 8:**



**FINANCIAL STATEMENT**

**GENETHERA, INC.**

**AND SUBSIDIARY**

**CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2013

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**Notes to Consolidated Financial Statements**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of

GeneThera, Inc.

Westminster, Colorado

We have audited the accompanying consolidated balance sheets of GeneThera, Inc. and its subsidiaries (collectively, the Company) as of December 31, 2013 and 2012 and the related consolidated statements of operations, shareholders deficit, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting

Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of GeneThera, Inc. and its subsidiaries at December 31, 2013 and 2012 and results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has no revenues, no historical profitability, and has limited available funds that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ MaloneBailey, LLP

Houston, Texas

[www.malonebailey.com](http://www.malonebailey.com)

April xx, 2014

## GeneThera, Inc. - Consolidated Balance Sheets

<b>ASSETS</b>	<b>December 31, 2013</b>		<b>December 31, 2012</b>	
Current assets				
Cash	\$	1,331	\$	1,055
Receivable-related party		15,000		5,718
Total current assets		16,331		6,773
Property and equipment				
Total property and equipment, net		12,762		46,808
Other assets		7,000		7,000
<b>TOTAL ASSETS</b>	<b>\$</b>	<b>36,093</b>	<b>\$</b>	<b>60,581</b>
<b>LIABILITIES &amp; STOCKHOLDERS'</b>				
<b>DEFICIT</b>				
Current liabilities				
Accounts payable	\$	1,191,148	\$	1,035,436
Accounts payable-related party		314,652		173,573
Accrued expenses		2,261,572		1,877,547
Notes payable		10,800		10,800
Convertible notes payable		895,162		882,716
Loan from shareholder		645,271		645,271
Total liabilities		5,318,605		4,625,343
Stockholders' deficit:				
Series A preferred stock, par value \$0.001 per share, 20,000,000 shares authorized, 4,600 shares and 4,600 shares issued and outstanding as of December 31, 2013 and 2012, respectively		5		5
Series B preferred stock, par value \$0.001 per share, 30,000,000 shares authorized, 15,410,000 and 6,320,000 shares issued and outstanding as of December 31, 2013 and 2012, respectively		15,410		15,410
Common stock, par value \$0.001 per share, 300,000,000 shares authorized, 31,481,590 and 25,960,596 shares issued and outstanding as of December 31, 2013 and 2012, respectively		31,481		25,960
Additional paid-in capital		18,071,371		17,743,332
Accumulated deficit		(23,403,279)		(22,346,418)
Total stockholders' deficit of Genethera, Inc.		(5,282,512)		(4,561,711)

Non-controlling interest		(3,051)
Total stockholders' deficit	(5,282,512)	(4,564,762)
<b>TOTAL LIABILITIES &amp; STOCKHOLDERS' DEFICIT</b>	<b>\$ 36,093</b>	<b>\$ 60,581</b>

See accompanying notes to consolidated audited financial statements.

**GeneThera, Inc. - Consolidated Statements of Operations**

	<b>Year Ended December 31,</b>	
	2013	2012
Expenses		
Consulting	\$ -	\$ 240,000
General and administrative expenses	682,686	670,331
Payroll expenses	384,000	357,750
Depreciation	15,538	36,288
Equipment write-down	-	355,792
Laboratory expenses	17,736	147,228
Total operating expenses	1,099,960	1,807,389
Loss from operations	1,099,960	1,807,389
Other expenses		
Interest expense	-	1,072
Loss (Gain) on disposal of assets	(50,793)	
Foreign exchange loss	10,681	3,331
Total other expense	(40,112)	4,403
Net loss	\$ (1,059,848)	\$ (1,811,792)
Net loss attributable to non-controlling interest	\$ (2,987)	\$ 20,382
Net loss attributable to Genethera, Inc.	\$ 1,056,861	\$ 1,791,410
Loss per common share - Basic and diluted	\$ (0.04)	\$ (0.07)
Weighted average common shares outstanding - Basic and diluted	28,825,496	25,041,880

See accompanying notes to consolidated audited financial statements.





