ProtoKinetix, Inc.
Form 10-K
March 09, 2018

U. S. 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, 2017

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

For the transition period from _____ to _____

Commission File Number: 000-32917

PROTOKINETIX, INCORPORATED
(Name of small business issuer as specified in its charter)

Nevada	94-3355026
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

412 Mulberry Street
Marietta, Ohio 45750
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code:	**304-299-5070**
Securities registered pursuant to Section 12(b) of the Act:	**None**
Securities registered pursuant to Section 12(g) of the Act:	**$.0000053 par value common stock**

_____

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

(§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). þ Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $ 13,337,413 based upon the closing price of our common stock which was $0.074 as of June 30, 2017, the last business day of the Company's most recently completed second fiscal quarter. Shares of common stock held by each officer and director and by each person or group who owns 10% or more of the outstanding common stock amounting to shares have been excluded in that such persons or groups may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 8, 2018, there were 254,711,673 shares of our common stock that were issued and outstanding.

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PROTOKINETIX, INCORPORATED

PART I

ITEM 1. BUSINESS

ProtoKinetix, Incorporated ("ProtoKinetix," "we," "us," "our," or the "Company") is a research and development stage bio-technology company focused on scientific medical research of AFGPs (Anti-Freeze Glycoproteins) or anti-aging glycoproteins, trademarked as AAGPs™. The Company has recently been in the process of directing major efforts to the practical side of commercial validation. The commercial applications for AAGPs™ in large markets such as targeted health care solutions are numerous, and ProtoKinetix is currently working with researchers, business leaders and advisors and commercial entities to bring AAGP™ to market.

ProtoKinetix was incorporated as RJV Network, Inc. under the laws of the State of Nevada on December 23, 1999 for the primary purpose of developing an internet-based listing site that would provide detailed commercial real estate property listings and related data. In July 2003, the Company entered into an assignment of license agreement with BioKinetix Research, Incorporated for the assignment of rights relating to proprietary technologies of BioKinetix Research, Incorporated for the creation and commercialization of "superantibodies." On July 8, 2003, the Company changed its name to "ProtoKinetix, Incorporated."

The Company's executive (or corporate) offices are located at 412 Mulberry Street, Marietta, Ohio 45750. Our telephone number is (304) 299-5070 and our website is www.protokinetix.com.

Cautionary Note Regarding Forward-Looking Statements

The information discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as well as some statements in press releases and some oral statements of the Company's officers during presentations about the Company include "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). All statements, other than statements of historical facts, included herein and therein concerning, among other things, planned capital expenditures, future cash flows and borrowings, pursuit of potential acquisition opportunities, our financial position, business strategy and other plans and objectives for future operations, are forward looking statements. These forward looking statements are identified by their use of terms and phrases such as "may," "expect," "estimate," "project," "plan," "believe," "intend," "achievable," "anticipate," "will," "continue," "potential," "should," "could," and similar terms and phrases. Although we believe that the expectations reflected in these forward looking statements are reasonable, they do involve certain assumptions, risks and uncertainties and are not (and should not considered to be) guarantees of future performance. Our results could differ materially from those anticipated in these forward looking statements as a result of certain factors, including, among others:

- Our capital requirements and the uncertainty of being able to obtain additional funding on terms acceptable to us;
- Our plans to develop and commercialize products from the AAGP™ molecule;
- Ongoing testing of the AAGP™ molecule;
- Our intellectual property position;
- Our commercialization, marketing and manufacturing capabilities and strategy;
- Our ability to retain key members of our senior management and key scientific consultants;
- The effects of competition;
- Our potential tax liabilities resulting from conducting business in the United States and Canada;

- The effect of further sales or issuances of our common stock and the price and volume volatility of our common stock; and
- Our common stock's limited trading history.

Finally, our future results will depend upon various other risks and uncertainties, including, but not limited to, those detailed in the section entitled "Risk Factors" included elsewhere in this Annual Report. All forward looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements in this section and elsewhere in this Annual Report. Other than as required under securities laws, we do not assume a duty to update these forward looking statements, whether as a result of new information, subsequent events or circumstances, changes in expectations or otherwise.

BACKGROUND

Native AFGP Compound

AFGP (Anti-Freeze Glycoprotein) is found in nature as a compound produced by some fish, insects, reptiles, bacteria and plants that enable survival in freezing temperatures.

