10-K/A 1 pvotf_10ka.htm FORM 10-K/A

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

# FORM 10-K/A

**Amendment No. 1**

(Mark One)

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

For the fiscal year ended **January 31, 2015**

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

For the transition period from [_____] to [_____]

Commission file number **333-161157**

# PIVOT PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

| **British Columbia** | **N/A** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **1275 West 6th Avenue, Vancouver, British Columbia** | **V6H 1A6** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: **(604) 805-7783**

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

| Title of Each Class | Name of Each Exchange On Which Registered |
|---|---|
| **N/A** | **N/A** |

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

**N/A**

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 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 last 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-K (§229.405 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/A or any amendment to this Form 10-K/A.

☐

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☒ |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of Common Stock held by non-affiliates of the Registrant on July 31, 2014 was $139,908.07 based on a $0.0044 average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

Indicate the number of shares outstanding of each of the registrant's classes of common stock as of the latest practicable date.

78,763,767 common shares as of May 15, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

None.

## EXPLANATORY NOTE

This Annual Report on Form 10-K/A ("Form 10-K/A") is being filed as Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended January 31, 2015, which was filed with the Securities and Exchange Commission on May 15, 2015 (the "Original Filing").

This Form 10-K/A is being filed to:

(a) Amend the financial statements for the year ended January 31, 2015 to reflect common stock at no par value, to reflect foreign exchange on common stock issued during the year and to remove certain redundant notes to the financial statements;

(b) Amend results disclosed in the Form 10-K/A for the above noted changes to the financial statements.

For the convenience of the reader, this Form 10-K/A sets forth the Original Filing in its entirety. However, this Form 10-K/A only amends and restates the Items described above, and we have not modified or updated other disclosures presented in our Original Filing. Accordingly, this Amendment No. 1 does not reflect events occurring after the filing of our Original Filing and does not modify or update those disclosures affected by subsequent events, except as specifically referenced herein. Information not affected by this restatement is unchanged and reflects the disclosures made at the time of the Original Filing on May 15, 2015.

**TABLE OF CONTENTS**


| | | |
|---|---|---|
| Item 1. | Business | 4 |
| Item 1A. | Risk Factors | 33 |
| Item 1B. | Unresolved Staff Comments | 41 |
| Item 2. | Properties | 42 |
| Item 3. | Legal Proceedings | 42 |
| Item 4. | Mine Safety Disclosures | 42 |
| Item 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 43 |
| Item 6. | Selected Financial Data | 47 |
| Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 47 |
| Item 7A. | Quantitative and Qualitative Disclosures About Market Risk | 55 |
| Item 8. | Financial Statements and Supplementary Data | 56 |
| Item 9. | Changes in and Disagreements With Accountants on Accounting and Financial Disclosure | 57 |
| Item 9A. | Controls and Procedures | 57 |
| Item 9B. | Other Information | 58 |
| Item 10. | Directors, Executive Officers and Corporate Governance | 59 |
| Item 11. | Executive Compensation | 63 |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 66 |
| Item 13. | Certain Relationships and Related Transactions, and Director Independence | 67 |
| Item 14. | Principal Accounting Fees and Services | 68 |
| Item 15. | Exhibits, Financial Statement Schedules | 69 |

# PART I

## Item 1. Business

This annual report contains forward-looking statements. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled “Risk Factors”, that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are stated in Canadian Dollars (CDN$) and are prepared in accordance with United States Generally Accepted Accounting Principles.

In this annual report, unless otherwise specified, all dollar amounts are expressed in Canadian dollars and all references to “common shares” refer to the common shares in our capital stock.

As used in this annual report, the terms “we”, “us”, “our” and “our company” mean Pivot Pharmaceuticals Inc., unless otherwise indicated.

### General Overview

We are a development stage biopharmaceutical company. We were incorporated in the Province of British Columbia, Canada under the name “649186 B.C. Ltd.”, on June 10, 2002. On September 9, 2003, we changed our name to “Xerxes Health Corp.” and on June 26, 2007, we changed our name to “Neurokine Pharmaceuticals Inc.”.

Effective June 4, 2014, we filed with the British Columbia Registrar of Companies a Form 11, Notice of Alteration, wherein we have increased our authorized share capital from 500,000,000 common shares without par value to an unlimited number of common shares without par value. The increase of authorized capital was approved by our stockholders at the annual and special meeting held on June 3, 2014.

On September 26, 2014, our company held a special meeting of stockholders to approve the removal of our company's Pre-Existing Company Provisions, the cancellation of our current Articles and the adoption of new Articles and to approve a reverse stock split on the basis of up to 1:100.

Effective October 8, 2014, we filed with the British Columbia Registrar of Companies a Form 11, Notice of Alteration, wherein we have removed our Pre-Existing Company Provisions.

Effective April 7, 2015, we filed with the British Columbia Registrar of Companies a Form 11, Notice of Alteration, wherein we changed our name to "Pivot Pharmaceuticals Inc.".

Effective at the opening of trading on April 20, 2015, as approved by FINRA, our company effected a reverse stock split of our issued and outstanding common shares on a 10 old for 1 new share basis, and approved the change of our name from “Neurokine Pharmaceuticals Inc.”, to “Pivot Pharmaceuticals Inc.”.

Our principal executive office is located at 1275 West 6th Avenue, Vancouver, British Columbia, Canada, V6H 1A6. Our telephone number is (604) 805-7783.

We are engaged in the development and commercialization of therapeutic pharmaceutical products with a strategic emphasis on research and development to innovate new applications for existing drugs. This is commonly known as drug re-profiling. Our research and development activities are focused on assessing known drugs and compounds, developing hypotheses concerning their usage for new indications (diseases), and conducting experimentation and clinical research to test those hypotheses. Where appropriate based on our research, we intend to depart from a strict re-profiling strategy to develop new variants of, or delivery methods for, or new dosage regimens for existing drugs or compounds.

Our business model currently includes the following activities:

- identifying new indications for approved and marketed products;
- securing intellectual property rights to those products;
- conducting preliminary laboratory tests and clinical trials; and
- establishing partnerships with large pharmaceutical, specialty pharmaceutical companies and biotechnology companies to develop and commercialize products outside of the initial market focus.

Our management believes that our strategic emphasis on drug re-profiling is superior to a strategy based exclusively on new drug development because the drugs we are seeking to re-profile have already passed a significant number of required regulatory tests. Similarly, when compared to developing a new drug, re-profiling typically requires less research and development time and cost and offers a greater possibility of obtaining regulatory approval and ultimately achieving commercialization. On the other hand, drug re-profiling can also pose certain challenges such as securing intellectual property rights generic drugs, the cost of which may make re-profiling prohibitive. In spite of any advantages our strategy may provide, we will likely face a wide range of common pharmaceutical industry challenges. For example, any products that we may develop will be required to undergo a time-consuming, costly and burdensome pre-market approval process for efficacy and we may be unable to obtain regulatory approval for them.

We may not commence clinical testing of any products that we may develop and the commercial value of any clinical study that we conduct will depend significantly upon our choice of indication and our patient population selection. If we are unable to commence clinical testing or if we make a poor choice in terms of clinical strategy, we may never achieve revenues. Our clinical trials may also fail to adequately demonstrate the efficacy of our product candidates for our chosen indications, which may force us to abandon our business plan. Even if we are able to ultimately obtain regulatory approval for any products that we may develop, we may never become profitable.

To date, we have concentrated our research and development activities on innovating uses for existing drugs for the treatment of diseases mediated by acute and chronic inflammatory reactions. Our new activities for 2015 and on will focus on repositioning drugs into the underserved markets of Women's Health indications as well as additional targets in Neurology. We have identified three drug classes (P-001, P-002, P-003) that can serve unmet or underserved indications in the Women's Health market if we can demonstrate efficacy. Through the research executed previously by Neurokine, target drugs have been identified and, where required, secured the rights necessary to develop two anti-inflammatory products, NK-001 and NK-002, that we believe hold promising prospects for the treatment of neurocognitive impairment that occurs in patients that have undergone cardiac artery bypass and Alzheimer's disease, respectively.

P-001 is a new application of an existing generic drug class and therefore adheres to our re-profiling strategy. We anticipate that P-001 will require minimal pre-clinical studies for the new indication in Women's Health (including dysmenorrhea, kidney stones and urinary tract indications), but will not require preliminary safety or pharmacokinetic data (the process by which the drug is metabolized by the body) studies. P-001 is a new application of the drug class that blocks alpha-adrenergic receptors, several of which are marketed under United States Food and Drug Administration ("FDA") approval as a treatment for benign prostrate hyperplasia in men. Because this class has several candidates that have already been the subject of safety studies on a patient population similar to patients targeted by P-001, we do not anticipate having to complete these additional studies before proceeding to later-stage clinical trials, such as going directly into a Phase IIa. Although unlikely, it remains that the Regulatory Authorities may require additional studies as part of the

application for marketing.

P-002 is a new application of an existing generic drug class and therefore adheres to our re-profiling strategy. We anticipate that P-002 will require minimal pre-clinical studies for the new indication in Women's Health (including hot flushes in peri-menopause), but will not require preliminary safety or pharmacokinetic data (the process by which the drug is metabolized by the body) studies. P-002 is a new application of the drug class that blocks central-adrenergic receptors, several of which are marketed under United States Food and Drug Administration ("FDA") approval as a treatment for hypertension. Because this class has several candidates that have already been the subject of safety studies on a patient population similar to patients targeted by P-002, we do not anticipate having to complete these additional studies before proceeding to later-stage clinical trials, such as going directly into a Phase IIa. Although unlikely, it remains that the Regulatory Authorities may require additional studies as part of the application for marketing.

P-003 is a new application of an existing generic drug class and therefore adheres to our re-profiling strategy. We anticipate that P-003 will require minimal pre-clinical studies for the new indication in Neurology (dementia, migraine prevention), but will not require preliminary safety or pharmacokinetic data (the process by which the drug is metabolized by the body) studies. P-003 is a new application of the drug class that act as angiotensin-2 inhibitors, several of which are marketed under United States Food and Drug Administration ("FDA") approval as a treatment for hypertension. Because this class has several candidates that have already been the subject of safety studies on a patient population similar to patients targeted by P-003, we do not anticipate having to complete these additional studies before proceeding to later-stage clinical trials, such as going directly into a Phase IIa. Although unlikely, it remains that the Regulatory Authorities may require additional studies as part of the application for marketing.

NK-001 is a new application of an existing new drug and therefore adheres to our re-profiling strategy. We do not anticipate that NK-001 will require pre-clinical, preliminary safety or pharmacokinetic (the process by which the drug is metabolized by the body) studies. NK-001 is a new application of the drug Etanercept, which is marketed under United States Food and Drug Administration ("FDA") approval as a treatment for rheumatoid arthritis. Because Etanercept has already been the subject of safety studies on a patient population similar to patients targeted by NK-001, we do not anticipate having to complete these additional studies before proceeding to later-stage clinical trials, and we have previously received approval to conduct clinical trials in South Africa on that basis.

In contrast, NK-002 is a new formulation for the delivery of an existing drug and is therefore properly classified as a new drug. As a new drug, NK-002 will require a complete development program, including the full range of successful pre-clinical, safety and pharmacokinetic studies before advanced clinical testing will be permitted to occur. Both of our planned products, including our leading candidate, NK-001, are in the development stage as of the date of this annual report and neither has been approved to date for sale to the public in any country.

To date, we have outsourced all other research and development work to third parties, including clinical trial planning, laboratory services, data management, statistical services and report writing. We anticipate that we will continue to rely on third parties to satisfy our research and development requirements until such time as it becomes cost effective to hire employees to satisfy those requirements. We have not carried on any research and development activities since January 2009 and our ability to continue our research and development activities depends on securing additional financing.

A brief summary of the major stages of our business plan that we are seeking to complete over the next 12 months and the cost estimates to complete each step are as follows:

- Screening from classes of drugs to select P-001, P-002, P-003 in specific in vitro and in vivo models either gender specific or indication specific - $1,500,000;
- Reformulation and dosage regimen testing for P-001, P-002, P-003 - $1,500,000;
- commence and complete planned Phase II clinical trial of NK-001 (50 patients) - $2,355,000; and
- complete pre-clinical studies of NK-002 - $800,000.

We will also be required to complete additional steps in order to market and sell any of our products to the public. Our determination of which specific additional steps we will need to complete before any of our products become marketable may vary depending on the results of the clinical trials and studies mentioned above. The following table sets out the various steps we anticipate we must complete in order to carry out our business plan for our planned products. Estimated costs and completion times have been indicated where estimable, as has any progress made to date.

| | **Products** | | |
|---|---|---|---|
| **Anticipated Steps** | **P-001** | **P-002** | **P-003** |
| Intellectual Property | Screening in female tissues/models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application | Screening in female tissues/models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application | Screening in female tissues/models, neurological models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application |
| Secure Rights to Use Re-Profiled Drugs | Not Required (generic drug) | Not Required (generic drug) | Not Required (generic drug) |
| Pre-Clinical Testing | Required to select specific drug within class ($500,000) | Required to select specific drug within class ($500,000) | Required to select specific drug within class ($500,000) |
| Secure Investigational New Drug Approval or Equivalent | Not required (Generic drug) | Not required (Generic drug) | Not required (Generic drug) |
| Phase I Clinical Trials | Not Required | Not Required | Not Required |
| Phase II Clinical Trials | Required | Required | Required |
| Phase III Clinical Trials | Required | Required | Required |
| Submit New Drug Application or Equivalent and Obtain Marketing Approval | Required | Required | Required |
| Finance Marketing and Manufacturing of Approved Drug or Secure Marketing and Manufacturing Partner | Required | Required | Required |

| | **Products** | |
|---|---|---|
| **Anticipated Steps** | **NK-001** | **NK-002** |
| Secure Intellectual Property Protection of Drug Concept | Patent Application Submitted | Patent Application Submitted |
| Secure Rights to Use Re-Profiled Drug | Not Required (Generic Drug) | Not Required (Generic Drug) |
| Pre-Clinical Testing | Not Required | Pre-Clinical Trials Delayed Until Sufficient Financing is Secured Estimated Cost: $800,000 Estimated Completion Date: Unknown |
| Secure Investigational New Drug Approval or Equivalent | Not Required (Generic Drug) | Required |
| Phase I Clinical Trials | Not Required | Required |
| Phase II Clinical Trials | Clinical Trial Protocol Complete and Approved for Implementation Clinical Trials Delayed Until Sufficient Financing is Secured | Required |

| | | |
|---|---|---|
| | Estimated Cost: $2,355,000<br>Estimated Completion Date: Unknown | |
| Phase III Clinical Trials | Required | Required |
| Submit New Drug Application or Equivalent and Obtain Marketing Approval | Required | Required |
| Finance Marketing and Manufacturing of Approved Drug or Secure Marketing and Manufacturing Partner | Required | Required |

**Our Current Business**

We are a development stage biopharmaceutical company engaged in the development and commercialization of therapeutic pharmaceutical products, with a strategic emphasis on the innovation of new therapeutic uses for existing drugs. This is commonly known as drug re-profiling. Our research and development activities are focused on assessing known drugs and compounds, developing hypotheses concerning their usage for new indications (diseases), and conducting experimentation and clinical research to test those hypotheses. Where appropriate based on our research, we intend to depart from a strict re-profiling strategy to develop new variants of, or delivery methods for, existing drugs or compounds.

Our focus on drug re-profiling, although not uncommon amongst pharmaceutical companies, differs from traditional drug development practices which focus largely on the development of new drugs.

To date, we have concentrated our research on innovating applications for existing drugs for the treatment of diseases and conditions mediated by acute and chronic inflammatory reactions in neurological indications as well as testing existing drugs in specific women's health indications. The diseases and conditions that have been the subject of our previous research include:

- neurocognitive impairment, and specifically, neurocognitive impairment in post-coronary artery bypass graft (also known as "CABG" or "heart bypass") surgery patients;
- degenerative central nervous system diseases, and specifically, Alzheimer's disease; and
- degenerative disk disease, and specifically, discogenic neck and back pain conditions.

Our planned research and development for the next 12 months will look at three well characterized, safe and broadly prescribed generic drugs.

**Our Strategy: A Focus on Drug Re-Profiling Complimented by Strategic New Drug Development**

Our highly experienced management team has implemented a business-minded and cost-conscious approach to product research and development by focusing on innovating new uses for existing drugs on the market, also known as drug re-profiling, while also engaging in selective research and development regarding the innovation of new drugs.

In order for a drug to be successful, it must be both efficacious and acceptably safe. Therefore, before a drug may be commercially marketed, it must be scrutinized and approved by applicable health authorities (such as the FDA in the United States) in each country or jurisdiction where it is sought to be sold. In pharmaceutical research and development, clinical trials are conducted to allow safety and efficacy data to be collected for new drugs or devices. Health authorities then scrutinize the clinical trial results and determine, based on the results, whether a drug may be sold to the public. Similarly, clinical trials may only take place once satisfactory information has been gathered on the quality of the product and its non-clinical safety, and approval to conduct the trials has been granted by the health authority in the country where the trial is scheduled to take place.

Clinical trials involving new drugs are commonly classified into four phases. Each phase of the drug approval process is treated as a separate clinical trial. The drug-development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV trials are 'post-approval' studies. Due to the considerable cost that may be required to complete a full series of clinical trials, the burden of paying for all the necessary people and services is usually borne by the sponsor, who may be the pharmaceutical or biotechnology company that developed the drug that is the subject of the study. Since the diversity of roles may exceed the resources of the sponsor, clinical trials are often managed by outsourced partners such as contract research organizations. Furthermore, approval rates for new drugs at each clinical trial stage are prohibitively low, which may require the sponsor to finance additional trials or abandon the drug under development altogether. The various phases of clinical trials and the anticipated clinical trial requirements of our planned products are described in detail in this section under the heading "Clinical Trial Phases".

The strategy of drug re-profiling seeks to avoid the cost of repeating one or more pre-clinical, safety, pharmacokinetic or Phase I clinical tests by applying existing drug research to new indications. In doing so, a company may reduce the time required to complete the necessary research and development activities, which can typically take in excess of 10 years, by more than half, as well as reduce the corresponding development costs. Significantly, a re-profiled drug, if efficacious for its new indication, is also more likely to be approved by an applicable health authority because it has already been shown to meet regulated safety standards that the vast majority of developmental drugs fail to achieve. If a re-profiled drug is no longer protected by patent, no relationship between the original owner or developer of the drug and the re-profiler of the drug need exist. However, it may in some circumstances be beneficial for the re-profiler to obtain a license from the original owner of the drug where there exists an opportunity to receive development, manufacturing, marketing or financing assistance from such owner.