**GENETHERA, Inc. CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS DEFICIT****For the years ended December 31, 2013 and 2012**

	Series A Preferred Stock	Series B Preferred Stock	Common Stock	Additional Paid-in	Accumulated	Non- Controlling	Total
	Shares	Shares	Shares	Capital	Deficit	Interest	Equity
Balance at December 31, 2011	4,600	515,410,000	15,410,596	23,710,582	(20,555,008)	17,331	(3,017,970)
Issuance of common stock for cash	-	-	1,250,000	23,750	-	-	25,00
Shares issued for consulting services	-	-	1,000,000	1,250	239,000	-	240,000
Net loss	-	-	-	-	(1,791,410)	(20,382)	(1,811,792)
Balance at December 31, 2012	4,600	515,410,000	25,960,596	17,743,332	(22,346,418)	(3,051)	(4,564,762)
Issuance of common stock for cash	-	-	1,000,000	1,000	(800)	-	200



## GeneThera, Inc. - Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2013	2012
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,059,848)	\$ (1,811,792)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	333,306	-
Depreciation and amortization	15,538	36,288
Shares issued for services	-	240,000
Loss (Gain) on disposal of assets	(50,793)	355,792
Changes in operating assets and liabilities:		
Accounts receivable - related parties	(2,827)	3,500
Accounts payable - related parties	-	173,212
Accounts payable and accrued expenses	625,936	397,589
<b>Net cash used in operating activities</b>	<b>(138,688)</b>	<b>(605,411)</b>
<b>Cash flows from investing activities</b>		
Cash used in Mexico subsidiary	(725)	
Cash paid for purchase of property and equipment	-	(45,482)
<b>Net cash used in investing activities</b>	<b>(725)</b>	<b>(45,482)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of stock	200	25,000
Net advance from related parties	141,079	-
Capital contribution by non-controlling interest to Applied Genetics	-	55,468
Proceeds from convertible notes	-	575,497
<b>Net cash provided by financing activities</b>	<b>141,279</b>	<b>655,965</b>
Net effect of exchange rates change	(1,590)	(5,453)
<b>Net increase in cash</b>	<b>276</b>	<b>(381)</b>
<b>Cash at the beginning of the year</b>	<b>\$ 1,055</b>	<b>\$ 1,436</b>
<b>Cash at the end of the year</b>	<b>\$ 1,331</b>	<b>\$ 1,055</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$ -	-
Cash paid for income taxes	\$ -	-
<b>Non-cash investing and financing transactions:</b>		
Equipment purchased on credit	\$ -	355,792
Conversion of convertible notes payable to common stock	\$ -	-

See accompanying notes to consolidated audited financial statements



**GENETHERA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2013**

**Note 1 Organization, nature of operations and summary of significant accounting policies**

*Organization and nature of operations*

The consolidated financial statements include GeneThera, Inc. and its wholly owned subsidiary GeneThera, Inc. (Colorado) (collectively GeneThera or the Company ). In addition, the Company has a 90% ownership (increased from 50% on January 2, 2012) in Applied Genetics S.A. de C.V. ( Applied Genetics ), a Mexico Company which was formed on September 28, 2007, but which had no business activities until 2012.

GeneThera is a biotechnology company that develops molecular assays for the detection of food contaminating pathogens, veterinary diseases and genetically modified organisms.

*Use of estimates*

The preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. There were no revenues from the subsidiary in Mexico due to lack of reliable funding.

*Cash and cash equivalents*

Cash equivalents are highly liquid investments with an original maturity of three months or less.

***Principles of consolidation***

The consolidated financial statements include the accounts of the Company, its controlled subsidiary and our subsidiary which we own 90% of and are the primary beneficiary. Our Mexican subsidiary was shut down due to lack of funding in 2013 and all assets abandoned.

***Property and equipment, net***

Property and equipment consists primarily of office and laboratory equipment and leasehold improvements and is stated at cost. Depreciation is computed on a straight-line basis over the estimated useful lives ranging from five to seven years. Leasehold improvements are amortized over the shorter of their economic lives or lease terms.

### ***Impairment of long-lived assets***

The Company reviews the recoverability of its long-lived assets to determine whether events or changes in circumstances occurred that indicate the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the asset from the expected future cash flows of the related operations. If these cash flows are less than the carrying value of such asset, an impairment loss is recognized for the difference between the estimated fair value and carrying value. The measurement of impairment requires management to make estimates of these cash flows related to long-lived assets, as well as other fair value determinations.

### ***Revenue recognition***

Research and development contracts are on a pre-paid basis in order to reflect milestones during research investigation. Revenues are recognized when services are completed. There were no revenues during the years ended December 31, 2013 and 2012.