One of the many accomplishments from pioneering research of the U.S. Antarctic Program was the discovery, in the early sixties, that fish living year-long in subzero temperature are extremely resistant to freezing. The substances that prevent these fish from freezing were isolated, characterized and designated as AFGP. Various kinds of AFGP were isolated from many species of fishes, and in some amphibians, plants and insects. All of the AFGPs share a common characteristic that prevents ice crystals from growing and connecting to each other. Research has also confirmed a cell membrane stabilizing characteristic of native AFGP.

There has been much scientific research done in an attempt to synthetically replicate AFGPs in research institutions because the protective properties of AFGPs could have commercial applications, primarily in food and crop preservation at freezing temperatures. The native antifreeze glycoproteins are very large molecules that are often made up of a repeating series of smaller molecules, glycoproteins. Glycoproteins are often very biologically active, but they are inherently unstable. The oxygen-glycosidic link is readily cleaved by glycosidases, resulting in a low bio-availability of these glycoconjugate based molecules.

Scientific research prior to AAGP™ has focused on building a stable and more efficient compound with a strong bond.

AAGP™ – The Core Technology of ProtoKinetix

AAGP™ Invention

Dr. Geraldine Castelot-Deliencourt, along with Dr. Jean-Charles Quirion at the Research Institute of Organic Chemistry in Rouen, France, developed a patented process to stabilize the oxygen-glycosidic bond in these sugar based molecules. This patented process replaces the weaker oxygen bond with a $C\text{-}F_2$ mimetic. The resultant molecules are biologically active and stable over a pH range of 2 to 13. They are not broken down by glycosidases.

AAGP™ Toxicity Tests

Tests have shown that cells exposed to AAGP™ at low and high concentrations have remained viable. A common viability test used on cell cultures using trypan blue dye exclusion method has been used to show AAGP™ non-toxicity.

AAGP™ Stability Tests

AAGP™ molecules have remained stable when subjected to three tests:

1. pH ranging from a strong acid level of 1.8 (stronger than stomach acid) to a strong alkali level of 13.8. (the pH scale is calibrated from 1, highly acidic, to 14, highly alkali);

2. Enzymatic action using protease, which targets the amino acid bonds, and glycosidase, which targets the amino acid bonds, and glycosidase, which targets the sugar molecules; and

3. Temperatures ranging from -196°C (cryopreservation) to +37°C (body temperature).

Stress Tests on 12 Different Cell Lines

Cell lines are selected for their high level of sensitivity. Cell lines are also selected for their potential role in adding value in medical applications, enhancing health and extending life. All tests are designed to explore how cells from different cell lines act biologically in the presence of AAGP™ when subjected to health and life threatening inflammatory stress conditions and agents.

Cell Lines Tested

§ Stem cells (human)
§ Whole blood cells
§ Blood Platelet cells
§ Heart tissue
§ Hela (cancer) cells
§ Kidney (vero) cells
§ Adult skin fibroblast cells
§ Heart cells (cardiac myocytes)
§ Liver cells (hepatocytes)
§ Embryonic skin fibroblast cells
§ Islet cells (pancreatic)
§ Stem cells (mouse)

Stress Conditions and Agents

Temperature
§ temperatures ranging from -80° C to +37° C

UV-C Radiation
§ harsh sterilizing radiation
§ 254 nanometer wavelength

Oxidation
§ hydrogen peroxide (H_2O_2)
§ powerful oxidant

Starvation
§ serum free culture media
§ food/growth/nutrients factors (fetal bovine serum) withheld

Inflammation
§ Interleukin 1 Beta, a standard agent for stimulating inflammation in cell testing

Nonclinical Efficacy Testing (Human Islets)

For the last five years, AAGP™ testing has been conducted pursuant to a comprehensive transplantation testing program in conjunction with the University of Alberta transplant research team. The Company entered into a consulting agreement in May 2015 with Dr. James Shapiro to collaborate with the James Shapiro Laboratory at the University of Alberta in Edmonton, Alberta, Canada. Dr. Shapiro directs the largest clinical islet transplantation program in the world. Dr. Shapiro and his team have conducted extensive testing with our AAGP™ molecule using human islet cells in transplantation, investigating its effect on engraftment, insulin production, protective effect against anti-rejection drugs and investigation of the mechanism of action. The results provided consistent encouragement to continue testing to develop protocols that can be applied to transplantation medicine. In December of 2016, the Governors of the University of Alberta submitted an Investigational Testing Authorization Application To Health Canada to evaluate the safety and efficacy of transplantation of AAGP™ treated human islets as an addition to the already established Edmonton Protocol for the treatment of Type 1 Diabetes.