We anticipate that our re-profiling approach will result in faster, more efficient clinical trials and dramatically increase the chance of obtaining regulatory approval at each clinical trial stage. In some cases (as in the case of NK-001, P-001, P-002 and P-003), we anticipate that we will be able to obtain a regulatory waiver and bypass certain clinical trial stages as a result of basing our products on re-profiled drugs.

**Our Products**

Our product research will have two clear lines for Women's Health and Neurological targets with a path of innovating existing drugs carefully selected into new indications.

The first target focus is on small molecule chemical entities that have been broadly used but not specifically tailored or personalized to women's health indications. To date we have identified three classes of drugs from which a specific drug candidate will be selected as the most efficacious in women including:

- P-001 for the potential treatment of dysmenorrhea, lower urinary tract symptoms and kidney stones;
- P-002 for the potential treatment of peri-menopausal 'hot flushes'; and
- P-003 for the potential prevention and treatment of migraine headaches and the progression from mild cognitive impairment to dementia (Alzheimer's Disease progression).

***P-001***

The P-001 programs are based upon a class of drugs that block the alpha adrenergic receptor. There are several generic compounds in this drug class available for us to select from. We plan to screen for the best female target/tissue/animal model specific compound from this class and file a patent application on our findings.

For P-001 to become profitable, we will require our patent application to be successful. If our application is not ultimately successful, we may be forced to abandon our development of P-001. For our patent application to succeed, we may be required to complete additional research in order to respond to enquiries from the United States Patent Office or to defend against challenges to our patent once it is published, if at all.

*First P-001 Program: Dysmenorrhea*

Dysmenorrhea is a medical condition of pain during menstruation that interferes with daily activities. Dysmenorrhea is often defined simply as menstrual pain, or at least menstrual pain that is excessive. Menstrual pain is often used synonymously with menstrual cramps, but the latter may also refer to menstrual uterine contractions, which are generally of higher strength, duration and frequency than in the rest of the menstrual cycle.

Dysmenorrhea can feature different kinds of pain, including sharp, throbbing, dull, nauseating, burning, or shooting pain. Dysmenorrhea may precede menstruation by several days or may accompany it, and it usually subsides as menstruation tapers off. Dysmenorrhea may coexist with excessively heavy blood loss, known as menorrhagia.

Secondary dysmenorrhea is diagnosed when symptoms are attributable to an underlying disease, disorder, or structural abnormality either within or outside the uterus. Primary dysmenorrhea is diagnosed when none of these are detected.

The main symptom of dysmenorrhea is pain concentrated in the lower abdomen, in the umbilical region or the suprapubic region of the abdomen. It is also commonly felt in the right or left abdomen. It may radiate to the thighs and lower back. Symptoms often co-occurring with menstrual pain include nausea and vomiting, diarrhea or constipation, headache, dizziness, disorientation, hypersensitivity to sound, light, smell and touch, fainting, and fatigue. Symptoms of dysmenorrhea often begin immediately following ovulation and can last until the end of menstruation. This is because dysmenorrhea is often associated with changes in hormonal levels in the body that occur with ovulation. The use of certain types of birth control pills can prevent the symptoms of dysmenorrhea, because the birth control pills stop ovulation from occurring.

During a woman's menstrual cycle, the endometrium thickens in preparation for potential pregnancy. After ovulation, if the ovum is not fertilized and there is no pregnancy, the built-up uterine tissue is not needed and thus shed. Molecular compounds called prostaglandins are released during menstruation, due to the destruction of the endometrial cells, and the resultant release of their contents. Release of prostaglandins and other inflammatory mediators in the uterus cause the uterus to contract. These substances are thought to be a major factor in primary dysmenorrhea. When the uterine muscles contract, they constrict the blood supply to the tissue of the endometrium, which, in turn, breaks down and dies. These uterine contractions continue as they squeeze the old, dead endometrial tissue through the cervix and out of the body through the vagina. These contractions, and the resulting temporary oxygen deprivation to nearby tissues, are responsible for the pain or "cramps" experienced during menstruation.

Compared with other women, women with primary dysmenorrhea have increased activity of the uterine muscle with increased contractility and increased frequency of contractions.

The diagnosis of dysmenorrhea is usually made simply on a medical history of menstrual pain that interferes with daily activities. However, there is no universally accepted gold standard technique for quantifying the severity of menstrual pains. Yet, there are quantification models, called menstrual symptometrics, that can be used to estimate the severity of menstrual pains, as well as correlate them with pain in other parts of the

body, menstrual bleeding and degree of interference with daily activities.

Current treatments include non-steroidal anti-inflammatory drugs ("NSAIDs") which are effective in relieving the pain of primary dysmenorrhea but can have side effects of nausea, dyspepsia, peptic ulcer, and diarrhea. Women that are unable to take the more common NSAIDs may be prescribed a COX-2 inhibitor, however these have been 'black-box' labeled with possible significant cardiac side effects.

In addition, hormonal contraceptives are also used to treat dysmenorrhea. Although use of hormonal contraception can improve or relieve symptoms of primary dysmenorrhea, there are no clear conclusions can be made about the efficacy of commonly used modern lower dose combined oral contraceptive pills for primary dysmenorrhea.

The prevalence of dysmenorrhea is estimated to be approximately 25% of women. Complaints of dysmenorrhea are greatest among women in their late teens and 20s, with reports usually declining with age. The prevalence in adolescent females is reported to be greater than 50%.

Treatment with alpha adrenergic blockers: The uterine muscle is mainly enervated by alpha adrenergic nerve endings. This enervation is similar to that of the bladder lower part called the trigon. The use of effective alpha adrenergic blockers can significantly reduce or eliminate the excessive uterine contractions, the phenomenon behind the dysmenorrheal symptoms. There are several alpha adrenergic blockers on the market with varying specificity to the sub-types of the alpha adrenergic receptor. This selection gives us the opportunity to discover the compound with the best efficacy/risk ratio. Currently, alpha adrenergic blockers are indicated for the treatment of hypertension (very old and non-selective alpha blockers) and Benign Prostatic Hyperplasia (BPH). Their quick mode of action, excellent efficacy in alleviation of the BPH symptoms and almost perfect safety and tolerability profile make them the drug class of choice for BPH. The similarity in denervation between the trigon and uterus lends to our confidence in the efficacy and safety of alpha adrenergic blockers in dysmenorrhea. In addition, the effect of alpha blockers on dysmenorrhea lends itself to further development of a combination of formulations containing alpha adrenergic blockers and very low doses of NSAIDS reducing the side effects of NSAIDS while increasing the combined efficacy (by blocking prostaglandins).

*Second P-001 Program: Lower Urinary Tract Symptoms*

Lower urinary tract symptoms (LUTS) are the name given to a group of symptoms including dysuria and incontinence. The term was first coined to describe symptoms in men, which had previously been known as prostatitis. An underlying cause is often not found. LUTS come and go and will spontaneously resolve in nearly half of all cases. Experts recommend making a specific diagnosis when possible and treating any underlying cause. LUTS may be divided into:

- Filling or irritative symptoms - eg, frequency, urgency, dysuria, nocturia, stress incontinence, urge incontinence; and

- Voiding or obstructive symptoms - eg, poor stream, hesitancy, terminal dribbling, incomplete voiding, overflow incontinence (due to chronic urinary retention).

Risk factors that can influence LUTS in women include: age, postmenopausal urogenital changes, obesity, smoking, number of childbirths, poor obstetric care and abnormalities of the urogenital system, both congenital or due to pelvic organ prolapse.

Symptoms can be divided into the following groups:

- Storage: increased daytime urinary frequency, nocturia, urgency, incontinence, enuresis, continuous urinary leakage, interstitial cystitis;

- Voiding symptoms: urinary retention, poor stream, hesitancy, intermittent stream, straining, terminal dribble;

- Postmicturition symptoms: postmicturition dribble, feeling of incomplete emptying;

- Symptoms associated with sexual intercourse: dyspareunia, vaginal dryness, incontinence;
- Symptoms associated with genitourinary prolapse: feeling of 'something coming down', low backache, heaviness, dragging sensation;
- Genital and lower urinary tract pain: pain may be associated with bladder filling, micturition, and postmicturition, or continuous; and
- Genitourinary pain syndromes and lower urinary tract dysfunction (LUTD): symptom syndromes suggestive of LUTD may be those of an overactive bladder or of bladder outlet obstruction.

Current treatments for LUTS that do not involve administration of drugs include 'bladder' training with careful attention to fluid intake, reduction or avoidance of caffeine, cranberry use, pelvic floor exercises, weight loss, smoking cessation and even surgery.

Current treatments that involve medications include antibiotics, antimuscarinic drugs, botulinum toxin, antidepressants, hormone replacement therapy, and duloxetine. Many of the drugs used have significant side effects or should be used for short term relief only.

Traditionally, focus has been on UI in women and on other LUTS, known as "prostatism", in men. The new term subsequently proved to be relevant since large population-based surveys in recent years have shown that bladder control symptoms are neither sex-, nor age- or disease-specific.

Urinary incontinence is, nevertheless, still the most familiar LUTS in women. Estimates of prevalence range from a few percent to around 50% in different studies. The wide variation in the reported prevalence can be explained by various reasons such as the use of different definitions, the heterogeneity of different study populations and also population sampling procedures. Large cross-sectional population-based samples have however concluded that the prevalence of any female urinary incontinence ranges from 20% to 40% in young and middle-aged women, and then steadily increases with age. Approximately half of the incontinence is stress type (SUI), about 10% urge urinary incontinence (UUI) and one third mixed incontinence (MUI). Stress leakage occurs more frequently in younger women whereas urge and mixed urinary incontinence are more prevalent in the older women.

Similarly to UI, the estimated prevalence of other LUTS varies considerably between different surveys. In the EPIC study, which was a large European population-based survey of UI, Overactive bladder (OAB) and other LUTS, 66% of the participating women reported at least one LUTS. The most common LUTS, in both men and women, was nocturia (48.6% men, 54.5% women), which, in women, was followed by UI and urgency (13.1% and 12.8% respectively). The overall prevalence of OAB, in the EPIC study, was 11.8%. Other large surveys from Europe and the United States have estimated the prevalence of OAB to approximately 17% in both men and women. Several other authors have described the bother of various LUTS and their negative impact on quality of life. UI has been shown to have a negative effect on physical activities, confidence, self-perception and social activities, UUI and MUI being more detrimental than SUI in this respect. In a recent study, Coyne *et al.* also reported greater rates of co-morbidities and depression as well as significantly worse health-related quality of life and lower work productivity in individuals with OAB symptoms as compared to controls. Nevertheless, several investigations have shown that only a small number of women actually seek help from the medical health care system.

Treatment with alpha adrenergic blockers: Since there is no known gender specific characteristics of bladder function and since bladder dysfunction is at the root of both filling or obstructive types of LUTS, significant reduction in lower bladder (trigon) tension should effectively reduce LUTS symptoms. Prostatism is composed of both obstruction and filling elements. Alpha adrenergic blockers are the main stream treatment for benign prostrate hyperplasia (Prostatism) delivering very effective reduction of symptoms with minimal risk or side effect. It is suggested that the use of this drug class will have similar effect on the LUTS symptoms in women with no additional risk or side effects. This profile is significantly different from the currently used drugs that deliver partial relief with significant and often severe side effects and risk. As with dysmenorrhea, innovative delivery systems/formulations and fixed dose combinations with low doses of existing treatments to LUTS can potentially optimize efficacy with minimal addition of side effects.

***P-003***

*Migraine Prevention (Prophylaxis Treatment) by Angiotensin Receptor Blockers (ARB) and Angiotensin Converting Enzyme Blockers (ACE Inhibitors)*

There are two intertwining theories as to the pathophysiology of migraine headache. The classical one proposes that as a reaction to external (food, wine, smoke, etc.) or internal (hormonal fluctuations, stress, sleep deprivation etc.) triggers, susceptible patients develop severe vasoconstriction followed by vasodilatation of the meningeal vessels in the cranial cavity that cause the pain and associated symptoms (nausea, vomiting, photophobia, phonophobia and sensitivity to smell). Another theory points out that the symptoms are a result of sterile inflammation of the meningeal vessels caused by pro-inflammatory substances (such as CGRP) released from the peri-vascular nerves The current consensus is that most probably the cause of migraine is a combination of these 2 phenomenon which influence each other in yet unknown fashion. Angiotensin is a potent vasoconstrictor with pro-inflammatory effects. The safety profile of the marketed ARBs and ACEI show a significant reduction in headaches compared with placebo. Naturally, the reduction in blood pressure as a result of inhibiting Angiotensin (the main indication for these 2 classes of drugs) can reduce headache. However, the inhibition of the vasoconstrictive effect of Angiotensin and of its pro-inflammatory effect, lends to believe that inhibitors at the level of the converting enzyme or receptor, can prevent the development of a migraine attack. This theory has been supported by small pilot studies. The development of fixed dose combinations of ARB or ACEI with low dose aspirin or NSAID delivered by a novel formulation can be effective, safe and patentable. The safety/tolerability of ARB and ACEI are similar to placebo.

*The Use of ARB for the Delay in the Conversion of Minimal Cognitive Impairment (MCI) to Full Blown Dementia*

MCI is a state in which cognitive functions start to decline gradually with slowly increasing debilitating effect on daily function. Due to the variable degree of MCI, people suffering of mild forms perform well at work and life outside work, but with noticeable decline in their capacities. Full blown Dementia is a state where cognition is at such low level that daily functions are severely disrupted. The classical approach differentiates between Vascular Dementia and Alzheimer's disease. In the past, these conditions were considered different in both pathophysiology and clinical aspects, a growing overlap has been lately discovered, such as the effect of high blood pressure on the development of Lewy Bodies in Alzheimer's. The combined effect of ARBs on reducing blood pressure and their profound anti inflammatory effect should delay the progression of MCI into Dementia. The role of Angiotensin in the development of vascular dementia and even Alzheimer's Disease is currently under investigation, however, there is a large body of evidence that supports the notion that reduction of blood pressure improves cognition and delays dementia.

The second target focus is on biologics (vaccines, blood and blood components), allergenics, somatic cells (cells relating to the wall of the body cavity), gene therapy, tissues, and recombinant therapeutics (drugs produced by genetic engineering) that cause cell death in tumors. Such biologics are known as anti-tumor necrosis factors. To date, we have identified two products as ideal candidates for development:

- NK-001 for the potential treatment of neurocognitive impairment in post-coronary artery bypass graft (commonly known as "CABG" or "heart bypass") surgery patients; and

- NK-002 for the potential treatment of Alzheimer's disease.

***NK-001***

NK-001 is a new application of the generic drug Etanercept for treating neurocognitive impairment in CABG surgery patients. We consider NK-001 to be our flagship product as it is at a more advanced stage of development than our other planned products, and we intend to apply our resources toward its development in priority to our other planned products. Etanercept is the generic version of the drug Enbrel, which is currently under patent protection in the United States. While the original Amgen patent on Enbrel was set to expire in 2012, on November 2011 Amgen announced that the United States patent office has extended that patent until November 2028.

On April 18, 2008, we filed a single United States Patent Application (No. 61-046061) regarding the use of NK-001 (Etanercept) and similar TNF-Alpha targeting drugs (which can generally be described as anti-inflammatory drugs) in the treatment of post-CABG cognitive impairment. This patent application is under examination, and a patent has not yet been granted to us or published and is currently on hold pending submission of additional data. Also if our research and development activities are successful, we will require license and partnership with Amgen to launch NK001.

For NK-001 to become profitable, we will require our patent application to be successful. If our application is not ultimately successful, we may be forced to abandon our development of NK-001. For our patent application to succeed, we may be required to complete additional research in order to respond to enquiries from the United States Patent Office or to defend against challenges to our patent once it is published, if at all.

*TNF-Alpha Inhibitors*

NK-001 is a recombinant, or an artificially created human-soluble tumor necrosis factor protein characterized by its tendency to specifically bind to and inhibit TNF-Alpha. Tumor necrosis factor ("TNF") is a category of protein that induces the death of tumor cells and possesses a wide range of actions that induce inflammation. TNF-Alpha is a cytokine, a category of polypeptide (small protein) regulator that is produced widely throughout the body by cells of diverse origin. It is involved in systemic inflammation and is a member of a group of cytokines that stimulate the acute phase reaction. Acute phase reaction is the process where, in response to injury, the body's inflammatory cells secrete cytokines into the bloodstream to destroy or inhibit the growth of microbes, viruses or other foreign materials. The body's immune cells secrete TNF-Alpha and other cytokinesto defend against infectious disease and foreign materials, and TNF-Alpha is capable of inducing inflammation and inhibiting the growth of tumors and replication of viruses. Dysregulation and, in particular, overproduction of TNF-Alpha have been implicated in a variety of human diseases, including rheumatoid arthritis, ankylosing spondylitis (the inflammation of joints in the spine), psoriatic arthritis and psoriasis. NK-001 has been used since 1998 to treat a number of these diseases.

*CABG and Neurocognitive Impairment*

We intend to apply NK-001 to the treatment of neurocognitive impairment in post-coronary artery bypass graft surgery patients. This surgery is commonly known as CABG or heart bypass surgery. CABG has become a standard method of treatment and has become one of the most commonly performed 'open heart' operations in the United States. According to a 1999 study by Selnes, Goldsbrough, Borowicz and McKhann entitled "Neurobehavioral Sequelae of Cardiopulmonary Bypass" (*The Lancet*, Vol. 353, May 8, 1999), about 800,000 patients internationally and 650,000 patients in the United States undergo heart bypass surgery every year.

Heart bypass surgery is recommended for selected groups of patients with significant narrowing and blockages of the heart arteries, or coronary artery disease. It creates new routes around narrowed and blocked arteries, allowing sufficient blood flow to deliver oxygen and nutrients to the heart muscle. This surgery is usually performed with the heart stopped, necessitating the usage of cardiopulmonary bypass, a technique where a pump temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and the oxygen content of the body.