### ***Stock-Based Compensation***

Stock-based compensation is accounted for under FASB ASC Topic No. 718 *Compensation - Stock Compensation*. The guidance requires recognition in the financial statements of the cost of employee services received in exchange for an award of equity instruments over the period the employee is required to perform the services in exchange for the award (presumptively the vesting period). The guidance also requires measurement of the cost of employee services received in exchange for an award based on the grant-date fair value of the award. The Company accounts for non-employee share-based awards in accordance with guidance related to equity instruments that are issued to other than employees for acquisition, or in conjunction with selling, goods or services.

### ***Income taxes***

Income taxes are accounted for in accordance with the provisions of FASB ASC Topic No. 740 - *Income Taxes*. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

*Basic and diluted net loss per common share*



Basic and diluted net loss per share calculations are presented in accordance with FASB ASC Topic No. 260 *Earnings per Share*, and are calculated on the basis of the weighted average number of common shares outstanding during the period. Diluted net loss per share calculations includes the dilutive effect of common stock equivalents in years with net income. Basic and diluted loss per share is the same due to the absence of common stock equivalents.

***Fair value of financial instruments***

The carrying value of cash, accounts payable and accrued expenses approximates fair value due to the short term nature of these accounts.

***Recently issued accounting pronouncements***

The Company does not expect the adoption of any recently issued accounting pronouncements to have a significant effect on its consolidated financial position or results of operations.

**Note 2- Going Concern**

As reflected in the accompanying consolidated financial statements, the Company has an accumulated deficit of \$23,416,418 and negative working capital of \$5,323,951 as of December 31, 2013. This raises substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital and implement its business plan. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Management believes that actions presently being taken to obtain additional funding and implement its strategic plans provide the opportunity for the Company to continue as a going concern.

**Note 3 Accrued expenses**

The following is the breakdown of the Company's accrued expenses as of December 31, 2013 and 2012:

	2013	2012
	\$	
	\$	
Accrued officer salaries	2,130,904	1,746,904
Accrued interest	24,237	24,237
Accrued expenses- other	106,431	106,406
	\$	\$
Total accrued expenses	2,261,572	1,877,547

**Note 4 Related party transactions**

The Company has an outstanding loan payable to Antonio Milici, its CEO and shareholder amounting to \$645,271 as of December 31, 2013 and 2012, respectively. This outstanding loan to the Company is unsecured and non-interest bearing.

The Company issued 6,400,000 Series B Preferred shares to its CEO during 2011; these shares were issued as restitution for the CEO converting 1,000,000 Preferred shares ( Series B ) into 10,000,000 common shares in 2009. The 6,400,000 Preferred shares ( Series B ) are convertible into common shares (see note 7). The Preferred shares were valued using a price of \$0.05, which is 10 times the stock price of \$0.005, the Company's stock price on the date of issuance. The Company recorded a total of \$320,000 in restitution expense.

The Company issued 2,690,000 Series B Preferred shares to its CFO during 2011; these shares were issued for compensation. The Preferred shares ( Series B ) are convertible into common shares (see note 7). The Preferred shares were valued using a price of \$0.05, which is 10 times the stock price of \$0.005, the Company's stock price on the date of issuance. The Company recorded a total of \$134,500 in compensation expense.

As of December 31, 2013, the Company still owes Setna Holdings, a related party \$173,573. The total is non- interest bearing and due on demand.

The Company has amounts receivable from these related parties of \$15,000 and \$5,718 as of December 31, 2013 and 2012, respectively.

#### **Note 6 Convertible notes payable**

During 2011, the Company received \$392,267 in total from a single investor, plus \$10,800 issued to other investors. These amounts are repayable on demand with 8% interest. \$85,048 was converted into common shares during 2011, leaving a balance of \$318,020 principal and \$21,975 accrued interest as of December 31, 2011. These amounts were converted into common shares during 2011. There are no payments owed on these notes. As of December 31, 2013, the Company does not owe any principle amount of \$882,716 to single investor due to the escrow agreement stipulation of All or nothing; and 10,800. There is no accrued interest as of December 31, 2012 is \$24,237.

On September 8, 2011, an investor agreed to invest a total of \$1,000,000 on or before September 30, 2012, and was to receive their 24,000,000 common shares back upon the completion of such investment at a share price of \$0.0416. To date, the investor has invested \$882,716, this has been invested in the form of escrow agreement; there were no convertible notes to date because they had to invest the additional \$1M to get those shares. The Company evaluated the embedded conversion features within the convertible debt under ASC 815 Derivatives and Hedging and determined the embedded conversion feature should be classified in equity. On September 30, 2012, Gold X Change defaulted on the Escrow Agreement by failing to complete the \$1 million investment stipulated on the Escrow Agreement on that specific period of time. No extension was granted and no settlement agreement has been reached.