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Additional studies will be expanded to include whole organ transplantation and other cell therapies used in regenerative medicine.

AAGP™ testing is conducted to international standards in outsourced research laboratories in North America and Europe. All tests are designed to explore both the safety and effectiveness of AAGP™ when challenged to enhance the health and extend the life of cells.

Allogeneic transplantation is the transplanting of cells, tissues or organs from the same species, but from a donor different than the recipient. Serious issues that have to be addressed are the engraftment of the transplanted organ or cells and the subsequent protection against the immune rejection of the foreign organ or cells. The protection, in the form of anti-rejection drugs, is toxic and causes damage to the graft. AAGP™ has been shown in these nonclinical studies to increase engraftment and reduce the toxicity damage.

Dr. Shapiro and his team are developing further testing based on three primary activities:

1. The ongoing testing and refinement of cellular transplantation using human islet cells as the demonstrated model. In particular, AAGP™ may provide powerful protection against hostile agents that severely inhibit engraftment success. Cell therapies are currently being developed in the industry around the world for the treatment of spinal cord injury, damaged heart tissue, stroke, diabetes as well as many other conditions.
2. Human organ preservation. The program will assess the effect of AAGP™ in extending the transplant viability of donor organs. The Canadian National Transplant Research Program is a major national initiative involving the Federal Institutes of Health, all Provinces and the private sector (see http://www.cntrp.ca/). The first testing will be conducted on livers to determine whether AAGP™ can extend the ex-vivo functionality of the organ.
3. Auto immune disease. This class of diseases occur where the body's immune system starts to attack healthy cells and organs. Diseases in this category include, rheumatoid arthritis, multiple sclerosis and Type 1 diabetes. Using the Non Obese Diabetic (NOD) mice as a model, the Edmonton team will be specifically assessing the potentially protective effect of AAGP™ against the immune system attacks against the islet cells in the pancreas.

The Governors of the University of Alberta submitted an Investigator Sponsored Clinical Trial Application to Health Canada. This trial will be conducted by Dr. Shapiro and his team at the University of Alberta on the well-established, Edmonton Protocol used for treatment of Type 1 Diabetes through islet cell transplants. Subsequent to December 31, 2016, the Investigator Sponsored Clinical Trial Application was approved by Health Canada. In preparation for the Phase 1 / 2 clinical trials as well as for the Clinical Trial Application, ProtoKinetix has:

- Completed the production of AAGP™ under strict GMP (Good Manufacturing Practice) standards as required by Health Canada and US FDA (United States Food and Drug Administration) for human use;
- Completed the validated sterilization and vialing of AAGP™ to become the drug product, designated PKX-001, that will be used in the clinical trials at the University of Alberta.
- Completed stability tests on AAGP™ at different temperature ranges.
- Completed genotoxicity studies under GLP (Good Laboratory Practice) at ITR Laboratories Canada, Inc..
- Completed carryover studies, to comply with the clinical test protocols, at BRI Pharmaceutical Research, Inc..
- Competed PK (Pharmacokinetics) studies at BRI Pharmaceutical Research, Inc. in Vancouver.

Nonclinical Efficacy Testing (Neuronal Retinal Cells)

During the year ended December 31, 2016, ProtoKinetix entered into a Collaborative Research Agreement with the University of British Columbia, under the guidance of Dr. Gregory-Evans, to commence testing of neuronal retinal cells in living tissue for the treatment of Macular Degeneration. AAGP™ has been tested previously in tissue culture in the lab and was found to improve the survival of cells. Dr. Gregory-Evans is taking those results and applying them to living tissue. He has established a new type of model for retinal degeneration in rabbits and is currently working on injecting neuronal stem cells plus AAGP™ to test for long term improvements in cell survival and integration into the retina that should ultimately lead to vision restoration in the animals. Project to date has shown very positive results. Final testing on this project estimated to be March 2018. Results will be evaluated. Researchers believe they will send the results to a peer review by May, 2018.

AAGP™ Commercial Applications

The extent of the value of the ProtoKinetix family of AAGPs™ is subject to investigation by commercial entities specializing in regenerative medicine, cellular and tissue therapies, organ transplantation, trauma, blood product banking, and anti-inflammation. The Company is targeting these entities in furtherance of product development.