In addition to stroke and postoperative delirium, cognitive impairment is a recognized adverse complication of heart bypass surgery. According to a 2009 study published in the CHEST journal of the American College of Chest Physicians, short-term post-CABG cognitive impairment has been reported as having an incidence ranging from 33% to 83%, and long-term cognitive impairment an incidence ranging of 20% to 60%. Post-heart bypass cognitive impairment exhibits itself as impairment of memory, concentration, language comprehension and social integration. It can present days to weeks after surgery and may remain a permanent disorder.

The cause of post-CABG cognitive impairment has been attributed to a number of factors, including obstruction of the blood vessels of the brain (cerebral microembolization), decreased blood flow through the brain (global cerebral hypoperfusion), systemic and cerebral inflammation, cerebral temperature changes, accumulation of fluid in the brain (cerebral edema), possible blood-brain barrier dysfunction and genetic

susceptibility.

*Post-CABG Surgery Cognitive Impairment: An Inflammatory Phenomenon*

Several reports have suggested that post-heart bypass cognitive impairment is an inflammatory phenomenon in which inflammatory mediators, such as cytokines (including the cytokines TNF-Alpha, interleukin -1, interleukin-8, and interleukin-6), are released to trigger the brain's inflammatory response. It has been further observed that elevated levels of inflammatory mediators, including TNF-Alpha, have been shown to be indicators of high morbidity (the presence of an abnormal condition that impairs bodily function) and mortality rates after heart bypass surgery. While most studies have looked at peripheral levels of cytokines in response to surgical stress, it has also been reported that elevated levels of pro-inflammatory cytokines have been detected in the cerebrospinal fluid after heart bypass surgery. Moreover, it has been shown that heart trauma leads not only to an increase in pro-inflammatory cytokine levels outside the brain, but also to a concurrent marked increase in brain cytokine levels. Accordingly, the apparent significance of pro-inflammatory cytokines, such as TNF-Alpha, has led to the suggestion that these inflammatory mediators may be considered as targets in the inflammatory process associated with post-CABG cognitive impairment.

*Current Treatment of Post-CABG Cognitive Impairment*

Currently, prevention is considered to be the most effective treatment strategy for post-CABG cognitive impairment, as preventative or therapeutic interventions are limited. It has been postulated that therapeutic interventions aimed at diminishing the inflammatory response might result in better outcomes; for example, the use of a synthetic non-psychotropic cannabinoid (a drug having certain attributes of cannabis that does not alter brain function) to treat mild cognitive impairment, including post-surgical cognitive impairment, has been described. The use of a protease inhibitor (a class of medication used to treat or prevent viral infection), such as aprotinin (TrasylolTM), has also been reported as having a marked protective effect on the brain in reducing the severity of cognitive deficit developing after heart bypass surgery.

*Therapeutic Applications of TNF-Alpha Antagonists*

The use of TNF-Alpha antagonists to treat various disorders has been described. TNF-Alpha is an intracellular mediator, a protein that mediates the immune responses produced by a variety of cells, including both types of white blood cells (macrophages and monocytes). The responses triggered by TNF-Alpha are initiated through its interaction with distinct TNF-Alpha cell surface receptors.

TNF-Alpha binds to these cell surface receptors and triggers an array of pro-inflammatory effects, including the release of other pro-inflammatory cytokines and chemokines (a type of cytokine); the release of enzymes which break down proteins (metalloproteinases); and an increase in the production of proteins that line the interior surface of blood vessels (endothelial adhesion molecules), thereby further amplifying the inflammatory and immune cascade and inducing a plethora of inflammatory and catabolic (molecule breakdown) effects. Interference in the binding of TNF-Alpha to cell surface receptors of the target cell results in the neutralization of TNF-Alpha and the blockage of its biologic effects. For example, TNF-Alpha receptor proteins that are naturally produced in soluble form (designated as TNF-R) inhibit TNF-Alpha action by competing with cell surface receptors for binding TNF-Alpha, thereby blocking its biologic effects. Various TNF-Alpha targeting drugs, also known as TNF-Alpha antagonists, TNF-Alpha inhibitors and TNF-Alpha blockers, have been developed to neutralize or inhibit TNF-Alpha activity. These drugs bind to inhibit TN F-Alpha from binding to its receptor and triggering the inflammatory response. In this way, TNF-Alpha targeting drugs deactivate TNF-Alpha.

A human-soluble TNF-Alpha receptor protein has been shown to suppress TNF-Alpha dependent inflammatory diseases, specifically arthritis. TNF-Alpha targeting drugs have also been shown to be effective in treating other inflammatory diseases such as Wegener's disease, Behçet's disease, keratoscleritis, lymphomatous tracheo-bronchitis, Cogan's syndrome, and rapidly destructive crystal arthropathy. Studies in rat models have also shown that TNF-Alpha targeting drugs can potentially be used to treat brain injuries. The use of TNF-Alpha antagonists has also been described for the treatment of various neuropsychiatric and neurological disorders including multiple sclerosis, Alzheimer's disease, Huntington's disease, Parkinson's disease, Bell's palsy, PHN (shingles), influenza and HIV.

*TNF-Alpha in the Treatment of Neural Disorders*

While TNF-Alpha targeting drugs have been shown to be effective in treating various diseases associated with inflammation, their use in the treatment of neural disorders is hampered by the inability of most TNF-Alpha targeting drugs to cross the blood-brain barrier. The blood-brain barrier is a cellular structure in the central nervous system that restricts the passage of certain chemical substances and microscopic objects (e.g. bacteria) between the bloodstream and the neural tissue itself, while still allowing the passage of substances essential to metabolic function (e.g. oxygen). For example, the TNF-Alpha targeting drug Etanercept, being both hydrophilic (able to bond with water or hydrogen) and of high molecular weight, is prevented from crossing the intact blood-brain barrier. It is also unlikely that any transport mechanism exists for TNF-Alpha targeting drugs to enter the central nervous system. Accordingly, for brain related diseases, conventional general administration (administration into the blood stream) of TNF-Alpha targeting drugs is not effective, and they must instead be administered locally (directly into the cerebrospinal fluid) to have effect. For example, to treat Alzheimer's disease with a TNF-Alpha targeting drug such as Etanercept, the drug must be administered adjacent to the spinal column.

*Commercially Available TNF-Alpha Inhibitors: Etanercept*

Etanercept is a recombinant (engineered) DNA drug made by combining two proteins (also known a fusion protein). It binds TNF-Alpha to human immunoglobulin G1 (IgG1) in the body. Immunoglobulins are proteins that play an essential role in the body's immune system by attaching to foreign substances, such as bacteria, and assisting to destroy them. In this way, Etanercept can regulate excess TNF-Alpha and decrease its role in disorders involving excess inflammation in humans and other animals, including autoimmune diseases such as ankylosing spondylitis, juvenile rheumatoid arthritis, psoriasis, psoriatic arthritis, rheumatoid arthritis, and, potentially, in a variety of other disorders mediated by excess TNF-Alpha.

The most common side effects of Etanercept are mild to moderate itching, pain, swelling and redness at the site of injection. Headache, dizziness, nasal and throat irritation also occur. Because TNF-Alpha plays an important role in the response of the immune system to infections, blocking the action of TNF-Alpha with Etanercept may worsen or increase the occurrence of infections, and patients with serious infections should not receive the drug.

Etanercept treatment should be discontinued if a patient develops a serious infection. Treatment using the drug is not initiated in patients with active infections or an allergy to any of its components, and children should receive their recommended immunizations before beginning any treatment involving Etanercept. Etanercept should also be used with caution in patients prone to infection, such as those with advanced or poorly-controlled diabetes.

Some reported associated conditions may or may not be related to Etanercept. Since Etanercept has been on the market, there have been reports of multiple sclerosis, myelitis (inflammation of the spinal cord) and optic neuritis (inflammation of the optic nerve) in patients using the drug. Etanercept is not recommended for persons with preexisting diseases of the central nervous system (brain and/or spinal cord) or for those with multiple sclerosis, myelitis or optic neuritis. Additionally, rare cases of seriously low blood counts (pancytopenia) have been reported in patients using the drug.

*Rational and Objectives for the Application of TNF-Alpha in the Treatment of Post-CABG Neurocognitive Impairment*

While it has been speculated that preventative treatment with an anti-TNF therapy might be a therapeutic approach to reducing inflammatory processes associated with heart bypass surgery, no experimental data has been provided to demonstrate the therapeutic effect of anti-TNF on post-CABG cognitive impairment. Nevertheless, based on a review of the current medical literature, we believe that there is sufficient rationale to pursue the development of the treatment. As the blood-brain barrier has been shown to be dysfunctional and leaky in this syndrome, it is expected that an unmodified TNF-Alpha antagonist such as NK-001 (Etanercept) will cross into the brain in sufficient amounts to diminish the inflammatory reaction.

Our research and development objectives in applying TNF-Alpha in the treatment of post-heart bypass neurocognitive impairment are:

- to evaluate the effects of NK-001 in preventing cognitive side effects following CABG surgery;
- to evaluate the safety and tolerability of NK-001 in patients undergoing heart bypass surgery;
- to assess blood plasma levels of NK-001 in patients undergoing CABG surgery. Blood plasma is the yellow liquid component of blood in which the blood cells are suspended. It makes up about 55% of total blood volume and is mostly composed of water (92% by volume). Blood plasma also contains dissolved proteins, glucose, clotting factors, mineral ions, hormones and carbon dioxide (plasma being the main medium for transporting products that are excreted by the body);
- to evaluate the effects of NK-001 on serum TNF-Alpha levels in patients undergoing heart bypass surgery (the serum is a fluid component of clotted blood and it lacks clotting factors and other elements which plasma includes, instead retaining antibodies, electrolytes and soluble proteins); and
- to examine the relationship between markers of blood brain barrier dysfunction and cognitive outcome in patients undergoing CABG surgery.

With the assistance of Virtus Clinical Development (Pty.) Limited, a contract research organization based in South Africa, we have designed Phase II human clinical trials of NK-001 to undertake the aforementioned research and development objectives. Virtus provides services to a wide range of international biotechnology and pharmaceutical companies, assisting them in implementing their drug development programs and specifically the design, management and monitoring of the clinical phases of such programs. We intend to begin our clinical trials of NK-001 using 50 post-CABG surgery patients. Our trials will be conducted in four to six separate locations in and around Cape Town, South Africa.

To date, we have received approval for our proposed Phase II clinical trial protocol from the Medicines Control Council of the Department of Health (South Africa) and from the central ethics board of that country. The protocol describes the scientific rationale, objective(s), design, methodology, statistical considerations and organization of the planned trials. Our ability to pursue our clinical trials was subject to the approval of our research protocol by the Medicines Control Council.

In the case of NK-001, we believe that it is unnecessary to conduct pre-clinical studies and Phase I clinical trials of the drug for the following reasons:

- preclinical, Phase I safety and pharmacokinetic studies have already been successfully completed on Etanercept;
- Etanercept has already been tested in different patient populations (both genders, all age groups, and multiple ethnic groups);
- Phase II and II studies have been completed for Etanercept as applied to a number of indications, providing additional safety information for the use of the drug on older populations who are the target population for NK-001; and
- there are no existing animal models for post CABG cognitive impairment by which we could conduct additional safety tests on animals.

On January 28, 2009, we submitted amendments to our clinical trial protocol that were subsequently approved by the Medicines Control Council on May 12, 2009. As a result, we now have full authority to proceed with our Phase II clinical trial of NK-001.

Our study will involve identifying 50 otherwise healthy individuals undergoing heart bypass surgery,

performing pre-surgery cognitive assessment, administering NK-001 (Etanercept) pre and post-surgery and six months of follow up. We anticipate that we will begin our trial 6 months after the completion of the required financing estimated at $2,350,000.

*Regulatory and Patent Issues*

Etanercept was first released for commercial use in late 1998. In North America, it is co-marketed by Amgen Inc. and Pfizer Inc. under the trade name Enbrel in two separate formulations, one in powder form and the other as a pre-mixed liquid. Pfizer Inc. is the sole marketer of Enbrel outside of North America.

In our research, we have worked with the generic form of Etanercept. We currently have not sourced a generic form of Etanercept. In order for us to conduct our NK-001 and NK-002 successfully, we will need to source a generic form of Etanercept.

In the United States the FDA has licensed Etanercept for the following therapeutic applications:

- moderate to severe rheumatoid arthritis (November 1998);
- moderate to severe polyarticular juvenile idiopathic arthritis (1999);
- psoriatic arthritis (2002);
- ankylosing spondylitis (July 2003); and
- moderate to severe plaque psoriasis (April 2004).

The United States Patent on Etanercept (Enbrel) in the United States expired in 2009. Patent protection for Etanercept in South Africa has already lapsed, and the drug is commercially available in generic form.

On April 18, 2008, we filed a single United States Patent Application (No. 61-046061) for the use of TNF-Alpha targeting drugs (including NK-001 and similar anti-inflammatory drugs) in the treatment of post-heart bypass cognitive impairment. The application is currently under review by the United States Patent Office and is on hold pending submission of additional data.

**NK-002**

NK-002 is a development stage drug for the treatment of Alzheimer's disease. We filed a United States Patent Application for NK-002 on January 31, 2008 (No. 61-02540). The application is currently under review by the United States Patent Office.

*Liposome Encapsulated NK-001 for the Treatment of Alzheimer's and Other Neurodegenerative Diseases*

We are developing a novel liposome based on transferring protein. Transferrin is a blood plasma protein for iron ion delivery. When a transferrin protein loaded with iron encounters a transferrin receptor on the surface of a cell, it binds to it and, as a consequence, is transported into the cell in a vesicle. By enclosing NK-001 in a transferrin-based liposome, the drug is able to cross the blood brain barrier. As described above, the blood-brain barrier is a metabolic or cellular structure in the central nervous system that restricts the passage of various chemical substances and microscopic objects (e.g. bacteria) between the bloodstream and the neural tissue, while still allowing the passage of substances essential to metabolic function (e.g. oxygen). In its neuroprotective role, the blood-brain barrier functions to hinder the delivery of many potentially important diagnostic and therapeutic agents to the brain. Therapeutic molecules and genes that might otherwise be effective in diagnosis and therapy do not cross the blood-brain barrier in adequate amounts. We anticipate that NK-002 will succeed in overcoming these limitations for the delivery of NK-001 in the treatment of Alzheimer's disease.

Our management believes that there is currently no promising drug on the market for the treatment of Alzheimer's disease. Although understanding of the disease in the medical community is not conclusive, over 1,000 scientific articles on Alzheimer's disease identify it as an autoimmune condition. To that effect, anti-inflammatory drugs have been tested in treating Alzheimer's disease with promising results, although a significant lack of progress in the application of anti-inflammatory drugs in the treatment of the disease has

been attributed to poor brain penetration due to the blood-brain barrier. NK-002 promises to overcome this obstacle.

NK-001 is currently used in the treatment of arthritis and psoriasis to block the actions of TNF-Alpha made by the body's immune system. TNF-Alpha is a protein that triggers an array of pro-inflammatory effects. In patients with Alzheimer's disease, NK-001 appears to have an effect that is sustained beyond six months of treatment. In fact, a small pilot study conducted by researchers at the University of California, Los Angeles, in 15 patients administering 25-50 milligrams of NK-001 significantly improved MMS (Mini-Mental Status Examination), ADAS-Cog (Alzheimer's Disease Assessment Skill) and SIB (Severe Impairment Battery) results (See Tobinick, Gross, Weinberger, Cohen: "TNF-Alpha Modulation for Treatment of Alzheimer's Disease: A 6-Month Pilot Study" (MedGenMed 2006, 8(2):25)). These results show great promise, exceeding the exhibited short-lived effects of traditional cholinesterase treatment. However, NK-001 is noted for its poor blood-brain barrier penetration. In fact, naked protein drugs like NK-001 traverse the blood-brain barrier at a rate of approximately 0.001% to 9%. However, if appropriately encapsulated, protein drugs traverse the blood brain barrier at a rate of between 1% and 20%. According to a 2006 study, encapsulation increases the rate of drug uptake by 100% to 1000% (See Mishra, Mahor, Rawat, et al., "Targeted brain delivery of AZT via transferrin anchored pegylated albumin nanoparticles" (J Drug Target 2006; 14:45-53)).

On October 2, 2007, we entered into a master service agreement with Northern Lipids pursuant to which Northern Lipids developed certain liposomal encapsulation formulas for NK-002 on our behalf. The proprietary formulations were completed at a cost of approximately $36,000 and all intellectual property rights in the results and proceeds of the agreement were transferred to us. In April 2008, Globe began testing three different encapsulation preparations in rodent trials on our behalf. On January 31, 2008, we filed a United States Patent Application (No. 61-02540) for the therapeutic use of a liposome formulation for the delivery of drugs across the blood-brain barrier. Our United States Patent Application filed on April 18, 2008 (No. 61-046061) also pertains to certain aspects of NK-001, namely the delivery of TNF-Alpha targeting drugs (including NK-001and similar anti-inflammatory drugs) across the blood-brain barrier.

We employ our own proprietary encapsulation technology developed on our behalf by Northern Lipids in accordance with our master service agreement.

Unlike NK-001, NK-002 falls under the category of a new drug and will require a complete range of successful pre-clinical and clinical trials before we can seek marketing approval.

**Clinical Trial Phases**

The following section describes the most common phases of clinical drug trials with reference to the clinical trial requirements that we anticipate will be required for each of our planned products.

***Pre-Clinical Trials***

Pre-clinical trials involve *in vitro* (test tube) and *in vivo* (animal) experiments using wide-ranging doses of the study drug to obtain preliminary efficacy, toxicity and pharmacokinetic (how the body processes the drug) information. Such tests assist pharmaceutical companies in deciding whether a drug candidate possesses scientific merit for further development as an investigational new drug.

Of our current planned products, the P-001, P-002 and P-003 will require some pre-clinical work to select the best drug in class for female therapy. In addition formulation and dosage regimen work studies may need to be conducted. We estimate the screening studies for the three drug classes to cost approximately $500,00 per program with an aggregate cost of $1.5 M. If formulation and dosage regimen needs to be modified for intellectual property protection, the three candidates will also require formulation work at a cost of approximately $500,00 per class with an aggregate cost of $1.5 M. Subject to our ability to obtain adequate funding, all of these studies could be performed in a period of 18-24 months. NK-001 will not require any additional pre-clinical testing. NK-002 will require us to undertake pre-clinical trials. Subject to our ability to obtain adequate financing, we anticipate completing pre-clinical trials of NK-002 at a cost of approximately $800,000 over a period of 12 months. It is our goal to begin pre-clinical trials of NK-002 4 months after the completion of the required financing; however we will not establish a firm start date until we raise sufficient financing, which there is no guarantee that we will be able to do.