On **December 11, 2013**, the Company signed a Subordinated Convertible Promissory Note with Bruiser Investments, LLC in the amount of \$15,000. Currently, the entity opted to do conversion to GTHR stock.

The Company has also recognized \$2,500 beneficial conversion feature relating to the convertible debt.

**Note 7- Shareholders equity**

*Convertible preferred stock rights*

Preferred Stock ( Series A ) shall be convertible into Common Stock any time at the holder s sole discretion in part or in whole by dividing the Purchase Price per Share by 110% of the Market Value on the Closing Date. Market Value on any given date shall be defined as the average of the lowest three intra-day trading prices of the Company s common stock during the 15 immediately preceding trading days.

Preferred Stock ( Series B ) shall be convertible into ten common shares at any time and holders are entitled to 20 common share votes per such preferred share.

The Company analyzed Preferred Stock ( Series A and B ) for embedded conversion option for derivative accounting consideration under ASC 815-15 Derivatives and Hedging and determined that the conversion options should be classified as equity.

Because it is theoretically possible that full conversion of all convertible preferred and convertible notes would exceed the authorized number of common shares, the CEO and majority shareholder has agreed not to convert enough preferred shares to cause such an event. This avoids derivatives valuation.

*Common stock*

For the year ended December 31, 2013

During 2013, the Company issued 5,393,294 shares valued at \$331,006 for services.

During 2013, the Company issued 127,700 shares at \$0.02 per share to settle debt of \$2,554.

For the year ended December 31, 2012

During 2012, the Company issued 1,000,000 shares valued at \$240,000 for services.

During 2012, the Company sold 1,250,000 shares at \$0.02 per share for total proceeds of \$25,000.

*2004 Equity Incentive Plan Does this still exists in our books? I think it expired a couple years ago*

\*\*\*\*The Company's 2004 Senior Executive Officer Option Plan provides for the grant of equity incentives to senior employees of the Company. A maximum of 3,000,000 common shares are available for issuance under the 2004 Plan.

**Note 8 Commitments and contingencies**

***Operating leases***

On November 30, 2010, the Company signed a 38-month lease agreement commencing on December 1, 2010. The office space is located in Westminster, Colorado. The space is approximately 9,681 square feet intended specifically for a biotechnology company's use. The base rent was free during the first and second months; another free month rate is still due to the Company thanks to the three-year lease: one free month for each year leased; \$7,000 per month during the next 12 months; \$10,970 during the following 12 succeeding months; and \$12,584 during the last 12 months, for a total guaranteed base rent of \$366,648 during the 38-month lease term. This lease expires on January 31, 2014 and required a security deposit of \$7,000. The Company is in the process of renewing this lease for an additional 6 years at \$7,000 per month lease payment throughout the duration of the first three years of the lease; the remaining three years would be negotiated in 2017.

During 2011, the Company signed a 62 month lease commencing on June 13, 2011 for 3,100 square feet of space in Monterrey, Mexico. The base rent was free during the first and second months and approximately \$3,000 per month thereafter.

Years ended December 31	Operating Leases
2014	67,412
2015	54,828
Thereafter	27,414
	\$
Total minimum lease payments	149,654

Total rent expense for 2013 and 2012 was \$149,394 and \$182,498, respectively.

***Employment agreements***

On January 8, 2012, the Company entered into an employment agreement with its chief executive officer and scientific officer for a five year term and providing for compensation of \$18,000 per month. On the same date, the Company also entered into an employment agreement with its chief administrative and financial officer for a five year term and providing for compensation of \$14,000 per month. Both employment contracts expire on January 7, 2017.

*Legal contingencies*

The Company is involved in claims arising during the ordinary course of business resulting from disputes with vendors and shareholders over various contracts and agreements.

**Note 9 Income taxes**



The Company has no current or deferred income tax due to its operating losses.

The Company has a federal net operating loss carry forward at December 31, 2013 and 2012 of \$9,741,795 and \$9,027,598, respectively, subject to Section 382 annual limitations prescribed by the Internal Revenue Code, that are available to offset future taxable income through 2029. Net deferred taxes are \$3,409,628 and \$3,159,659 as of December 31, 2013 and 2012. A 100% valuation allowance has been recorded to offset the net deferred taxes due to uncertainty of the Company's ability to generate future taxable income.