In an ongoing collaborative project with Proactive Immune Sciences, we are testing AAGP™ in Immune Cell Cryopreservation Recovery. Results to date have been very encouraging. We are hoping to prove the functionality of cryopreserved immune cells increases with the addition of AAGP™ on the immune cell cryopreservation protocols used by Proactive Immune Sciences. Testing is ongoing. Preliminary results have been received with final results due April.

Health Care

Acute medical problems are increasingly reliant on, and benefit from, solutions that can deal with the fundamental factors of inflammation and oxidation. Both are well-known causes of life-threatening conditions and diseases, and accelerated aging. In addition, many acute medical problems are benefiting from cell therapies and transplantation of cells, tissues and time sensitive organs.

Health Care Applications of AAGP™ fall into two main categories: (i) harvesting, storage and transplanting cells, tissues and organs; and (ii) treatments for conditions and diseases caused by stress factors, including UV radiation, oxidation and inflammation. These are all areas that expand into many sub-categories of existing and future health care solutions.

AAGP™ continues to receive exposure in the industry; it was presented at the Congress of the International Pancreas and Islet Transplant Association in Melbourne, Australia in November, 2015. Currently, researchers from the University of Alberta's Faculty have completed a peer review and have been published in the prestigious, American Diabetes Association's Journal: Diabetes.

Patents

On or about January 5, 2015, the Company entered into an Assignment of Patents and Patent Application (the "Patent Assignment") between the Company and Institut National des Sciences Appliquées de Rouen ("INSA") for the assignment of certain patents and all rights associated therewith (the "Patents"). The Company and INSA had previously entered into a licensing agreement for the Patents in August 2004. The Patent Assignment transferred all of the Patents and rights associated therewith to the Company upon payment to INSA of the sum of 25,000 Euros.

Through this assignment, ProtoKinetix is now the sole owner of all issued patents of the "Gem difluorinated C-glycopeptides, their preparation and their use for the preservation of biological materials and/or in cryosurgery" family, and all the rights associated therewith. Importantly, this family includes issued patents in Canada (Patent No. CA2,558,801), England, France, and Germany (Patent No. EP1,817,329) and the United States (Patent No.

US8,394,362).

On or about April 8, 2015, ProtoKinetix entered into a Royalty Agreement (the "Agreement") between the Company and the Governors of the University of Alberta ("UAB") for the assignment of UAB's portion of certain patent applications and all rights associated therewith (the "Patent Rights"). The Agreement also grants UAB a royalty of 5% of the gross revenue from the assignment, manufacturing, sale, distribution, or licensing of the Patent Rights and any commercial products generated from the Patent Rights. The Company had a now expired irrevocable option to purchase the royalty for CAD $5,000,000 (approximately US $4,000,000) for two years from the earlier of September 1, 2015 or the first date UAB publishes its research related to the Patent Rights. UAB published its research related to the Patent Rights on November 18, 2015. The Company's option to purchase the royalty from UAB expired on September 1, 2017.

Through this assignment, the Company has gained UAB's portion of US provisional patent application no. 62/007,626, and International Patent Application no. PCT/CA2015/050509, and corresponding patent applications filed in Australia, Canada, China, Europe, India, Japan, Korea and New Zealand, as well as U.S. Patent Application no. US 14/728,535, all of which claim priority from said provisional patent application related to the use of anti-aging glycopeptides to enhance beta cell health, survival and improve transplant outcomes.

On or about April 22, 2015, ProtoKinetix entered into a Technology Transfer Agreement with Grant Young for the assignment of Mr. Young's portion of certain patent applications and all rights associated therewith. In exchange for these rights, Mr. Young was paid $10,000 in cash and a five-year warrant to purchase 6,000,000 shares of the Company's common stock at an exercise price of $0.10 per share.

Through this assignment, the Company has gained Mr. Young's portion of US provisional patent application no. 62/007,626 and applications claiming priority therefrom as well as patent issuing therefrom, related to the use of anti-aging glycopeptides to enhance beta cell health, survival and improve transplant outcomes.

On or about May 20, 2016, Grant Young assigned his intellectual property rights associated with US provisional patent application no. 62/287,657, and future applications to be derived therefrom to ProtoKinetix, thus gaining Mr. Young's rights to inventions related to the use of anti-aging glycopeptides to enhance survival of neurosensory precursor cells, and all patents issuing from and claiming priority to such application. These patent rights secure, amongst other things, key intellectual property rights to the Company's use of the AAGP™ lead compound in regenerative medicine.

The patents from INSA and patent rights from UAB and Mr. Young secure, amongst other things, key intellectual property rights to the Company's use of the AAGP™ lead compound in regenerative medicine.