*Phase 0*

Phase 0 is a recent designation for exploratory, first-in-human trials conducted in accordance with the FDA's 2006 Guidance on Exploratory Investigational New Drug (IND)

Studies: Distinctive features of Phase 0 trials include the administration of single subtherapeutic doses (doses not intended to treat diseases) of the study drug to a small number of subjects (10-15) to gather preliminary data on the agent's pharmacokinetics (how the body processes the drug) and pharmacodynamics (how the drug works in the body).

Of our current planned products, only NK-002 will require us to undertake Phase 0 clinical trials. Subject to our ability to obtain adequate financing, we anticipate completing combined Phase 0 and Phase I clinical trials of NK-002 at a cost of approximately $1,100,000. We have not scheduled or completed trial protocols for these trials although we anticipate that they will require 12 to 24 months to complete.

*Phase I*

Phase I trials are the first stage of drug testing in human subjects. Normally, a small group of healthy volunteers (20-50) will be selected. This phase includes trials designed to assess the safety, tolerability and effects of the drug in relation to the human body, including how it is absorbed, distributed, metabolized and eliminated by the body. These trials are often conducted in an inpatient clinic, where the subject can be observed by full-time staff. The subject who receives the drug is usually observed until several half-lives of the drug have passed.

Phase I trials also normally include dose-ranging (or dose escalation) studies so that the appropriate dose for therapeutic use can be found. The tested range of doses will usually be a fraction of any dose that causes harm in animal testing.

Phase I trials most often include healthy volunteers; however, real patients are used in some circumstances, such as when patients have an end-stage disease and lack other treatment options. This exception to the rule most often occurs in oncology (cancer) and HIV drug trials. Volunteers are paid an inconvenience fee for the time they spend in the volunteer center. Pay ranges from a small amount of money for a short period of residence to a larger amount of up to approximately $6,000 depending on the length of the volunteer's participation in the trial.

Of our current planned products, we believe that only NK-002 will require us to undertake Phase I clinical trials. Subject to our ability to obtain adequate financing, we anticipate completing combined Phase 0 and Phase I clinical trials of NK-002 at a cost of approximately $1,100,000. We have not scheduled or completed trial protocols for these trials although we anticipate that they will require 12 to 24 months to complete. We do not anticipate requiring Phase I trials of NK-001 because equivalent trials of Etanercept, the drug underlying NK-001, have already been successfully completed by third parties.

*Phase II*

Once the initial safety of a study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments using a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned or to have toxic effects.

Phase II studies are sometimes divided into Phase IIA and Phase IIB. Phase IIA is specifically designed to assess dosing requirements (how much of the drug should be given), while Phase IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)).

Some trials combine Phase I and Phase II, and test both efficacy and toxicity.

All of our planned products must undergo Phase II clinical trials. Completion of these trials is subject to our ability to obtain adequate financing.

We anticipate completing our Phase II trial of NK-001 at a cost of approximately $2,355,000 over a 12 month period. It is our goal to begin our trial 6 months after the completion of the required financing; however, we will not establish a firm start date until we raise sufficient financing, which there is no guarantee that we will be able to do. The trial protocol for our Phase II trial is complete and has received full regulatory approval.

We have not completed a prospective budget or timetable for completing Phase II trials of P-001, P-002, P-003 or NK-002. Our ability to pursue Phase II trials for these programs is subject to our ability to obtain adequate financing and to successfully complete pre-clinical and Phase I trials on the drugs.

*Phase III*

Phase III studies are randomized controlled multi-center trials on large patient groups (300-3,000 or more, depending upon the disease or medical condition studied), and are intended to definitively assess the effectiveness of the drug as compared to the current "gold standard" treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions.

It is common practice that certain Phase III trials will continue while a regulatory submission is pending at the appropriate regulatory agency. This allows patients to continue to receive possibly lifesaving drugs until the drug can be obtained commercially. Other reasons for performing trials at this stage may include "label expansion" (to show the drug is suitable for additional types of patients/diseases beyond the original use for which the drug was approved for marketing), obtaining additional safety data, or to support marketing claims for the drug. Studies in this phase are categorized by some companies as "Phase IIIB studies".

While not required in all cases, it is typically expected that at least two successful Phase III trials will be necessary to demonstrate a drug's safety and efficacy in order to obtain approval from appropriate regulatory agencies, such as the FDA (United States), the Therapeutic Goods Administration (Australia) or the European Medicines Agency (European Union), for example.

Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details and shelf life. This collection of information makes up the regulatory submission that is provided for review to the appropriate regulatory authorities in different countries. They review each submission, and, it is hoped, give sponsors approval to market the particular drug.

Most drugs undergoing Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines, but the drugs must be recalled immediately from the market if any adverse effects are reported. While most pharmaceutical companies refrain from this practice, it is not abnormal to see many drugs undergoing Phase III clinical trials in the market.

We anticipate that all of our current planned products will require us to undertake Phase III clinical trials; however, we lack sufficient information to estimate the costs or timeframe required to complete any Phase III clinical trials at this time. Our ability to pursue Phase III trials will be subject to our ability to obtain adequate financing and successfully complete earlier trials phases for the products in question.

*Phase IV*

A Phase IV trial is also known as a post-marketing surveillance trial. Phase IV trials involve safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by a sponsoring company for competitive (to find a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I through III clinical trials. Harmful effects discovered by Phase IV trials may result in a drug no longer being sold or being restricted to certain uses.

We are unable to accurately anticipate at this time whether our current planned products will require us to undertake Phase IV clinical trials. Similarly, we are unable to accurately anticipate at this time what the costs or timeframe to complete those trials might be. Our ability to pursue any Phase IV trials which may be required of us or which we may undertake voluntarily will be subject to our ability to adequately finance those trials and to successfully complete Phase III trials.

**Markets for our Planned Products**

***P-001***

| | | | |
|---|---|---|---|
| **Women's Health** | Dysmenorrhea | P-001 | > $460 M |
| | Female Lower Urinary Tract Symptoms | P-001 | > $300 M |
| | Kidney Stones | P-001 | > $200M |

Sales are very conservatively estimated for US only, incidence of indication, modest pricing and market penetration.

***P-002***

| Therapeutic Area | Indication | Compound | Potential Sales (USD) |
|---|---|---|---|
| Women's Health | Peri-Menopausal Symptoms | P-002 | > $100M |

Sales are very conservatively estimated for US only, incidence of indication, modest pricing and market penetration.

***P-003***

| Therapeutic Area | Indication | Compound | Potential Sales (USD) |
|---|---|---|---|
| Neurology | Migraines + | P-003 | > $300M |
| | Dementia + | P-003 | > $ 1B |

Sales are very conservatively estimated for US only, incidence of indication, modest pricing and market penetration.

***NK-001***

We anticipate that our study of NK-001 in post-CABG patients will, if successful, generate a market for the drug as well as provide data that may lead to applying the drug in the treatment of other diseases such as Alzheimer's disease. Heart bypass surgery has become a standard method of treatment and has become one of the most commonly performed "open heart" operations in the United States. An estimated 800,000 patients throughout the world undergo heart bypass surgery every year and about 650,000 of those patients are located in the United States (Selnes, Goldsbrough, Borowicz and McKhann: *Neurobehavioral Sequelae of Cardiopulmonary Bypass (*The Lancet, Vol. 353, May 8, 1999)).

Heart bypass surgery is recommended for selected groups of patients with significant narrowing and blockage of the heart arteries. We envision that NK-001 will be used at the time of surgery to prevent cognitive impairment from occurring. We will test our hypothesis as part of our planned Phase II clinical trial of NK-001, in which trial participants will receive NK-001 (or a placebo) before undergoing CABG surgery. There is currently no effective therapy for post-CABG cognitive impairment, so if we are successful, we anticipate that all heart bypass patients will be prescribed NK-001. Accordingly, based on the annual number of worldwide heart bypass surgery patients and an estimated average treatment cost of approximately USD$1,000 per patient, we anticipate that the potential annual worldwide market for NK-001 will be approximately USD$800 million and USD$650 million in the United States alone.

***NK-002***

According to the United States Alzheimer's Association, approximately 5.3 million Americans suffered from Alzheimer's disease in 2009. According to Alzheimer's Disease International, there are an estimated 30 million people with dementia worldwide. By 2050, it is projected that this figure will have increased to over 100 million, with much of the increase occurring in developing countries. Already more than 60% of people with dementia live in developing countries, but by 2040 this is estimated to rise to 71%. The fastest growth in the elderly population is taking place in China, India and their south Asian and western Pacific neighbors. Alzheimer's disease accounts for more than 50% of cases of dementia in Caucasian populations, but this may not apply to other national or ethnic groups, as more research is needed in this area. We cannot yet anticipate what share of the market of Alzheimer's medication NK-002 is likely to assume if it is proven safe and effective.

**Research and Development**

We have spent $nil on research and development expenses for the last two fiscal years. From our inception on June 10, 2002 to January 31, 2015 we spent $282,715 on research and development activities. We anticipate that we will incur approximately $1.4 million in research and development expenses over the next 12 months; however this may change if we are unsuccessful in obtaining sufficient additional financing.

**Intellectual Property**

We own the common law trademark rights in our corporate name and logo. We have not registered any of our trademark rights for protection. We also own 100% of all right and title in and to the following patents:

- United States Patent Application No. 61-02540 (filed on January 31, 2008) for the therapeutic use of a liposome formulation for the delivery of drugs across the blood-brain barrier (NK-002).

- United States Patent Application No. 61-046061 (filed on April 18, 2008) for the use of TNF-Alpha targeting drugs (including NK-001and similar anti-inflammatory drugs) in the treatment of post CABG cognitive impairment.

We also own certain know-how and proprietary technology related to the production of certain liposomal encapsulation formulae forming part of NK-002. This know-how and technology was developed on our behalf by Northern Lipids at a cost of approximately $36,000 pursuant to a master service agreement dated October 2, 2007.

**Manufacturing**

We have limited experience in, and do not own facilities for, manufacturing any products or product candidates. We utilize contract manufacturers to produce clinical supplies of any components of our products that are not commercially available such as our proprietary encapsulation technology forming part of NK-002, which was developed on our behalf and manufactured by Northern Lipids at a cost of approximately $36,000 pursuant to our master service agreement. Although we intend to continue to rely on contract manufacturers to produce certain of our products for both clinical and commercial supplies, we will oversee the production of those products and do not anticipate relying on any particular contract manufacturer.

If we obtain FDA approval or approval outside the United States for our product candidates, we plan to rely on contract manufacturers to produce sufficient quantities for large-scale commercialization. These contract manufacturers will be subject to extensive government regulation. Regulatory authorities in the markets that we intend to serve require that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices as set by the FDA. In this regard, we plan to engage only contract manufacturers who have the capability to manufacture drug products in compliance with current Good Manufacturing Practices in bulk quantities for commercialization. We also intend to safeguard our intellectual property when working with contract manufacturers by working only with manufacturers who in our estimation have a strong track record of safeguarding confidential information and who are willing to enter into agreements with us that impose upon them strict intellectual property protection measures.

**Sales, Marketing and Distribution**

We currently have no sales or distribution capabilities and limited marketing capabilities. In order to commercialize our products, we must develop sales, marketing and distribution capabilities or make arrangements with other parties to perform these services for us.

If P-001, P-002, P-003 or NK-001 or any of our other products receives marketing approval from the FDA, we currently plan to build our own U.S. sales force to market our products directly to surgical and post-surgical centers and physicians in the United States who specialize in CABG surgery. We believe that we can best serve this market with a focused, specialty sales force. We also plan to conduct a variety of promotional and educational programs aimed at establishing awareness of NK-001 in the physician community as an approved treatment for post-heart bypass neurocognitive impairment. These programs will focus on differentiating NK-001 from other competing products and re planned to include sales representative promotion, publications in medical journals, continuing medical education, symposia, regional speaker programs and medical conference exhibits.

Outside of the United States, and subject to obtaining marketing approval in the applicable countries, we intend to engage sales, marketing and distribution partners in Europe, Asia and Latin America.

To the extent that we expand NK-001 for indications beyond post-CABG neurocognitive impairment, such as painful diabetic neuropathy ("PDN"), we may expand our sales force or establish partner relationships with larger pharmaceutical companies that have well-established sales forces in place to effectively carry our products to a broader physician market both in the United States and abroad.

**Competition**

If any of our products receive marketing approval, they may compete against, and may be used in combination with, well-established products currently used both on and off-label in the treatment of their respective indications. By the time we are able to commercialize a product candidate, the competition and potential competition may be greater and more direct. There are many other companies working to develop new drugs and other therapies to treat disease mediated by acute or chronic inflammation, including Alzheimer's disease and discogenic back pain. Many of the compounds in development by such companies are already marketed for other indications. Other companies are focusing on new compounds, most of which are in pre-clinical or early phases of development.

We expect to compete with others on, among other things, the safety and efficacy of our products. Competing successfully will depend on our continued ability to attract and retain skilled and experienced personnel; to identify, secure the rights to and develop pharmaceutical products and compounds; and to exploit these products and compounds commercially before others are able to develop competing products. In addition, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of generic products making branded products less attractive to buyers from a cost perspective.

**Patents and Proprietary Rights**

Our success will depend in part on our ability to protect our products and product candidates by obtaining and maintaining a strong proprietary position both in the United States and in other countries. To develop and maintain our proprietary position, we will rely on patent protection, regulatory protection, trade secrets, know-how, continuing technological innovations and licensing opportunities.

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the products or product candidates we acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be circumvented or challenged and found to be unenforceable or invalid. In limited instances, patent applications in the United States and certain other

jurisdictions are maintained in secrecy until a patent is issued, and since the publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that a court of competent jurisdiction would hold any patents, if issued, valid. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing our patents.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations will help us protect our products.

It is our policy to require our employees, consultants, contractors, or scientific and other advisors, to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. These agreements provide that all inventions related to our business that are conceived by the individual during the course of our relationship shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

**Subsidiaries**

We do not have any subsidiaries.

**Employees and Consultants**

As of May 15, 2015, we did not have any full-time or part-time employees. We currently engage independent contractors in the areas of accounting, legal and auditing services. We plan to engage independent contractors in the areas of clinical trial data management.

**Government Regulations**

In this section and throughout this annual report, the term "FDA" means the United States Food and Drug Administration.

Our current and future operations and research and development activities are or will be subject to various laws and regulations in the countries in which we conduct or plan to conduct our business, including but not limited to the United States, Canada and South Africa. These laws and regulations govern the research, development, sale and marketing of pharmaceuticals, taxes, labor standards, occupational health and safety, toxic substances, chemical products and materials, waste management and other matters relating to the pharmaceutical industry. We may require permits, registrations or other authorizations to maintain our operations and to carry out our future research and development activities, and these permits, registrations or authorizations will be subject to revocation, modification and renewal.

Governmental authorities have the power to enforce compliance with lease conditions, regulatory requirements and the provisions of required permits, registrations or other authorizations, and violators may be subject to civil and criminal penalties including fines, injunctions, or both. The failure to obtain or maintain a required permit may also result in the imposition of civil and criminal penalties, and third parties may have the right to sue to enforce compliance.

We expect to be able to comply with all applicable laws and regulations and do not believe that such compliance will have a material adverse effect on our competitive position. We have obtained and intend to obtain all permits, licenses and approvals required by all applicable regulatory agencies to maintain our current operations and to carry out our future research and development activities. We are not aware of any material violations of permits, licenses or approvals issued with respect to our operations, and we believe that we will continue to comply with all applicable laws and regulations.

***Pharmaceutical Regulatory Regimes***

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of pharmaceuticals. All of our product candidates will require regulatory approval by governmental agencies prior to commercialization. In particular, our products candidates are subject to rigorous pre-clinical testing and clinical trials and other premarketing approval requirements of the FDA and regulatory authorities in other countries. Various federal, state and foreign statutes and regulations govern or affect the manufacturing, safety, labeling, storage, record-keeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. When and if we obtain regulatory approval for any of our product candidates, the approval may be limited in scope, which may significantly limit the indicated uses for which our product candidates may be marketed, promoted and advertised. Further, approved pharmaceuticals and manufacturers are subject to ongoing review and previously unknown problems may be discovered that may result in restrictions on the manufacture, sale or use of approved pharmaceuticals or their withdrawal from the market.

**Pre-Clinical Studies**

Before testing any compounds with potential therapeutic value in human subjects in the United States, stringent governmental requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Pre-clinical testing results obtained from these studies, including tests in several animal species, are submitted to the FDA as part of an Investigational New Drug Application (and "IND Application") and are reviewed by the FDA prior to the commencement of human clinical trials. These pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for initial trials in human volunteers.

***Clinical Trials***

If a company wants to conduct clinical trials in the United States to test a new drug in humans, an IND Application must be prepared and submitted to the FDA. The IND Application becomes effective, if not rejected or put on clinical hold by the FDA, within 30 days of filing the application. In addition, an Institutional Review Board must review and approve the trial protocol and monitor the trial on an ongoing basis. The FDA may, at any time during the 30-day review period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials may commence or recommence without FDA authorization, and then only under terms authorized by the FDA. The IND Application process can result in substantial delay and expense.

***New Drug Application***

After completion of clinical trials, if there is substantial evidence that the drug is both safe and effective, a New Drug Application is prepared and submitted for the FDA to review. The New Drug Application must contain all of the essential information on the drug gathered to that date, including data from pre-clinical studies and clinical trials, and the content and format of a New Drug Application must conform with all FDA regulations and guidelines. Accordingly, the preparation and submission of a New Drug Application is an expensive and major undertaking for a sponsor.

The FDA reviews all New Drug Applications submitted before it accepts them for filing and may request additional information from the sponsor rather than accepting a New Drug Application for filing. In such an

event, the New Drug Application must be submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the New Drug Application. By law, the FDA has 180 days in which to review the New Drug Application and respond to the applicant. The review process is often significantly extended by the FDA through requests for additional information and clarification. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved and the scope of any approval. The FDA is not bound by the recommendation, but gives great weight to it. If the FDA evaluations of both the New Drug Application and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which usually contains a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the New Drug Application submission or manufacturing facility is not favorable, the FDA may refuse to approve the New Drug Application or issue a not approvable letter.