#### **Note 10 Subsequent events**

On **February 7, 2014**, the Company signed a Convertible Note with Richard Dupuis Logging, Inc. in the amount of \$10,000. The investor opted to do conversion to GTHR stock.

On **March 18, 2014**, the Company signed a Subordinated Convertible Promissory Note with Elliott's Stone Work, LLC in the amount of \$10,000.00.

On **April 8, 2014**, the Company signed a Subordinated Convertible Promissory Note with Bruiser Investments, LLC in the amount of \$10,000.00.

On **April 10, 2014**, the Company signed a Subordinated Convertible Promissory Note with Richard Dupuis Logging, Inc. in the amount of \$15,000.00.



**ITEM 9:**

**CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A:**

**CONTROLS AND PROCEDURES**

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the Exchange Act ) as of the end of the period covered by this Annual Report on Form 10-K. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on our evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting to ensure we maintain an effective internal control environment. There were no changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) 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. 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.

Management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control over Financial Reporting - Guidance for Smaller Public Companies.

There were no changes in our internal controls over financial reporting during the December 31, 2013. Based on our assessment and those criteria, our management believes that the Company does not maintain effective internal control over financial reporting as of December 31, 2013. We concluded that our internal controls are ineffective as the company has limited segregation of duties, insufficient written policies & procedures, and Inadequate financial statement closing process resulting in multiple audit adjustments .We will continue to improve the effectiveness of our internal controls.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report

### **PART III**

#### **ITEM 10:**

#### **DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

##### **DIRECTORS AND EXECUTIVE OFFICERS**

The following persons are currently serving as the Company s executive officers and directors.

Name

Age

Positions

Dr. Tony Milici

58

Chairman of the Board, Chief Executive

Officer and Chief Scientific Officer

Tannya L. Irizarry

54

Chief Financial Officer (Interim)

Dr. Antonio Milici founded GeneThera, Inc. in 1998 and has served as its Chairman and CEO since inception. Prior to founding GeneThera, Dr. Milici served as CEO and President of Genetrans, Inc., a genetic diagnostic company from 1993 to 1998. Dr. Milici was also an assistant professor in the department of Molecular Pathology at the University of Texas M.D. Anderson Cancer Center.

Tannya L. Irizarry served as Chief Administrative Officer from 1999 to Present. Since May 2007, she has served as Chief Financial Officer (Interim) of the Company. Ms. Irizarry has over 22 years of experience in medical technology and biotechnology industries. Ms. Irizarry worked at the University of Texas M.D. Anderson Cancer Center in the department of Neuro-Oncology with Dr. William S. Fields and the Office of Education with Dr. James Bowen. She also worked at the Medical College of Georgia and subsequently, at the St. Joseph Hospital in the biotechnology division. Ms. Irizarry was the Vice President of Genetrans, Inc. from 1994 to 1998. Ms. Irizarry relocated to Colorado in order to manage GeneThera, Inc. at the request of Dr. Milici.

Each Director is elected at the Company's annual meeting of shareholders and holds office until the next annual meeting of shareholders and/or until the successors are elected and qualified. At present, the Company's bylaws provide for not less than three or more than seven Directors. The Company is seeking new successors to complete our number of directors.

#### **SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our Executive Officers, Directors and 10% Shareholders to file reports regarding initial ownership and changes in ownership with the SEC. Executive Officers, Directors, and 10% Shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Our information regarding compliance with Section 16(a) is based solely on a review of the copies of such reports furnished to us by our Executive Officers, Directors and 10% Shareholders. These forms include (i) Form 3, which is the Initial Statement of Beneficial Ownership of Securities, (ii) Form 4, which is a Statement of Changes in Beneficial Ownership, and (iii) Form 5, which is an Annual Statement of Changes in Beneficial Ownership.

The Company has adopted a Code of Ethics applicable to its principal executive officer, principal financial officer, and principal accounting officer. Our Code of Ethics can be obtained by calling the Company at 303-439-2085.