Consistent with our agreements with the licensors of various technologies we license, we have no finished commercial product or products, and have received no FDA approvals for any product or diagnostic procedures. We are focused on the research and development of one lead compound known as AAGP™.

Trademarks

We filed a trademark application with the United States Patent & Trademark Office on September 15, 2005 with a registration date of August 7, 2007. The application was subsequently cancelled on March 14, 2014 because we did not file a renewal declaration. We filed a new application for registration of the mark and received approval of registration on November 7, 2017.

Subject to our available financial resources, our intellectual property strategy is to continue testing of the AAGP™ lead compound and develop marketable applications of the compound.

Trade Secrets and Know-How

The Company has developed a substantial body of trade secrets and know-how relating to the development, use and manufacture of AAGP™, including but not limited to the optimization of materials for efforts, and how to maximize sensitivity, speed-to-result, specificity, stability, purity and reproducibility.

Competition

The markets that the Company is focusing on are multi-billion dollar international industries which are intensely competitive. Many of the Company's competitors are substantially larger and have greater financial, research, manufacturing, and marketing resources.

Industry competition in general is based on the following:

§ Scientific and technological capability;
§ Proprietary know-how;
§ The ability to develop and market products and processes;
§ The ability to obtain FDA or other required regulatory approvals;
§ The ability to manufacture products that meet applicable FDA requirements, (i.e. FDA's Quality System Regulations) see also Governmental Regulation section;
§ Access to adequate capital;
§ The ability to attract and retain qualified personnel; and
§ The availability of patent protection.

The Company's ability to develop its research is in large measure dependent on having sufficient and additional resources and/or collaborative relationships.

The Company's access to capital is more challenging, relative to most of its competitors. This is a competitive disadvantage. The Company believes however that its access to capital may increase as it gets closer to the development of a commercially viable product.

The Company believes that its research has enabled it to attract and retain qualified consultants. Because of the greater financial resources of many of its competitors, the Company may not be able to complete effectively for the same individuals to the extent that a competitor uses its substantial resources to attract any such individuals.

Governmental Regulation

The Company's AAGPs™ have commercial applications in markets and circumstances that fall under government regulations ranging from none to limited to extensive.

Although there is no such immediate need to make any regulatory filing in the United States, the Company has limited or no experience with regard to obtaining FDA or other required regulatory approvals. In February 2015, the Company appointed Dr. Julia Levy to its Business and Scientific Advisory Board and intends to retain the services of additional appropriately experienced consultants. For this reason, should our research efforts continue to show promise, we will need to hire consultants to assist the Company with such governmental regulations.

As the Company continues to conduct research and testing programs, in collaboration with commercial entities, to expand and confirm the potential medical applications of AAGP™ in a number of fields, including regenerative medicine, cell therapy, blood products, and transplants, the Company intends to utilize the regulatory expertise of others, whether they are consultants or commercial entities involved on collaborative development programs with the Company.

The following discussion relates to factors that may come into play when and if the Company has a commercially viable product in an area which requires regulatory approval. These products may be regulated by the European regulatory agencies, FDA, U.S. Department of Agriculture, certain state and local agencies, and/or comparable regulatory bodies in other countries (collectively, these agencies shall be referred to as the "Agencies"). Government

regulation affects almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping. The products regulated by FDA and U.S. Department of Agriculture require some form of action by such agency before they can be marketed in the United States, and, after approval or clearance, the products must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties. The Company's proposed AAGP™ products will require government regulatory approval as a biologic agent. Such regulatory approval will be granted only after the appropriate preclinical and clinical studies are conducted to confirm efficacy and safety.

Every company that manufactures biologic products or medical devices distributed in the United States must comply with the FDA's Quality System Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with the Quality System Regulations is required before the FDA will approve an application. These requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, record keeping, and reporting of certain adverse reactions or events. The FDA regularly inspects companies to determine compliance with the Quality System Regulations and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

The Clinical Laboratory Improvement Act of 1988 prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. Although a certificate is not required for ProtoKinetix, the Company considers the applicability of the requirements of the Clinical Laboratory Improvement Act in the potential design and development of its products.

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. The extent of potentially adverse governmental regulation affecting ProtoKinetix that might arise from future legislative or administrative action cannot be predicted.

Research and Development

Our business depends on our ability to sponsor research and development activities. For the year ended December 31, 2016, the Company incurred total research and development expenses of $450,899. For the year ended December 31, 2017, the Company incurred total research and development expenses of $296,515. In order to reach the Company's goals of developing a marketable product, we will need to increase the funding of our research and development activities which at this time is limited by our ability to raise money to fund the Company.