***Fast Track Designation and Priority Review***

The FDA's fast track program is intended to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for their condition. Under the fast track program, the sponsor of a new drug may request the FDA to designate the drug for a specific indication as a fast track product at any time during the clinical development of the product. The FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request.

For a product candidate where fast track designation is obtained, the FDA may initiate review of sections of a New Drug Application before the application is complete. This rolling review is available if the applicant provides a schedule for the submission of the remaining information and pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing a New Drug Application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, the FDA may designate a product for priority review. A product is eligible for priority review, or review within a targeted six-month time frame from the time a New Drug Application is accepted for filing, if the product provides a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A fast-track designated product generally meets the FDA's criteria for priority review. We cannot guarantee that any of our products will receive a priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures.

When appropriate, we intend to seek fast track designations for our products. We cannot predict the ultimate impact, if any, of the fast track process on the timing or likelihood of FDA approval on any of our potential products. Importantly, fast track designation does not result in the elimination or waiver of any pre-clinical or clinical trial requirements.

***Orphan Drug Designation***

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a New Drug Application. If the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for up to seven years after receiving FDA approval.

When appropriate, we intend to seek orphan status for certain indications that may be treated with our products. We cannot predict the ultimate impact, if any, of orphan status on the timing or likelihood of FDA approval on any of our potential products. Importantly, if a company obtains orphan drug designation for a drug and indication equivalent to one of our products (i.e. the same underlying drug applied to the same indication), our product may not be approved for the same indication for up to seven subsequent years.

***The Hatch-Waxman Act***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs may benefit from a statutory period of non-patent marketing exclusivity in the United States. The Hatch-Waxman Act provides five years of marketing exclusivity to the first applicant to gain approval of a New Drug Application under Section 505(b) of the Food, Drug and Cosmetic Act for a new chemical entity. A drug qualifies as a new chemical entity if the FDA has not previously approved any other drug containing the same active ingredient. The Hatch-Waxman Act provides data exclusivity by prohibiting abbreviated New Drug Applications, and the submission of section 505(b)(2) applications, which are marketing applications where the applicant does not own or have a legal right of reference to all the data required for approval, by another company for another version of such drug during the exclusive period. Protection under the Hatch-Waxman Act will not prevent the filing or approval of a full New Drug Application for the same active ingredient, although the applicant would be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness.

***Other Regulatory Requirements***

Any products we manufacture or distribute under FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with current Good Manufacturing Practices, or cGMP, regulations which impose procedural and documentation requirements upon us and each third-party manufacturer we utilize.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers from communicating on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our programs or our future product candidates, or such approval of new indications for our future products. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action, either in the United States or abroad European Union.

*Clinical Trials*

In common with the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. The regulatory controls on clinical research in the European Union are now largely harmonized following the implementation of the Clinical Trials Directive 2001/20/EC, or CTD. Compliance with the national implementations of the CTD has been mandatory since May 1, 2004. However, variations in member state regimes continue to exist, particularly in the small number of member states that have yet to implement the CTD fully.

All member states currently require regulatory and independent ethics committee approval of interventional clinical trials. European regulators and ethics committees also require the submission of adverse event reports during a study and a copy of the final study report.

*Marketing Authorization*

In the European Union, approval of new medicinal products can be obtained through the mutual recognition procedure or the centralized procedure. The mutual recognition procedure entails initial assessment by the

national authorities of a single member state and subsequent review by national authorities in other member states based on the initial assessment. The centralized procedure requires the submission of a single Marketing Authorization Application (a "MAA") to the European Medicines Agency (the "EMA") leading to an approval that is valid in all European Union member states. It is required for certain medicinal products, such as biotechnology products and certain new chemical entities, and is optional, or available at the EMA's discretion, for other new chemical entities or innovative medicinal products with novel characteristics.

Under the centralized procedure, a MAA is submitted to the EMA. Two European Union member states are appointed to conduct an initial evaluation of each MAA. These countries each prepare an assessment report, which are then used as the basis of a scientific opinion of the Committee for Medicinal Products for Human Use. If this opinion is favorable, it is sent to the European Commission which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

The European Union expanded its membership by ten states in May 2004. Two more countries joined on January 1, 2007. Several other European countries outside of the European Union, particularly those intending to accede to the European Union, accept European Union review and approval as a basis for their own national approval.

*Advertising*

In the European Union, the promotion of prescription medicines is subject to intense regulation and control, including a prohibition on direct-to-consumer advertising. Some jurisdictions require that all promotional materials for prescription medicines be subjected to either prior internal or regulatory review or approval.

*Data Exclusivity*

For an MAA filed after October 30, 2005, European Union regulators offer eight years of data exclusivity during which generic drug manufacturers cannot file abridged applications. This is followed by two years of market exclusivity during which generic MMAs may be reviewed and approved but during which generic drug manufacturers cannot launch products. The manner in which these new exclusivity provisions will be applied in practice remains far from clear and there can be no assurance that our programs or our other current or future product candidates will qualify for such exclusivity.

*Other Regulatory Requirements*

If a marketing authorization is granted for our products in the European Union, the holder of the marketing authorization will be subject to ongoing regulatory obligations. A holder of a marketing authorization for our products is legally obliged to fulfill a number of obligations by virtue of its status as a Marketing Authorization Holder (a "MAH"). While the associated legal responsibility and liability cannot be delegated, the MAH can delegate the performance of related tasks to third parties, provided that this delegation is appropriately documented. A MAH can therefore either ensure that it has adequate resources, policies and procedures to fulfill its responsibilities, or can delegate the performance of some or all of its obligations to others, such as distributors or marketing partners.

The obligations of a MAH include:

- Manufacturing and Batch Release: MAHs should guarantee that all manufacturing operations comply with relevant laws and regulations, applicable good manufacturing practices, the product specifications and manufacturing conditions set out in the marketing authorization and that each batch of product is subject to appropriate release formalities.

- Pharmacovigilance: MAHs are obliged to monitor the safety of products post-approval and to submit to the regulators safety reports on an expedited and periodic basis. There is an obligation to notify regulators of any other information that may affect the risk benefit ratio for the product.

- Advertising and Promotion: MAHs remain responsible for all advertising and promotion of their products in the relevant jurisdiction, including promotional activities by other companies or individuals on their behalf. Some jurisdictions require that a MAH subject all promotional materials to either prior internal or regulatory review and approval.

- Medical Affairs/Scientific Service: MAHs are required to have a function responsible for disseminating scientific and medical information on their medicinal products, predominantly to healthcare professionals, but also to regulators and patients.

- Legal Representation and Distributor Issues: MAHs are responsible for regulatory actions or inactions of their distributors and agents, including the failure of distributors to provide a MAH with safety data within a timeframe that allows the MAH to fulfill its reporting obligations.

- Preparation, Filing and Maintenance of the Application and Subsequent Marketing Authorization: MAHs have general obligations to maintain appropriate records, to comply with the marketing authorization's terms and conditions, to submit renewal applications and to pay all appropriate fees to the authorities. There are also general reporting obligations, such as an obligation to inform regulators of any information that may lead to the modification of the marketing authorization dossier or product labeling, and of any action to suspend, revoke or withdraw an approval or to prohibit or suspend the marketing of a product.

We may hold marketing authorizations for our products in our own name, or appoint an affiliate or a collaboration partner to hold the marketing authorization on our behalf. Any failure by a MAH to comply with these obligations may result in regulatory action against the MAH and its approvals and ultimately threaten our ability to commercialize our products.

***Approvals Outside of the United States and the European Union***

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval or European marketing authorization has been obtained, approval of a product by the comparable regulatory authorities of other foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval or a European marketing authorization. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

***Third-Party Reimbursement and Pricing Controls***

*General*

In the United States and elsewhere, patients' access to pharmaceutical products depends in significant part on the coverage and reimbursement of a product or service by third-party payors, such as government programs, private insurance plans and employers. Third-party payors increasingly are challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare, Medicaid and private payors. We may be unable to achieve reimbursement from some payors because they may not consider our products to be "reasonable and necessary" or cost-effective. Furthermore, it is possible that even if payors are willing to reimburse patients for our products, the reimbursement levels may not be sufficient to allow us to sell our products on a competitive and profitable basis.

In many foreign markets, including the countries in the European Union, the pricing of pharmaceutical products is subject to direct governmental control and to drug reimbursement programs with varying price control mechanisms. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and the control of national health care systems that fund a large

part of the cost of such products to consumers. The approach taken varies from member state to member state: some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed, and other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the United Kingdom which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement means by which the government can negotiate lower drug prices for Medicare and Medicaid beneficiaries. While we cannot predict whether such legislative bills will become law, their enactment could have a material adverse effect on our business, financial condition and results of operations.

*Medicare*

In the following section, all references to "CMS" refer to the Centers for Medicare and Medicaid Services.

We expect that in the United States a majority of the patients who are treated with our products will be Medicare beneficiaries. The CMS is the agency within the Department of Health and Human Services that administers both Medicare and Medicaid. Two aspects of Medicare reimbursement will be relevant to our products: the availability of reimbursement for physician services for administration of our products and the availability of reimbursement for our products themselves.

The CMS has asserted the authority of Medicare not to cover particular products or services if it determines that they are not "reasonable and necessary" for Medicare beneficiaries. The CMS may create a national coverage determination (a "NCD") for a product, which establishes on a nationwide basis the indications that will be covered and the frequency limits for administration of the product. However, for most new drugs that are eligible for payment, the CMS does not create a NCD. We do not know whether we will seek or obtain a NCD for any of our current or potential products or whether any NCD we obtain will contain favorable coverage terms. As mentioned above, if Medicare coverage for our products is available, the CMS may decide to provide reimbursement through one of two avenues: Part B coverage for physician-administered drugs, or Part D coverage for outpatient prescription drugs. Under Part B coverage, Medicare reimburses purchasers of drugs that meet three statutory requirements:

- the product is reasonable and necessary;
- the product is not usually self-administered and as such is incidental to a physician's service in the office setting; and
- the administering physician bills Medicate directly for the product.

Currently, topical products are considered "usually self-administered"; therefore, coverage under Part B would require a specific determination that any of our products differ from most topical products and should therefore be covered under Part B. There can be no guarantee that we will obtain such a determination. For the reasons discussed below, the failure to obtain such a determination could materially and adversely affect our ability to generate revenue.

If there is not a national coverage decision, the local Medicare contractors that are responsible for administering the Part B program on a regional basis may have the discretion to decline coverage and reimbursement for a drug or to issue a local coverage decision (an "LCD"). These policies can include both coverage criteria for the drug and frequency limits for the administration of the drug. The local contractors in different areas of the country may determine that our products should be treated like most topical patches and may deny coverage under Part B or, even if they allow coverage, may establish varying coverage criteria and frequency limits for any product. Furthermore, obtaining LCDs in the various regions can be a time-consuming and expensive process.

Medicare payment for physician services related to the administration of any of our products, if any, will most likely be determined according to a prospectively set payment rate, determined by a procedure code established by the American Medical Association. These codes, called Current Procedural Terminology ("CPT") codes, describe the procedure performed and can be specific or more general in nature. We believe that although there are existing CPT codes that could be used, a specific code for the administration of each of our products would be preferable. We plan to apply for a specific CPT code. If, at launch, a specific CPT code is not available, local Medicare contractors will advise which existing CPT code should be used for services related to the administration of our products.

The CMS has been considering changes to Medicare reimbursement that could result in lower payments for physician-administered drugs, and Congress may also consider legislation that would mandate lower reimbursement levels. A reduction in reimbursement levels could materially and adversely affect our revenue.

The CMS may determine that any of our products do not qualify for Part B coverage and should instead be covered under the Part D outpatient prescription drug benefit. Because, unlike Part B, Part D coverage reimburses patients only for the drug itself and does not provide reimbursement for the physician's administration services (though a physician can bill for service under Part B and it is possible that the CMS will provide such coverage for the administration of any of our products, even if the product in question is covered under Part D), physicians may not consider our products as attractive a treatment option if they are reimbursed under Part D instead of Part B. In addition, under Part D, there are multiple types of plans and numerous plan sponsors, each with its own formulary and product access requirements. While the CMS evaluates Part D plans' proposed formularies for potentially discriminatory practices, the plans have considerable discretion in establishing formularies, establishing tiered co-pay structures and placing prior authorization and other restrictions on the use of specific products. Moreover, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. Revenue for our products will be substantially affected by their respective formulary status on Part D plans and the rebates that Part D plan sponsors are able to negotiate.

*Medicaid*

Most State Medicaid programs have established preferred drug lists, and the process, criteria and timeframe for obtaining placement on the preferred drug list vary from state to state. A federal law establishes minimum rebates that a manufacturer must pay for Medicaid utilization of a product, and many states have established supplemental rebate programs as a condition for including a drug product on a preferred drug list. Submitting a preferred drug list application to each state will be a time-consuming and expensive process, and it is not clear how many or which state programs will accept the applications. Review times for these applications can vary from weeks to 14 months or more.

*Private Insurance Reimbursement*

Commercial insurers usually offer two types of benefits: medical benefits and pharmacy benefits. In most private insurance plans, physician-administered drugs are provided under the medical benefit. If private insurers decide to cover any of our products, they will reimburse for the drug(s) and its administration in a variety of ways, depending on the insurance plan's revenue targets, employer and benefit manager input and the contract negotiated with their physicians. Like Medicare and Medicaid, commercial insurers have the authority to place coverage and utilization limits on physician-administered drugs. Many private insurers tend to adopt reimbursement methodologies for a product similar to those adopted by Medicare. Revenue for our products may be materially and adversely affected if private payors make unfavorable reimbursement decisions or delay making favorable reimbursement decisions.

## REPORTS TO SECURITY HOLDERS

We are required to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission and our filings are available to the public over the internet at the Securities and Exchange Commission's website at http://www.sec.gov. The public may read and copy any materials filed by us with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 100 F Street N.E. Washington D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-732-0330. The SEC also maintains an Internet site that contains reports, proxy and formation statements, and other information regarding issuers that file electronically with the SEC, at http://www.sec.gov.

**Item 1A. Risk Factors**

**Risks Related to Our Business and Industry**

*There is substantial doubt as to whether we will continue operations. If we discontinue operations, you could lose your investment.*

Our financial statements have been prepared on the going concern basis, which assumes that we will be able to realize our assets and discharge our liabilities in the normal course of business. However, as at January 31, 2015 we have not earned any revenues and had a deficit of $4,171,294. We anticipate that we will incur increased expenses without realizing sufficient revenues (if any) to offset those expenses and we therefore expect to incur significant losses for the foreseeable future. Our ability to continue our operations is dependent on obtaining additional financing and generating future revenues, and no assurance can be given that we will successfully be able to do so. Accordingly, our auditor has indicated in our financial statements that these factors raise substantial doubt about our ability to continue as a going concern. Importantly, the inclusion in our financial statements of a going concern opinion may negatively impact our ability to raise future financing and achieve future revenue. The threat of our ability to continue as a going concern will be removed only when, in the opinion of our auditor, our revenues have reached a level that is able to sustain our business operations.

If we are unable to obtain additional financing from outside sources and eventually generate enough revenues, we may be forced to sell a portion or all of our assets, or curtail or discontinue our operations. If any of these happens, you could lose all or part of your investment. Our financial statements do not include any adjustments to our recorded assets or liabilities that might be necessary if we become unable to continue as a going concern.

*We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future. If we cannot generate sufficient revenues to operate profitably, we may suspend or cease our operations.*

We have not generated any revenue since our inception on June 10, 2002 and we have incurred operating and net losses in each year of our existence. We experienced a net loss of $1,257,047 for the year ended January 31, 2015, compared to a net loss of $753,875 for the year ended January 31, 2014. We expect to incur substantial and increasing losses for the foreseeable future as we develop, seek regulatory approval for and commercialize our product candidates and pursue our other research and development activities. If our products are not successful in clinical trials, does not gain regulatory approval or does not achieve market acceptance, we may never generate any revenue. We also cannot assure you that we will be profitable even if we successfully commercialize our products. If we fail to generate sufficient revenues to operate profitability, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

*Our business is to research and develop new applications of existing therapeutic drugs and enhancements to those drugs, and if we are unable to market our new applications and enhancements we may never generate revenues.*

We have concentrated our efforts on developing new, proprietary substances, methods and processes intended to enhance the therapeutic effects of existing anti-inflammatory drugs in the treatment of diseases mediated by acute and chronic inflammatory conditions. The existing drugs that form the basis of our efforts to develop our new substances, methods and processes are relatively new, and any scientific evidence that may exist to support the feasibility of our goals is not conclusive. If we are not successful in developing and marketing any new applications or enhancements for these existing drugs we may never generate revenues and our business may fail.

*We will require substantial additional funds to complete our research and development activities, and if such funds are not available we may need to significantly curtail or cease our operations.*

We will require substantial funds to research, develop, test and protect our product candidates, and to

manufacture and market any such candidates that may be approved for commercial sale. Based on our current cash levels, we do not have sufficient cash to meet our planned day-to-day operating needs through January 2016, including our planned research and development activities. We raised $nil through private placements during the year ended January 31, 2015 and $9,500 from the issuance of convertible debentures. Based on our planned research and development activities, we anticipate that we will require additional funds of approximately $40,000 to meet our planned day-to-day operating needs for the next 12 months. If we do not raise sufficient funds, our plan of operation will be delayed until such time as we raise sufficient funds, provided we are able to do so. Further, the cost of carrying out our operating activities and research and development activities is not fixed, and our cash levels may at any time prove to be insufficient to finance them. Our financing needs may change substantially because a number of factors which are difficult to predict or which may be outside of our control. These include increased competition, the costs of licensing existing drugs and protecting rights to our proprietary technology, the resources required to complete pre-clinical and clinical studies, and the length and results of the regulatory approval process.

We may not succeed in raising the additional funds that we require because such funds may not be available to us on acceptable terms, if at all. We intend to seek additional funding through strategic alliances or through public or private sales of our equity securities, and we may also obtain equipment leases and pursue opportunities to obtain debt financing in the future. If we are unable to obtain sufficient funding on a timely basis, we may be forced to significantly curtail or cease our operations.