#### **ITEM 11:**

#### **EXECUTIVE COMPENSATION**

#### **SUMMARY COMPENSATION TABLE**

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The following table sets forth certain summary information for the fiscal years ended December 31, 2013, 2012, and 2011 concerning the compensation awarded to, earned by, or paid to those persons serving as Chief Executive Officer and Chief Financial Officer of the Company during those years (the Named Executive Officers). No other executive officer of the Company had a total annual salary and bonus for the years presented that exceeded \$100,000. Antonio Milici, M.D., Ph.D., and Tannya L. Irizarry were the only executive officers during the year ended December 31, 2013.

The following table also summarizes the annual and long-term compensation paid to Dr. Tony Milici, our Chief Executive Officer. Except for Dr. Milici, no other executive officer received annual remuneration in excess of \$100,000 during 2013 or 2012. This summary compensation table shows certain compensation information for services rendered in all capacities during each of the last two completed fiscal years.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
<b>Dr. Tony Milici</b> <b>Chief Executive Officer</b>	2010	\$144,000							\$144,000
	2011	\$144,000							\$144,000
	2012	\$168,000							\$168,000
	2013	\$216,000							\$216,000
		\$							\$
<b>Tannya Irizarry</b> <b>Chief Financial Officer</b>	2010	90,000		45,000					\$135,000
	2011	\$90,000		45,000					\$135,000
	2012	\$90,000		45,000					\$135,000
	2013	\$123,000		45,000					\$168,000

Does not include perquisites and other personal benefits in amounts less than 10% of the total annual salary and other compensation. No executive officer of the Company received any Non-Equity Incentive Plan Compensation or Nonqualified Deferred Compensation Earnings during the periods presented.





No other officer or director received in excess of \$100,000 for the years ending December 31, 2013, December 31, 2012, and December 31, 2011.

**Board of Directors Compensation:**

The following table sets forth summary information concerning the compensation we paid to directors during the year ended December 31, 2013:

NAME	FEES EARNED OR PAID IN CASH (\$)	OPTION AWARDS (\$)	TOTAL (\$)
------	-------------------------------------	--------------------	------------

No Director received any Stock Awards, Non-Equity Incentive Plan Compensation, Nonqualified Deferred Compensation Earnings or other Compensation other than what is disclosed above during the year ended December 31, 2013.

(1) Dr. Milici did not receive any compensation separate from the consideration he received as an officer of the Company for the year ended December 31, 2013 in consideration for his service to the Board as a Director of the Company.

**COMPENSATION OF DIRECTORS AND EXECUTIVE OFFICERS**

On January 8, 2012, the Company entered into an employment agreement with Antonio Milici, M.D., Ph.D., to serve as the Chief Executive Officer and Chief Scientific Officer of the Company through January 7, 2017. Unless either party gives notice to terminate the agreement at least thirty days prior to expiration of the agreement, the agreement will automatically be extended for an additional two year period. In consideration for his services, Dr. Milici receives a base salary of \$216,000 per annum throughout the term of the agreement plus bonuses as may be determined by the Compensation Committee of the Board of Directors in its discretion or if the Company achieves net income in excess of \$2,000,000 per year. As part of his employment agreement, Dr. Milici has agreed not to compete with the Company, solicit any of its customers or solicit any of its employees for a period of two years after the term of the agreement. Dr. Milici is also subject to confidentiality obligations in favor of the Company and has agreed to transfer

to the Company all of his interests in any idea, concept, technique, inventory or written work developed by him during the term of his employment agreement. The Company also provides a company vehicle and gas allowance for him and his scientific consultants. No director received compensation for his services to the Company.

On January 8, 2012, the Company entered into an employment agreement with Tannya L Irizarry to serve as the Chief Administrative Officer and Chief Financial Officer (Interim) of the Company until January 31, 2017. Unless either party gives notice to terminate the agreement

at least thirty days prior to expiration of the agreement, the agreement will automatically be extended for an additional two year period. In consideration for her services, Ms. Irizarry receives a base salary of \$123,000 per annum throughout the term of the agreement plus \$45,000 worth on common stock issuance every March of every year of her employment agreement. If the Company achieves net income in excess of \$2,000,000 per year, Ms. Irizarry is entitled to a company vehicle, gas expenses, and auto repairs. No director received compensation for her services to the Company.