Environmental Laws

To date, the Company has not encountered any costs relating to compliance with any environmental laws.

Employees

To date, the Company does not have any employees. The Company's President and Chief Executive Officer and the Chief Financial Officer are both engaged as consultants to the Company.

ITEM 1A. RISK FACTORS

The Company's securities are highly speculative and involve a high degree of risk, including among other items the risk factors described below. The below risk factors are intended to generally describe certain risks that could materially affect the Company and its current business operations and activities.

You should carefully consider the risks described below and elsewhere herein in connection with any decision whether to acquire, hold or sell the Company's securities. If any of the contingencies discussed in the following paragraphs or other materially adverse events actually occur, the business, financial condition and results of operations could be materially and adversely affected. In such case, the trading price of our common stock could decline, and you could lose all or a significant part of your investment.

Our Company has a lack of operating history and lack of revenues from operations. Our Company has no revenues and very limited operating history. As of the date of this Annual Report, our most significant assets are cash and our intellectual property. Our ability to successfully generate revenues from our intellectual property is dependent on a number of factors, including availability of funds to complete development efforts, to adequately test and refine our products, and to commercialize our products. There can be no assurance that we will not encounter setbacks with our products, or that funding will be sufficient to bring our products to the point of commercialization.

We are dependent on our key personnel, and the loss of any could adversely affect our business. We depend on the continued performance of the members of our management team and our Business and Scientific Advisory Board who have contributed significantly to the expertise of our team and the position of our business. If we lose the services of members of our management teams, and are unable to locate a suitable replacement in a timely manner, it could have a material adverse effect on our business. We do not expect to obtain key man life insurance for any members of management in the foreseeable future.

We may experience difficulty implementing our business plan. Our business plan is to continue with the development of the Company's intellectual property and to develop a product for sale commercially. We may require additional capital in order to develop our products for sale commercially. There can be no assurance that we would be able to obtain additional capital on reasonable terms, or at all.

We have been and expect to be significantly dependent on our collaborative agreements for the research, development and testing of AAGP™, which exposes us to the risk of reliance on the performance of third parties. In conducting our research and development activities, we currently rely, and expect to continue to rely, on numerous collaborative agreements with third parties such as contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development and commercialization activities. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operations.

We may have difficulty raising any needed additional capital. We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of revenues from operations, as well as the inherent business risks associated with our Company and present and future market conditions. Our business currently generates no revenue from operations. We will likely require additional funds to conduct research and development, establish and conduct non-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for marketing and distribution. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

We are a research and product development stage company that has not yet developed or sold any products. To date, we have not yet developed nor marketed a product. Ongoing testing of the AAGP™ molecule with three amino acids joined to a monosaccharide by a gemdiflouride bond continues to show that there is significant promise in the field of medicine of preserving cells, tissue and organs from various stresses. Tests have confirmed that the AAGP™ molecule improves the harvest of cells from cryopreservation by 30% to 120%. We believe there is a market for AAGP™ to preserve cells, particularly various stem cells, and we will continue testing with potential customers. At the same time, we are taking steps to improve the manufacturing process to reduce costs and improve purity and biochemical activity.

Even if we develop product candidates which obtain regulatory approval they may never achieve market acceptance or commercial success. Even if we develop products and obtain FDA or other regulatory approvals, our products may not achieve market acceptance among physicians, patients and third party payors and, ultimately, may not be commercially successful. Market acceptance of our product candidates for which we receive approval depends on a number of factors. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our financial results.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

The market for our product candidates is rapidly changing and competitive, and new technologies treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive. The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and our product candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others now existing or diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.

Risks Related to Product Development and Regulation

Our ability to generate revenues will be dependent on our ability to develop a product that complies with legal requirements. Although the laws and regulations of the various jurisdictions in which we may operate vary in their technical requirements and are subject to amendment from time to time, virtually all of these jurisdictions require licenses, permits, and other forms of approval. We will have to apply for, and obtain, all requisite government licenses, registrations, findings of suitability, permits and approvals necessary for us to do business in these new markets. We cannot offer any assurance that we will be able to obtain all necessary licenses, registrations, findings of suitability, permits, or approvals.

Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and product candidates could delay or limit introduction of our products and result in failure to achieve revenues or maintain our ongoing business. Our research and development activities and the manufacture and marketing of our product