*Our inability to complete our research and development projects in a timely manner could have a material adverse effect of our results of operations, financial condition and cash flows.*

If our research and development projects are not completed in a timely fashion (by the end of December 2015), our company could experience:

- substantial additional cost for re-application to obtain clinical trial approvals;
- additional competition as other groups may enter the area of use of anti-inflammatory application to treat neurocognitive impairment;
- up to six months delay in obtaining approvals; and
- delay in obtaining future inflow of cash from financial or partnership activities, any of which could have a material adverse effect of our results of operations, financial condition and cash flows.

Any products that we may develop will be required to undergo a time-consuming, costly and burdensome pre-market approval process, and if we are unable to obtain regulatory approval for our products we may never become profitable.

Any products that we may develop will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. In the United States, for example, the prospective therapeutic products that we intend to develop and market are regulated by the FDA under its new drug development and review process. Before such therapeutic products can be marketed, we must obtain clearance from the FDA by submitting an investigational new drug application, then by successfully completing human testing under three phases of clinical trials, and finally by submitting a new drug application.

The time required to obtain approvals for our prospective therapeutic products from the FDA and other agencies in foreign locales with similar processes is unpredictable. We expect to be able to accelerate the approval process and to increase the chances of approval by using existing and approved drugs as the basis for our own technology. However, we cannot guarantee that our expectations will be realized, and there is no assurance that we will ever receive regulatory approval to use our proprietary substances, methods and processes. If we do not obtain such regulatory approval, we may never become profitable.

*We may not commence clinical testing for any of our prospective therapeutic products and the commercial value of any clinical study that we may conduct will depend significantly upon our choice of indication and our patient population selection. If we are unable to commence clinical testing or if we make a poor choice in terms of clinical strategy, we may never achieve revenues.*

In order to commence clinical testing we must successfully complete and obtain positive scientific results from pre-clinical studies and, in the case of an existing drug that we are re-profiling for a new indication, adopt existing pre-clinical or early stage clinical studies to our own research. If we successfully complete any clinical study of our own, the commercial value of any such study will significantly depend upon our choice of indication and our patient population selection for that indication.

We plan to employ existing drugs for new indications, and these drugs may have the ability to treat different kinds of indications. As a result, we may incorrectly assess the market opportunities of an indication or may incorrectly estimate or fail to fully appreciate the scientific and technological difficulties associated with treating an indication. In addition, the quality and robustness of the results and data of any clinical study that we may conduct will depend upon our selection of a patient population for clinical testing, and if we select a patient population that is not representative of our intended target market, or rely on pre-existing clinical results and data that do not reflect our intended target market or selected patient population, we may be forced to complete supplemental pre-clinical and/or clinical testing of our product candidates or terminate our research and development activities related to those candidates. The utility of any clinical results and data produced by third parties that we may apply to our own research will also depend upon the similarity between the patient population studied to obtain those results and data and the patient population that we select for our own clinical testing. Our inability to commence clinical testing or our choice of clinical strategy could therefore compromise our business prospects and prevent us from achieving revenues.

*Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could force us to abandon our business plan.*

Before obtaining regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that each product is both safe and effective for use in each target indication. Clinical trial results are inherently difficult to predict, and the results we have obtained or may obtain from third-party trials or from our own trials may not be indicative of results from future trials. We may also suffer significant setbacks in advanced clinical trials even after obtaining promising results in earlier studies.

Although we intend to modify any of our protocols in ongoing studies to address any setbacks, there can be no assurance that these modifications will be adequate or that these or other factors will not have a negative effect on the results of our clinical trials. This could significantly disrupt our efforts to obtain regulatory approvals and commercialize our product candidates. Furthermore, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable safety risk to patients, either in the form of undesirable side effects or otherwise. If we cannot show that our product candidates are both safe and effective in clinical trials, we may be forced to abandon our business plan.

*We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not perform as contractually required or otherwise expected we may not be able to obtain regulatory approval for our product candidates, which may prevent us from becoming profitable.*

*If we are unable to establish a sales, marketing and distribution infrastructure or enter into collaborations with partners to perform these functions, we may not be successful in commercializing our product candidates. This could cause us to cease our operations.*

In order to successfully commercialize any of our product candidates, we must either develop a satisfactory sales, marketing and distribution infrastructure or enter into collaborations with partners to perform these services for us. We will require substantial resources to create such an infrastructure, and we may never possess the resources to do so. For example, we may be unable to recruit and retain an adequate number of effective sales and marketing personnel or we may incur unforeseen costs and expenses in connection with developing the necessary infrastructure.

Although we plan to develop our own sales and marketing organizations in some markets, we intend to enter into partnering, co-promotion and other distribution arrangements to commercialize our products in most markets. We may not be able to enter into collaborations on acceptable terms, if at all, and we may face competition in our search for partners with whom we may collaborate. If we are not able to build a satisfactory sales, marketing and distribution infrastructure or collaborate with one or more partners to perform these functions, we may not be able to successfully commercialize our product candidates, which could cause us to cease our operations.

*Our product candidates may never gain market acceptance even if we obtain the necessary regulatory approvals, which could prevent us from generating revenues.*

Even if we receive the necessary regulatory approvals to commercially sell our product candidates, the success of these candidates will depend on their acceptance by physicians and patients, among other things. Market acceptance of, and demand for, any product that we develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- the availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our or our collaborators' sales, marketing and distribution strategy; and
- publicity concerning our products or competing products and treatments.

If our product candidates fail to gain market acceptance, we may be unable to generate sufficient revenue to continue our business

*We will depend on other parties to manufacture our product candidates. If these parties fail to meet our manufacturing requirements and applicable regulatory requirements, our product development and commercialization efforts could suffer and we may never realize a profit.*

If we obtain the necessary regulatory approvals to market our products, we will rely on contract manufacturers as single source suppliers for the components of our product candidates. Our product candidates are based (either entirely, as with NK-001, P-001, P-002 and P-003, or partially, as with NK-002) upon existing generic drugs and therefore we do not anticipate having to obtain those products from their original developers. However, we will rely on manufacturers with expertise in producing certain generic drugs and other components and we do not plan to enter into long-term supply agreements with any of these manufacturers. As a result, any of them could terminate their relationship with us at any time and for any reason.

Because of our planned reliance on contract manufacturers, we may also be exposed to additional risks, including those related to intellectual property and the failure of such manufacturers to comply with strictly-enforced regulatory requirements, manufacture components to our specifications, or deliver sufficient component quantities to us in a timely manner. For example, a contract manufacturer working on our behalf may violate the intellectual property rights of a third party in manufacturing a component of one of our products, and if such a violation occurs without our knowledge, we may be held vicariously liable for the acts of our contractor, incur related costs and court mandated damages, or become enjoined from selling products which violate those third-party intellectual property rights. Similarly, if a contract manufacturer working on our behalf is found to be in violation of FDA or other national regulatory standards regarding the manufacture, packaging or labeling of any of our products, we could face any of a number of adverse consequences including costly regulatory investigations and fines, interruptions in the flow of our products or materials, product recalls, or liability to consumers regarding any of our products that do not meet such regulatory requirements. If any of these events occurs, if our relationship with any of our potential contract manufacturers terminates, or if any such manufacturer is unable fulfill its obligations to us for any reason, our product development and commercialization efforts could suffer and we may never realize a profit.

*We face potential product liability exposure, and any claim brought against us may cause us to divert resources from our normal operations or terminate selling, distributing and marketing any product for which we have received regulatory approval. This may cause us to cease our operations.*

The use of our product candidates in clinical trials and the sale of any products for which we obtain regulatory approval may expose us to product liability claims from consumers, health care providers, pharmaceutical companies or other entities. Although we plan to obtain product liability insurance coverage for our clinical

trials with limits that we hope will be customary and adequate to provide us with coverage for foreseeable risks associated with our product development efforts, our insurance coverage may be insufficient to reimburse us for the actual expenses or losses we may suffer.

To date, we have received a comfort letter from the insurer Marsh Inc. stating that our planned clinical trials of NK-001 are eligible for customary insurance subject to the approval of our clinical trial protocol by the requisite health authorities. If we obtain sufficient financing to proceed with our planned clinical trials, we intend to purchase insurance in amounts customary for trials comparable to our own. To that effect, we intend to consult with industry professionals to determine the optimal amount of coverage. In order to obtain insurance, we must subject our clinical trial protocol to a full review by our eventual insurance provider. The process of binding an insurance policy for a clinical trial can take as long as three months.

We also plan to expand our insurance to cover the commercial sale of products if we obtain the necessary regulatory approval to do so; however, the same product liability risks apply in those circumstances as in clinical trials. Further, even if we are able to successfully defend ourselves against any potential claims, we will likely incur substantial costs in the form of unanticipated expenses and negative publicity. This could result in decreased demand for our product candidates, the withdrawal of clinical trial participants, an impaired business reputation, revenue loss or an inability to commercialize our product candidates. Any of these consequences could cause us to cease our operations.

*We face substantial competition in the therapeutic pharmaceutical research and development industry, which could harm our business and our ability to operate profitably.*

Our industry is highly competitive, and many of our potential competitors, either alone or together with their partners, have substantially greater financial resources, research and development programs, clinical trial and regulatory experience, expertise in the protection of intellectual property rights, and manufacturing, distribution and sales and marketing capabilities than us. As a result, they may be able to:

- develop product candidates and market products that are less expensive, safer, more effective or involve more convenient treatment procedures than our future products;
- commercialize competing products before we can launch any of our product candidates;
- initiate or withstand substantial price competition more successfully than us;
- enjoy greater success in recruiting skilled scientific workers from a limited pool of available talent;
- more effectively negotiate third-party licenses and strategic alliances; and

*All of our product candidates and product development processes will be subject to ongoing regulatory requirements, and may therefore be the subject of regulatory or enforcement action. The associated costs could prevent us from achieving our goals or becoming profitable.*

Our product candidates, clinical data, third-party manufacturing facilities and processes and advertising and promotional activities for any product that receives regulatory approval will be subject to significant review and ongoing and changing regulation by various regulatory agencies. Our failure to comply with any regulatory requirements may subject us to administrative and judicial sanctions, which may include warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production, or the denial of pending product marketing applications.

Even if we receive regulatory approval to market a particular product candidate, such approval could be conditional upon our conducting costly post-approval studies or could limit the indicated uses that we are able to include on our product labels. In addition, regulatory or enforcement actions could adversely affect our ability to develop, market and sell our prospective products successfully and harm our reputation, which could lead to reduced market demand for such products. Consequently, the costs associated with any such action could cause our business to suffer and prevent us from achieving our goals or becoming profitable.

*Since our place of business and several of our officers, directors and business assets are located in Canada, you may be limited in your ability to enforce U.S. civil actions against them for damages to the value of your investment.*

*We may indemnify our directors and officers against liability to us and our security holders, and such indemnification could increase our operating costs.*

Our Articles allow us to indemnify our directors and officers against claims associated with carrying out the duties of their offices. Our Articles also allow us to reimburse them for the costs of certain legal defenses. Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to our directors, officers or control persons, we have been advised by the SEC that such indemnification is against public policy and is therefore unenforceable.

Since our officers and directors are aware that they may be indemnified for carrying out the duties of their offices, they may be less motivated to meet the standards required by law to properly carry out such duties, which could increase our operating costs. Further, if our officers and directors file a claim against us for indemnification, the associated expenses could also increase our operating costs.

**Risks Related to Our Intellectual Property**

*If we are unable to maintain and enforce our proprietary intellectual property rights, we may not be able to operate profitably.*

Our commercial success will depend, in part, on obtaining and maintaining patent protection, trade secret protection and regulatory protection of our technologies and product candidates as well as successfully defending third-party challenges to such technologies and candidates. We will be able to protect our technologies and product candidates from use by third parties only to the extent that valid and enforceable patents, trade secrets or regulatory protection cover them and we have exclusive rights to use them. The ability of our licensors, collaborators and suppliers to maintain their patent rights against third-party challenges to their validity, scope or enforceability will also play an important role in determining our future.

In addition, our commercial success will depend, in part, on maintaining patent rights we have licensed or plan to license related to products we may market in the future. Since we will not fully control the patent prosecution of any licensed patent applications, it is possible that our licensors will not devote the same resources or attention to the prosecution of the licensed patent applications as we would if we controlled the prosecution of the applications ourselves. Consequently, the resulting patent protection, if any, may not be as strong or comprehensive as it would be had we done so.

The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions that include unresolved principles and issues. No consistent policy regarding the breadth of claims allowed regarding such companies' patents has emerged to date in the United States, and the patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict with any certainty the range of claims that may be allowed or enforced concerning our patents or third-party patents.

We also rely on trade secrets to protect our technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we seek to protect confidential information, in part, through confidentiality agreements with our consultants and scientific and other advisors, they may unintentionally or willfully disclose our information to competitors. Enforcing a claim against a third party related to the illegal acquisition and use of trade secrets can be expensive and time consuming, and the outcome is often unpredictable. If we are not able to maintain patent or trade secret protection on our technologies and product candidates, then we may not be able to exclude competitors from developing or marketing competing products, and we may not be able to operate profitability.

*If we are the subject of an intellectual property infringement claim, the cost of participating in any litigation could cause us to go out of business.*

There has been, and we believe that there will continue to be, significant litigation and demands for licenses in our industry regarding patent and other intellectual property rights. Although we anticipate having a valid defense to any allegation that our current product candidates, production methods and other activities infringe the valid and enforceable intellectual property rights of any third parties, we cannot be certain that a third party will not challenge our position in the future. Other parties may own patent rights that we might infringe with our products or other activities, and our competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. These parties could bring claims against us that would cause us to incur substantial litigation expenses and, if successful, may require us to pay substantial damages. Some of our potential competitors may be better able to sustain the costs of complex patent litigation, and depending on the circumstances, we could be forced to stop or delay our research, development, manufacturing or sales activities. Any of these costs could cause us to go out of business.

*We may in the future be required to license patent rights from third-party owners in order to develop our products candidates. If we cannot obtain those licenses or if third-party owners do not properly maintain or enforce the patents underlying such licenses, we may not be able to market or sell our planned products.*

Although we are not currently dependent on any third-party intellectual property rights to execute our research and development activities, we plan to license patent-protected technologies and other intellectual property if we believe it is necessary or useful to use third-party intellectual property to develop our products, or if our product development threatens to infringe upon the intellectual property rights of third parties. Typically, we would seek to negotiate and obtain any required third party licenses immediately following the completion of preliminary research to establish a concept and plan of development for a new product candidate. However, depending on the ongoing results and requirements of pre-clinical or clinical trials, which may unexpectedly vary from our anticipated plan of development, we may be required to seek additional third-party licenses at later stages of product development. We may be required to pay license fees or royalties or both to obtain such licenses, and there is no guarantee that such licenses will be available on acceptable terms, if at all. Even if we are able to successfully obtain a license, the rights may be non-exclusive, and this would give our competitors access to the same intellectual property as us, which could ultimately prevent us from commercializing a product.

Should we succeed in obtaining a license, our business prospects will depend, in part, on the ability of our licensors to obtain, maintain and enforce patent protection on our licensed intellectual property. Our licensors may terminate our license, may not pursue and successfully prosecute any potential patent infringement claim, may fail to maintain their patent applications, or may pursue any litigation less aggressively than we would. Without protection for the intellectual property that we license, other companies may be able to offer substantially similar products for sale, and we may not be able to market or sell our planned products or generate any revenues.

*If the FDA grants one of our competitors an orphan drug designation for a drug and indication combination that is identical to the drug and indication combination used and targeted by one of our products, we will prevented from marketing that product for seven years.*

The FDA may grant an orphan drug designation to a drug intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. An orphan drug designation must be requested before a sponsor submits a New Drug Application to the FDA, and if the FDA grants such a designation the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. An orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process that a drug must undergo; however, if a product that is the subject of an orphan drug designation subsequently receives FDA approval for the indication for which it has such a designation, the product is entitled to orphan exclusivity for up to seven years after receiving FDA approval. This means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances.

Therefore, if one of our competitors obtains an orphan drug designation for a drug and indication combination that is identical to the drug and indication combination of one of our products (i.e. the same underlying drug applied to the same indication), our product may not be approved for the same indication for up to seven subsequent years.

**Risks Associated with Our Securities**

*Trading on the OTC Bulletin Board may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.*

Our common stock is quoted on the OTC Bulletin Board service of the Financial Industry Regulatory Authority. Trading in stock quoted on the OTC Bulletin Board is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Bulletin Board is not a stock exchange, and trading of securities on the OTC Bulletin Board is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like Amex. Accordingly, shareholders may have difficulty reselling any of their shares.

Our stock is a penny stock. Trading of our stock may be restricted by the SEC's penny stock regulations and FINRA's sales practice requirements, which may limit a stockholder's ability to buy and sell our stock.

Our stock is a penny stock. The Securities and Exchange Commission has adopted Rule 15g-9 which generally defines "penny stock" to be any equity security that has a market price (as defined) less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors". The term "accredited investor" refers generally to institutions with assets in excess of $5,000,000 or individuals with a net worth in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in, and limit the marketability of, our common stock.

In addition to the "penny stock" rules promulgated by the Securities and Exchange Commission, the Financial Industry Regulatory Authority has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, the Financial Industry Regulatory Authority believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. The Financial Industry Regulatory Authority requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock.

*You will experience dilution or subordinated stockholder rights, privileges and preferences as a result of our financing efforts.*

We must raise additional capital from external sources to carry out our business plan over the next 12 months. To do so, we may issue debt securities, equity securities or a combination of these securities; however, we

may not be able to sell these securities, particularly under current market conditions. Even if we are successful in finding buyers for our securities, such buyers could demand high interest rates or require us to agree to onerous operating covenants, which could in turn harm our ability to operate our business by reducing our cash flow and restricting our operating activities. If we choose to sell shares of our common stock, this will result in dilution to our existing stockholders. In addition, any shares of common stock we may issue may have rights, privileges and preferences superior to those of our current stockholders.

*We do not intend to pay dividends and there will thus be fewer ways in which you are able to make a gain on your investment, if at all.*

We have never paid dividends and do not intend to pay any dividends for the foreseeable future. To the extent that we may require additional funding currently not provided for in our financing plan, our funding sources may prohibit the declaration of dividends. Because we do not intend to pay dividends, any gain on your investment will need to result from an appreciation in the price of our common stock. There will therefore be fewer ways in which you are able to make a gain on your investment, if at all. There is also no guarantee that your investment will appreciate.