**ITEM 12:****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS**

The following table sets forth certain information concerning the beneficial ownership of our outstanding classes of stock as of December 31, 2013 by each person known by us to be (i) the beneficial owner of more than 5% of the outstanding shares of common stock, (ii) each current director and nominee, (iii) each of the executive officers who were serving as executive officers at the end of the December 31, 2013 fiscal year and (iv) all of our directors and current executive officers as a group. Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and investment power with respect to their shares of common stock except to the extent that authority is shared by spouses under applicable law. The calculation of percentage ownership for each listed beneficial owner is based upon the number of shares of common stock issued and outstanding on December 31, 2013, plus shares of common stock subject to options, warrants and conversion rights held by such person on December 31, 2013, and exercisable or convertible within 60 days thereafter. Unless otherwise indicated, the address of each person or entity named below is c/o GeneThera, Inc., 7577 W. 103<sup>rd</sup> Ave. Unit 212, Westminster, CO 80021.

Name of Beneficial Owner	Number of Shares Beneficially Owned (1)	Percent of Class
<b>Five Percent Shareholders:</b>		
Shawn T. Donahue	1,627,557	0.07%
Gold X Change, Inc.	4,003,860	0.08%
<b>Directors and Executive Officers:</b>		
Dr. Antonio Milici	-	-
Tannya L. Irizarry	-	-
<b>All Directors and Executive Officers as a Group</b>	5,631,417	0.15%

This table is based upon information supplied by officers, directors and principal shareholders and Schedules 13D and 13G filed with the SEC. Unless otherwise indicated in the footnotes to this Table and subject to community property laws where applicable, the Company believes that each of the shareholders named in this Table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 31,481,590 shares of common stock outstanding on December 31, 2013, adjusted as required by rules promulgated by the SEC.

**SERIES B PREFERRED STOCK**

Name of Beneficial Owner (1)	Common Stock Beneficially Owned (2)		Voting Preferred Stock Beneficially Owned (2)	
	Number	Percent	Number	%
Antonio Milici	0	0.00%	11,220,000	73%
Tannya L. Irizarry (3)	0	0.00%	4,190,000	27%
All Directors and Officers as a Group (2 persons)	0	0.00%	15,410,000	100%

This table is based upon information supplied by officers, directors, and principal shareholders and documents filed with the SEC. Unless otherwise indicated and subject to community property laws, if applicable, the Company believes that each of the shareholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

Applicable percentages are based on 31,481,590 shares of common stock outstanding and on 15,410,000 shares of Series B Preferred Stock outstanding on December 31, 2013, adjusted as required by rules promulgated by the SEC. Although the Series A Preferred Stock is convertible into approximately 7.2 million shares of our common stock (assuming all shares were converted as of the date of this filing), this Table does not give effect to the Series A Preferred Stock because these shares have no voting rights and their convertibility by the holder is currently being contested by the Company.

Ms. Irizarry is married to Dr. Antonio Milici. Therefore, she has a beneficial interest in his shares.

**ITEM 13:**

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

**Director Independence**

The Company is not required to have independent Directors, but will seek to appoint independent Directors, if and when it is required to do so.

**ITEM 14:**

**PRINCIPAL ACCOUNTING FEES AND SERVICES**

**AUDIT FEES**

The aggregate fees billed for each of the last two fiscal years for professional services rendered by our principal accountant for the audit of the Company's annual financial statements and review of financial statements included in the Company Form 10-K was as follows:

2011 \$18,000

2012 \$28,500

2013 \$15,400

**AUDIT-RELATED FEES**

None

**TAX FEES**

None

**ALL OTHER FEES**

None

The Company's audit committee, which consists of all directors, approved the services described above.





**ITEM 15:**

**EXHIBITS, FINANCIAL STATEMENTS**

**Exhibit   Description of Exhibit  
Number**

10.1(1)   Marketing and Sale Agreement

21.1\*   Subsidiaries

31.1\*   Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.

31.2\*   Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act.

32.1\*   Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act

32.2\*   Certification of Principal Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act

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

\* Filed herewith.

\*\* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

(1) Filed as an exhibit to our Report on Form 8-K, filed with the Commission on March 5, 2012 and incorporated herein by reference.



**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 31<sup>st</sup> day of January, 2014.

GeneThera, Inc.

By: /s/ Antonio Milici

Antonio Milici, MD, PhD

President

(Principal Executive Officer)

By: /s/ Tannya L. Irizarry

Tannya L. Irizarry

Chief Financial Officer (Interim)

(Principal Financial/Accounting Officer)

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

<b><u>Signature</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
/s/ Antonio Milici Antonio Milici, M.D., PhD.	President, Director	1/31/2014
/s/ Tannya L. Irizarry Tannya L Irizarry	Chief Financial Officer (Interim)	1/31/2014