You may face significant restrictions on the resale of your shares due to state "blue sky" laws.

Each state has its own securities laws, often called "blue sky" laws, which (1) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

**Other Risks**

*Because some of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against the non U.S. officers and directors for misconduct and may not be able to enforce judgment and civil liabilities against our officers, directors, experts and agents.*

Some of our directors and officers are nationals and/or residents of countries other than the United States, specifically Canada and Germany, and all or a substantial portion of such persons' assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof.

**Trends, Risks and Uncertainties**

We have sought to identify what we believe to be the most significant risks to our business, but we cannot predict whether, or to what extent, any of such risks may be realized nor can we guarantee that we have identified all possible risks that might arise. Investors should carefully consider all of such risk factors before making an investment decision with respect to our common stock.

**Item 1B. Unresolved Staff Comments**

As a "smaller reporting company", we are not required to provide the information required by this Item.

**Item 2. Properties**

We do not currently own or lease a dedicated executive office or laboratory space. We maintain a dedicated mailing address and telephone reception service located at 1275 West 6th Avenue, Vancouver, British Columbia, Canada V6H 1A6, at a cost of approximately $70 per month. We also have access to office and meeting space at that location for a nominal fee, on an as-used basis.

**Item 3. Legal Proceedings**

We know of no material, existing or pending legal proceedings against our company, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder, is an adverse party or has a material interest adverse to our interest.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock quoted on the OTC Bulletin Board under the Symbol "NEUKD", in connection with the approval of our change of name and reverse stock split which was effective on April 20, 2015, our trading symbol will change to " PVOTF" on or about May 18, 2015. Our common stock was listed for quotation on April 13, 2010.

The following table reflects the high and low bid information for our common stock obtained from Stockwatch and reflects inter-dealer prices, without retail mark-up, markdown or commission, and may not necessarily represent actual transactions.

The high and low bid prices of our common stock for the periods indicated below are as follows:

**OTC Bulletin Board[(1)]**

| Quarter Ended | High | Low |
|---|---|---|
| January 31, 2015 | $ 0.068 | $ 0.00 |
| October 31, 2014 | $ 0.068 | $ 0.019 |
| July 31, 2014 | $ 0.12 | $ 0.032 |
| April 30, 2014 | $ 0.395 | $ 0.055 |
| January 31, 2014 | $ 0.17 | $ 0.021 |
| October 31, 2013 | $ 0.2 | $ 0.023 |
| July 31, 2013 | $ 0.023 | $ 0.023 |
| April 30, 2013 | $ 0.05 | $ 0.02 |
| January 31, 2013 | $ 0.1 | $ 0.05 |

(1) Over-the-counter market quotations reflect inter-dealer prices without retail mark-up, mark-down or commission, and may not represent actual transactions.

As of May 15, 2015, there were approximately 52 holders of record of our common stock. As of such date, 108,363,784 common shares were issued and outstanding.

Our common shares are issued in registered form. ClearTrust LLC, 16540 Pointe Village Drive, Suite 206, Lutz, Florida 33558, telephone number (813) 235-4490, is the registrar and transfer agent for our common shares.

**Dividend Policy**

We have not paid any cash dividends on our common stock and have no present intention of paying any dividends on the shares of our common stock. Our current policy is to retain earnings, if any, for use in our operations and in the development of our business. Our future dividend policy will be determined from time to time by our board of directors.

**Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities**

Other than as set out below, we did not sell any equity securities which were not registered under the Securities Act during the year ended January 31, 2015 that were not otherwise disclosed on our quarterly reports on Form 10-Q or our current reports on Form 8-K filed during the year ended January 31, 2015.

Effective March 19, 2015, we entered into director services agreements with our president and director, BJ Bormann, and our directors, Dr. Wolfgang Renz and Dr. Patrick Frankham. Pursuant to the agreements each director shall provide director services to our company for a period of 24 months in consideration for 100,000,000 pre-split shares (10,000,000 post-split shares) of our common stock payable in installments of 25,000,000 (pre-split) or 2,500,000 (post-split) shares upon execution of the agreement, 25,000,000 (pre-split) or 2,500,000 (post-split) after 6 months, 25,000,000 (pre-split) or 2,500,000 (post-split) after 12 months, and 25,000,000 (pre-split) or 2,500,000 (post-split) after 24 months. Each agreement may be terminated by our company without notice for cause, or by any party with 30 days prior notice.

Also effective March 19, 2015, we entered into a management consulting agreement with Dr. Giora Davidai. Pursuant to the agreement Dr. Davidai shall provide consulting services to our company for a term of 12 months renewable by mutual agreement for an additional 12 months. In consideration of the services we have agreed to pay to Dr. Davidai 100,000,000 pre-split shares (10,000,000 post-split shares) shares of our common stock payable in installments of 25,000,000 (pre-split) or 2,500,000 (post-split) share upon execution of the agreement, 25,000,000 (pre-split) or 2,500,000 (post-split) after 6 months, 25,000,000 (pre-split) or 2,500,000 (post-split) after 12 months, and 25,000,000 (pre-split) or 2,500,000 (post-split) after 24 months (subject to renewal of the term).

On March 20, 2015, we issued 400,000,000 pre-split (40,000,000 post-split) common shares payable to Drs. Bormann, Renz, Frankham and Davidai pursuant to the above described agreements. The common shares not yet earned or payable will be held in escrow and released to the directors or consultant in accordance with the terms of their respective agreements. The 400,000,000 pre-split (40,000,000 post-split) common shares were issued to two (2) US persons in reliance on Rule 506 under Regulation D and/or Section 4(2) of the Securities Act of 1933 and to two (2) non-US persons (as that term is defined in Regulation S of the Securities Act of 1933), in offshore transactions relying on Regulation S of the Securities Act of 1933.

On March 20, 2015, we issued 299,202,532 pre-split (29,920,253 post-split) shares of our common stock to six subscribers at the price of $0.001 per share in full conversion of 6 outstanding convertible promissory notes held by the subscribers with an aggregate value US$299,203.53 including principle and accrued interest. We originally issued the convertible promissory notes for cash consideration on December 11, 2014, June 27, 2014, April 26, 2013, December 4, 2011, February 23, 2011 and December 16, 2010, respectively. The 299,202,532 pre-split (29,920,253 post-split) common shares were issued to six non-US persons (as that term is defined in Regulation S of the Securities Act of 1933), in offshore transactions relying on Regulation S of the Securities Act of 1933. 47,649,500 pre-split (4,764,950 post-split) of the common shares were issued to Sassel Investments Inc., a corporation beneficially owned and controlled by Hamid Doroudian, our former officer and director. Dr. Doroudian was also a member of our board of directors until his resignation on February 5, 2015. Dr. Doroudian remains as an affiliate of our company.

On April 21, 2015, we issued an aggregate of 2,500,000 (post-split) shares of our common stock to two individuals for services rendered. The shares were issued at a deemed price of $0.01 per share The 2,500,000 (post-split) common shares were issued to two non-US persons (as that term is defined in Regulation S of the Securities Act of 1933), in offshore transactions relying on Regulation S of the Securities Act of 1933.

**Equity Compensation Plan Information**

Except as disclosed below, we do not have a stock option plan in favor of any director, officer, consultant or employee of our company.

**Convertible Securities**

As of May 15, 2015, we had outstanding options to purchase 80,000 shares of our common stock at $0.05 exercisable until May 25, 2015. As of May 15, 2015, we had outstanding warrants to purchase 380,000 shares of our common stock at $0.05 per stock expiring on July 30, 2015.

*Convertible Debentures*

(a) On December 17, 2010, our company issued a convertible debenture with a non-related party for $65,079 (US$65,000). The debenture was unsecured, due interest at 8% per annum, and matured on September 17, 2011. The note is convertible into common shares at a conversion price equal to 55% of the average closing market price of the lowest three trading prices of our company's common stock during the preceding ten days prior to conversion. We recorded the conversion feature of the convertible debenture as a derivative liability at an estimated fair value of $65,079 with a corresponding discount to the convertible debenture. On June 23, 2011, we issued 14,546 shares of common stock to convert $11,674 (US$12,000). On June 29, 2011, we issued 16,970 shares of common stock to convert $13,792 (US$14,000). In January 2015, this convertible debenture, including accrued interest and accrued default penalty, was converted to 6,558,051 shares of common stock of our company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $22,276 (US$20,000)), plus the accrued default penalty of $nil (2014 - $11,138 (US$10,000)). As of January 31, 2015, the fair value of the conversion option derivative liability was $nil (2014 - $126,868).

(b) On February 23, 2011, our company issued a convertible debenture with a non-related party for $37,944 (US$40,000). The debenture was unsecured, due interest at 8% per annum, and matured on December 23, 2011. The note is convertible into common shares at a conversion price equal to 55% of the average closing market price of the lowest three trading prices of our company's common stock during the preceding ten days prior to conversion. We recorded the conversion feature of the convertible debenture as a derivative liability at an estimated fair value of $37,944 with a corresponding discount to the convertible debenture. On July 11, 2011, we issued 23,030 shares of common stock to convert $18,270 (US$19,000). In January 2015, this convertible debenture, including accrued interest and accrued default penalty, was converted to 3,221,849 shares of common stock of our company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $44,552 (US$40,000)), plus the accrued default penalty of $nil (2014 – $22,276 (US$20,000)). As of January 31, 2015, the fair value of the conversion option derivative liability was $nil (2014 - $73,133).

(c) On July 4, 2011, our company issued a note payable with a non-related party for $85,000. The note was unsecured, due interest at 24% per annum and matured on October 4, 2011. On October 4, 2011, the note was extended to January 4, 2012 under the same terms of the original agreement.

On December 4, 2011, we agreed to modify the principal balance owing of $85,000 and accrued interest of $8,551 into a new $101,855 (US$100,000) note payable, which was unsecured, due interest at 24% per annum, and matured on December 3, 2012. In addition, the note became convertible into common shares of our company at a conversion rate of US$0.01 per share. As part of the conversion to extend the note, we issued 1,000,000 common shares with a fair value of

$225,000 as a termination fee of the original note agreement.

As the modified debt terms include a beneficial conversion feature, we accounted for the modified debt terms in accordance with ASC 470, Debt – Debt with Conversions and Other Options. The conversion feature resulted in a discount on the convertible note of US$100,000.

On January 31, 2015, this convertible debenture and accrued interest was converted to 17,384,110 shares of common stock of our company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $111,380 (US$100,000)), plus accrued interest of $nil (2014 - $57,783 (US$51,879)).

(d) On April 26, 2013, our company issued a convertible debenture with a non-related party for $15,254 (US$15,000). The debenture was secured by 1,500,000 shares of common stock of our company, to be delivered to the lender if principal and interest are not repaid on maturity, due interest at 24% per annum, and matured on April 27, 2014. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

As the convertible debt terms include a beneficial conversion feature, we accounted for the debt terms in accordance with ASC 470, Debt – Debt with Conversions and Other Options. The conversion feature resulted in a discount on the convertible note of US$15,000.

On January 31, 2015, this convertible debenture and accrued interest was converted to 2,105,589 shares of common stock of our company (Note 7(d)). During the year ended January 31, 2015, we recorded accretion expense of $7,304 (2014 - $7,696). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $8,572 (US$7,696)), plus accrued interest of $nil (2014 - $2,974 (US$2,670)).

(e) On June 27, 2014, our company issued a convertible debenture with a non-related party for $7,500. The debenture is unsecured, due interest at 24% per annum and due on June 27, 2015. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

As the convertible debt terms include a beneficial conversion feature, we accounted for the debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options.* The conversion feature resulted in a discount on the convertible note of $7,500.

On January 31, 2015, this convertible debenture and accrued interest was converted to 725,988 shares of common stock of our company (Note 7(d)). During the year ended January 31, 2015, we recorded accretion expense of $2,275 (2014 - $nil). As of January 31, 2015 and 2014, the carrying value and accrued interest of the convertible debenture is $nil.

(f) On December 11, 2014, our company issued a convertible debenture with a non-related party for $2,000. The debenture is unsecured, due interest at 24% per annum and due on December 11, 2015. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

As the convertible debt terms include a beneficial conversion feature, we accounted for the debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options.* The conversion feature resulted in a discount on the convertible note of $1,200.

On January 31, 2015, this convertible debenture was converted to 174,666 shares of common stock of our company (Note 7(d)). During the year ended January 31, 2015, we recorded accretion expense of $133 (2014 - $nil). As of January 31, 2015 and 2014, the carrying value and accrued interest of the convertible debenture is $nil.

On March 20, 2015, we issued 299,202,532 pre-split (29,920,253 post-split) shares of our common stock to six subscribers at the price of US$0.001 per share in full conversion of 6 outstanding convertible promissory notes held by the subscribers with an aggregate value US$299,203.53 including principle and accrued interest. We originally issued the convertible promissory notes for cash consideration on December 11, 2014, June 27, 2014, April 26, 2013, December 4, 2011, February 23, 2011, and December 16, 2010, respectively. 47,649,500 pre-split (4,764,950 post-split) of the common shares were issued to Sassel Investments Inc., a corporation beneficially owned and controlled by Hamid Doroudian, our former officer and director. Dr. Doroudian remains as an affiliate of our company.

**Purchase of Equity Securities by the Issuer and Affiliated Purchasers**

We did not purchase any of our shares of common stock or other securities during our fourth quarter of our fiscal year ended January 31, 2015.

**Item 6. Selected Financial Data**

As a "smaller reporting company", we are not required to provide the information required by this Item.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion should be read in conjunction with our audited financial statements and the related notes for the years ended January 31, 2015 and January 31, 2014 that appear elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed below and elsewhere in this annual report, particularly in the section entitled "Risk Factors" beginning on page 31 of this annual report.

Our audited financial statements are stated in United States Dollars and are prepared in accordance with United States Generally Accepted Accounting Principles.

**Purchase of Significant Equipment**

We do not intend to purchase any significant equipment over the next twelve months.

**Personnel Plan**

We do not expect any material changes in the number of employees over the next 12 month period (although we may enter into employment or consulting agreements with our officers or directors). We do and will continue to outsource contract employment as needed.

**Results of Operations**

*For the Year Ending January 31, 2015 and 2014*

| | Year Ended January 31, | |
|---|---|---|
| | **2015** | **2014** |
| Revenue | $ Nil | $ Nil |
| Operating expenses | $ 130,810 | $ 76,887 |
| Accretion of discounts on convertible debentures | $ 9,712 | $ 7,696 |
| Financing costs | $ 170,078 | $ 63,000 |
| Loss (gain) on change in fair value derivative | $ (210,100) | $ 58,661 |
| Loss on settlement and conversions of debentures | $ 1,084,300 | $ 512,500 |
| Interest expense | $ 72,247 | $ 35,131 |
| Net income (loss) | $(1,257,047) | $ (753,875) |

**Expenses**

Our operating expenses for our years ended January 31, 2015 and 2014 are outlined in the table below:

| | Year Ended January 31, | |
|---|---|---|
| | **2015** | **2014** |
| Depreciation and amortization | $ 455 | $ 455 |
| Consulting | $ Nil | $ Nil |
| Foreign exchange loss (gain) | $ 58,933 | $ 31,029 |
| General and administrative | $ 34,080 | $ 25,436 |
| Management fees | $ 3,000 | $ Nil |
| Professional fees | $ 34,342 | $ 19,967 |
| Research and development | $ Nil | $ Nil |

Operating expenses for year ended January 31, 2015 increased by 70% as compared to the comparative period in 2014 primarily as a result of increased professional fees and general and administration related to conversions and settlement of debentures. As well, fluctuations in the US-Canadian exchange resulted in an increased foreign exchange loss.

**Revenue**

We have not earned any revenues since our inception and we do not anticipate earning revenues in the upcoming quarter.

**Equity Compensation**

We currently do not have any stock option or equity compensation plans or arrangements.

**Liquidity and Financial Condition**

Working Capital

| | At January 31, 2015 | At January 31, 2014 |
|---|---|---|
| Current Assets | $ 1,193 | $ 6,295 |
| Current Liabilities | $ 71,053 | $ 728,915 |
| Working Capital (Deficit) | $ (69,860) | $ (722,620) |

Cash Flows

| | Year Ended January 31, 2015 | Year Ended January 31, 2014 |
|---|---|---|
| Net Cash used in Operating Activities | $ (52,665) | $ (27,276) |
| Net Cash used in Investing Activities | $ Nil | $ Nil |
| Net Cash Provided by Financing Activities | $ 52,688 | $ 27,845 |
| **Increase (Decrease) in Cash During the Period** | **$ 23** | **$ (569)** |

We will require additional funds to fund our budgeted expenses over the next 12 months. These funds may be raised through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our shares. There is still no assurance that we will be able to maintain operations at a level sufficient for an investor to obtain a return on his investment in our common stock. Further, we may continue to be unprofitable. We need to raise additional funds in the immediate future in order to proceed with our budgeted expenses.

Specifically, we estimate our operating expenses and working capital requirements for the next 12 months to be as follows:

| Description | Estimated Expenses ($) |
|---|---|
| **Sales and Marketing Costs:** | |
| Advertising | 3,600 |
| Investor Relations | 60,000 |
| Literature | 6,000 |
| Conference Attendance | 21,000 |
| Travel | 22,000 |
| Entertainment and Promotion | 2,400 |
| Marketing Costs | 115,000 |
| **Operating Expenses:** | |
| Professional Fees | 60,000 |
| Employee Salaries and Benefits | 384,000 |
| Office Equipment | 1,600 |
| Office Supplies | 1,200 |
| Office and Lab Lease | 40,000 |
| Telephone, Fax, Cellular, Internet | 6,000 |
| Vehicles and Transportation | 14,400 |
| **Total:** | **737,200** |

Based on our planned expenditures, we will require additional funds of approximately $736,133 (a total of $737,200 less our cash of approximately $1,067 as of January 31, 2015) to proceed with our business plan over the next 12 months. If we secure less than the full amount of financing that we require, we will not be able to carry out our complete business plan and we will be forced to proceed with a scaled back business plan based on our available financial resources.

We anticipate that we will incur substantial losses for the foreseeable future. Even if we carry out our planned research and development activities on our products, there is no guarantee that we will be able to market them or derive any revenues from their sale. Currently, we intend to prioritize the allocation of any financing that we may receive toward the development of P-001 and NK-001. The final selection of P-001 and the significantly underserved market that it is targeting along with NK-001, which has reached the most advanced development stage of our product candidates we believe that prioritizing their development will afford us the greatest likelihood of generating revenues which will in turn allow us to finance the development of other product candidates. Although we intend to conduct research and development of our other planned products, P-002, P-003 and NK-002, we do not have a formal clinical trial protocol or formal budget in place at this time.

The following table sets out the various steps we will be required to complete in order to carry out our research and development of P-001, P-002, P-003, NK-001 and NK-002. Where estimated costs or completion times are known, they have been indicated, and where progress has been made, it has been indicated. Where estimated completion times and cost estimates are omitted for future business steps, they are omitted because (i) we believe no reliable estimate may be made until currently planned research is completed and assessed, and/or (ii) we do not currently have sufficient resources to complete research that may be required to provide a reliable estimate.

| | Products | | |
|---|---|---|---|
| **Anticipated Steps** | **P-001** | **P-002** | **P-003** |
| Intellectual Property | Screening in female tissues/models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application | Screening in female tissues/models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application | Screening in female tissues/models, neurological models, reformulation and assessment of dosage regimen ($500,000) Follow by submission of new patent application |
| Secure Rights to Use Re-Profiled Drugs | Not Required (generic drug) | Not Required (generic drug) | Not Required (generic drug) |
| Pre-Clinical Testing | Required to select specific drug within class ($500,000) | Required to select specific drug within class ($500,000) | Required to select specific drug within class ($500,000) |
| Secure Investigational New Drug Approval or Equivalent | Not required (Generic drug) | Not required (Generic drug) | Not required (Generic drug) |
| Phase I Clinical Trials | Not Required | Not Required | Not Required |
| Phase II Clinical Trials | Required | Required | Required |
| Phase III Clinical Trials | Required | Required | Required |
| Submit New Drug Application or Equivalent and Obtain Marketing Approval | Required | Required | Required |
| Finance Marketing and Manufacturing of Approved Drug or Secure Marketing and Manufacturing Partner | Required | Required | Required |

| | Products | |
|---|---|---|
| **Anticipated Steps** | **NK-001** | **NK-002** |
| Secure Intellectual Property Protection of Drug Concept | Patent Application Submitted | Patent Application Submitted |
| Secure Rights to Use Re-Profiled Drug | Not Required (Generic Drug) | Not Required (Generic Drug) |
| Pre-Clinical Testing | Not Required | Pre-Clinical Trials Delayed Until Sufficient Financing is Secured Estimated Cost: $800,000 Estimated Completion Date: Unknown |
| Secure Investigational New Drug Approval or Equivalent | Not Required (Generic Drug) | Required |
| Phase I Clinical Trials | Not Required | Required |
| Phase II Clinical Trials | Clinical Trial Protocol Complete and Approved for Implementation Clinical Trials Delayed Until Sufficient Financing is Secured Estimated Cost: $2,355,000 Estimated Completion Date: Unknown | Required |
| Phase III Clinical Trials | Required | Required |
| Submit New Drug Application or Equivalent and Obtain Marketing | Required | Required |

| | | |
|---|---|---|
| Approval | | |
| Finance Marketing and Manufacturing of Approved Drug or Secure Marketing and Manufacturing Partner | Required | Required |

We did not commence clinical trials of NK001 and NK002 during 2015 and 2014 due to insufficient cash. We are seeking to raise funds to continue testing and development.

We expect that we may obtain material net cash inflows from our projects 18 to 36 months following the start of our proposed clinical trials, which we expect will begin soon after the necessary funding is obtained. However, there can be no assurance we will obtain such cash inflows.

We intend to raise capital through equity and, if necessary, debt financing. We anticipate that the bulk of any additional funding we receive will be in the form of equity financing from the sale of our common stock. However, we do not have any financing arranged and we cannot provide any assurance that we will be able to raise sufficient funds from the sale of our common stock to fund our operations or planned research and development activities. In the absence of such financing, we will not be able to carry out our planned research and development activities. Even if we are successful in obtaining equity financing to fund our operations and research and development activities, there is no assurance that we will obtain the funding necessary to pursue any advanced research and development following the completion of our planned clinical trials. If we do not continue to obtain additional financing, we may be forced to abandon our business plan.

Any modifications to our plans will be based on many factors, including the results of our clinical trials and the amount of available capital. Further, the extent to which we carry out our development of planned products is dependent upon the amount of financing available to us.

**Future Financings**

We will require additional financing in order to enable us to proceed with our plan of operations, as discussed above, including approximately $150,000 over the next 12 months to pay for our ongoing expenses. These expenses include legal, accounting and audit fees as well as general and administrative expenses. These cash requirements are in excess of our current cash and working capital resources. Accordingly, we will require additional financing in order to continue operations and to repay our liabilities. There is no assurance that any party will advance additional funds to us in order to enable us to sustain our plan of operations or to repay our liabilities.

We anticipate continuing to rely on equity sales of our common stock in order to continue to fund our business operations. Issuances of additional shares will result in dilution to our existing stockholders. There is no assurance that we will achieve any additional sales of our equity securities or arrange for debt or other financing to fund our planned business activities.

We presently do not have any arrangements for additional financing for the expansion of our exploration operations, and no potential lines of credit or sources of financing are currently available for the purpose of proceeding with our plan of operations.

**Contractual Obligations**

As a "smaller reporting company", we are not required to provide tabular disclosure obligations.

**Going Concern**

We have not generated any revenues and are dependent upon obtaining outside financing to carry out our operations and pursue our pharmaceutical research and development activities. If we are unable to generate future cash flows, raise equity or secure alternative financing, we may not be able to continue our operations and our business plan may fail. You may lose your entire investment.

If our operations and cash flow improve, management believes that we can continue to operate. However, no assurance can be given that management's actions will result in profitable operations or an improvement in our liquidity situation. The threat of our ability to continue as a going concern will cease to exist only when our revenues have reached a level able to sustain our business operations.

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States of America. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our financial statements is critical to an understanding of our financial statements.

*Basis of Presentation*

The financial statements and the related notes of our company are prepared in accordance with generally accepted accounting principles in the United States and are expressed in Canadian dollars. Our company's fiscal year-end is January 31.

*Use of Estimates*

The preparation of these financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our company regularly evaluates estimates and assumptions related to the recoverability of long-lived assets, valuation of convertible debentures, assumptions used to determine the fair value of stock-based compensation and derivative liabilities, and deferred income tax asset valuation allowances. Our company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by our company may differ materially and adversely from our company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

*Cash and Cash Equivalents*

Our company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents.

*Property and Equipment*

Property and equipment is comprised of office equipment and is recorded at cost. Our company amortizes the cost of equipment on a straight-line basis over their estimated useful lives of five years.

*Long-lived Assets*

In accordance with ASC 360, "Property, Plant and Equipment", our company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value, which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value.

*Stock-Based Compensation*

Our company records stock-based compensation in accordance with ASC 718, *Compensation – Stock-Based Compensation*, using the fair value method. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

*Derivative Financial Instruments*

Derivative financial instruments that are not classified as equity and are not used in hedging relationships are measured at fair value. Subsequent changes to fair value are recorded in the statement of operations.

*Basic and Diluted Net Loss Per Share*

Our company computes net loss per share in accordance with ASC 260, *Earnings Per Share*. ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the income statement. Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible preferred stock using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Diluted EPS excludes all dilutive potential shares if their effect is anti dilutive. As at January 31, 2015, our company has 4,600,000 pre-split or 460,000 post-split (2014 – 27,142,888 pre-split or 2,714,289 post-split) potentially dilutive shares.

*Comprehensive Loss*

ASC 220, *Comprehensive Income*, establishes standards for the reporting and display of comprehensive loss and its components in the financial statements. As at January 31, 2015 and 2014, our company had no items representing comprehensive income or loss.

*Research and Development Costs*

Research costs are expensed in the period that they are incurred.

*Income Taxes*

Our company accounts for income taxes using the asset and liability method in accordance with ASC 740, "Income Taxes". The asset and liability method provides that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. Our company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized. As of January 31, 2015 and 2014, our company did not have any amounts recorded pertaining to uncertain tax positions.

Our company files federal and provincial income tax returns in Canada. Our company may be subject to a reassessment of federal and provincial income taxes by Canadian tax authorities for a period of three years from the date of the original notice of assessment in respect of any particular taxation year. For Canadian tax returns, the open taxation years range from 2003 to 2014. Tax authorities of Canada have not audited any of our company's income tax returns for the open taxation years noted above.

Our company recognizes interest and penalties related to uncertain tax positions in tax expense. During the years ended January 31, 2015 and 2014, there were no charges for interest or penalties.

*Financial Instruments and Fair Value Measures*

ASC 820, *Fair Value Measurements*, requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. ASC 820 prioritizes the inputs into three levels that may be used to measure fair value:

*Level 1* - Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.

*Level 2* - Level 2 applies to assets or liabilities for which there are inputs other than quoted prices that are observable for the asset or liability such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

*Level 3* - Level 3 applies to assets or liabilities for which there are unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

Our company's financial instruments consist principally of cash, amounts receivable, accounts payable and accrued liabilities, loan payable, due to related parties and convertible debentures. Pursuant to ASC 820, the fair value of our cash is determined based on "Level 1" inputs, which consist of quoted prices in active markets for identical assets. We believe that the recorded values of all of our other financial instruments approximate their current fair values because of their nature and respective maturity dates or durations.

*Foreign Currency Translation*

Our company's functional currency and its reporting currency is the Canadian dollar and foreign currency transactions are primarily undertaken in United States dollars. Monetary assets and liabilities are translated using the exchange rate prevailing at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are translated at rates of exchange in effect at the date of the transaction. Expenses are translated at average rates for the period. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in the determination of income.

**Recent Accounting Pronouncements**

In June 2014, the FASB issued ASU 2014-10, "Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation". The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. GAAP for development or exploration stage entities, primarily presentation of inception to date financial information. The provisions of the amendments are effective for annual reporting periods beginning after December 15, 2014, and the interim periods therein. However, early adoption is permitted. Accordingly, our company has adopted this standard as of January 31, 2015.

Our company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

As a "smaller reporting company", we are not required to provide the information required by this Item.

**Item 8. Financial Statements and Supplementary Data**

**PIVOT PHARMACEUTICALS INC.**
**(formerly Neurokine Pharmaceuticals Inc.)**
Financial Statements
Years ended January 31, 2015 and 2014
(Expressed in Canadian dollars)


## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Pivot Pharmaceuticals Inc.

We have audited the accompanying balance sheets of Pivot Pharmaceuticals Inc. (the Company) as of January 31, 2015 and 2014 and the related statements of operations, stockholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated 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 audits 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion the financial statements referred to above present fairly, in all material respects, the financial position of Pivot Pharmaceuticals Inc. as of January 31, 2015 and 2014, and the results of their operations and cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company had an accumulated deficit, negative working capital, and no revenue to date as of January 31, 2015 which raises substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ Sadler, Gibb & Associates, LLC*

Salt Lake City, UT
May 15, 2015

office 801.783.2950
fax 801.783.2960

www.sadlergibb.com | 2455 East Parleys Way Suite 320, Salt Lake City, UT 84109

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Balance Sheets
(Expressed in Canadian dollars)

| | January 31, 2015 $ | January 31, 2014 $ |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash | 1,067 | 1,044 |
| Amounts receivable | 126 | 5,251 |
| Total current assets | 1,193 | 6,295 |
| Property and equipment (Note 3) | 417 | 872 |
| Total assets | 1,610 | 7,167 |
| Liabilities and Stockholders' Deficit | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | 52,388 | 35,373 |
| Loans payable (Note 4) | – | 55,306 |
| Due to related party (Note 10) | – | 151,384 |
| Convertible debentures, net of unamortized discount of $nil and $7,304, respectively (Note 5) | – | 286,852 |
| Derivative liabilities – current portion (Note 6) | 18,665 | 200,000 |
| Total current liabilities | 71,053 | 728,915 |
| Derivative liabilities (Note 6) | – | 28,765 |
| Total liabilities | 71,053 | 757,680 |
| Stockholders' Deficit | | |
| Common stock: Unlimited shares authorized, without par value 65,863,767 and 10,076,707 shares issued and outstanding, respectively | 3,834,265 | 1,674,148 |
| Common stock issuable (Note 7) | – | 225,000 |
| Additional paid-in capital (Note 10) | 267,586 | 264,586 |
| Accumulated deficit | (4,171,294) | (2,914,247) |
| Total stockholders' deficit | (69,443) | (750,513) |
| Total liabilities and stockholders' deficit | 1,610 | 7,167 |

Nature of operations and continuance of business (Note 1)

Subsequent events (Note 12)

(The accompanying notes are an integral part of these financial statements)

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Statements of Operations
(Expressed in Canadian dollars)

| | Year Ended January 31, 2015 $ | Year Ended January 31, 2014 $ |
|---|---|---|
| Revenue | – | – |
| Expenses | | |
| Depreciation and amortization | 455 | 455 |
| Foreign exchange loss | 58,933 | 31,029 |
| General and administrative | 34,080 | 25,436 |
| Management fees (Note 10) | 3,000 | – |
| Professional fees | 34,342 | 19,967 |
| Total expenses | 130,810 | 76,887 |
| Loss from operations | (130,810) | (76,887) |
| Other (expenses) income | | |
| Accretion of discount on convertible debentures | (9,712) | (7,696) |
| Financing costs | (170,078) | (63,000) |
| Gain (loss) on change in fair value of derivative liabilities | 210,100 | (58,661) |
| Loss on settlement and conversions of debentures | (1,084,300) | (512,500) |
| Interest expense | (72,247) | (35,131) |
| Total other (expenses) income | (1,126,237) | (676,988) |
| Net loss | (1,257,047) | (753,875) |
| Net loss per share, basic | (0.11) | (0.20) |
| Net loss per share, diluted | (0.11) | (0.20) |
| Weighted average shares outstanding - basic | 11,599,995 | 4,828,702 |
| Weighted average shares outstanding - diluted | 11,599,995 | 4,828,702 |

(The accompanying notes are an integral part of these financial statements)

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Statements of Stockholders' Equity (Deficit)
(Expressed in Canadian dollars)

| | Common Stock | | Common Stock Issuable | Additional Paid-In Capital | Deficit | Total |
|---|---|---|---|---|---|---|
| | Shares # | Amount $ | $ | $ | $ | $ |
| Balance – January 31, 2013 | 3,576,707 | 1,086,148 | 225,000 | 174,586 | (2,160,372) | (674,638) |
| Contributed capital | – | – | – | 75,000 | – | 75,000 |
| Beneficial conversion feature of convertible debenture | – | – | – | 15,000 | – | 15,000 |
| Shares issued on default of loan debenture | 3,000,000 | 63,000 | – | – | – | 63,000 |
| Shares issued to settle due to related party | 3,500,000 | 525,000 | – | – | – | 525,000 |
| Net loss | – | – | – | – | (753,875) | (753,875) |
| Balance – January 31, 2014 | 10,076,707 | 1,674,148 | 225,000 | 264,586 | (2,914,247) | (750,513) |
| Contributed capital | – | – | – | 3,000 | – | 3,000 |
| Shares issued for termination fees | 1,000,000 | 225,000 | (225,000) | – | – | – |
| Shares issued on default of loans | 2,750,000 | 170,078 | – | – | – | 170,078 |
| Shares issued on settlement and conversion of debentures | 35,524,538 | 777,012 | – | – | – | 777,012 |
| Shares issued to settle amounts due to related party | 16,512,521 | 988,027 | – | – | – | 988,027 |
| Net loss | – | – | – | – | (1,257,047) | (1,257,047) |
| Balance – January 31, 2015 | 65,863,766 | 3,834,265 | – | 267,586 | (4,171,294) | (69,443) |

(The accompanying notes are an integral part of these financial statements)

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Statements of Cash Flows
(Expressed in Canadian dollars)

| | Year Ended January 31, 2015 $ | Year Ended January 31, 2014 $ |
|---|---|---|
| Operating activities | | |
| Net income (loss) | (1,257,047) | (753,875) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Accretion of discount on convertible debentures | 11,964 | 7,696 |
| Depreciation and amortization | 455 | 455 |
| (Gain) loss on change in fair value of derivative liabilities | (210,100) | 58,661 |
| Loss on settlement and conversions of debentures | 1,084,300 | 490,000 |
| Shares issued for loan defaults | 170,078 | 63,000 |
| Services contributed by related party | 3,000 | – |
| Changes in operating assets and liabilities: | | |
| Other receivable | 5,251 | (997) |
| Accounts payable and accrued liabilities | 98,838 | 52,933 |
| Due to related parties | 40,596 | 54,851 |
| Net cash used in operating activities | (52,665) | (27,276) |
| Financing activities | | |
| Proceeds from issuance of convertible debentures | 12,095 | 27,845 |
| Proceeds from related party loans | 40,593 | – |
| Net cash provided by financing activities | 52,688 | 27,845 |
| Increase in cash | 23 | 569 |
| Cash – beginning of period | 1,044 | 475 |
| Cash – end of period | 1,067 | 1,044 |
| Supplemental disclosures: | | |
| Interest paid | 274 | – |
| Income tax paid | – | – |
| Non-cash activities: | | |
| Contributed services | – | 75,000 |
| Debt discount on beneficial conversion feature | – | 15,000 |
| Shares issued for settlement and conversions of debentures | 777,012 | – |
| Shares issued for settlement of amounts due to related party | 988,027 | 35,000 |

(The accompanying notes are an integral part of these financial statements)

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

## 1. Nature of Operations and Continuance of Business

Pivot Pharmaceuticals Inc. (formerly Neurokine Pharmaceuticals Inc.) (the "Company") was incorporated in British Columbia under the Business Corporations Act on June 10, 2002. On April 7, 2015, the Company changed its name from Neurokine Pharmaceuticals Inc. to Pivot Pharmaceuticals Inc. The Company is in the business of developing and commercializing new uses for existing prescription drugs as well as developing proprietary encapsulation technology in the treatment of neurodegenerative diseases.

These financial statements have been prepared on the going concern basis, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. As at January 31, 2015, the Company has not earned any revenue, has a working capital deficit of $69,860 and an accumulated deficit of $4,171,294. The continued operations of the Company are dependent on its ability to generate future cash flows or obtain additional financing. These factors raise substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments to the recorded assets or liabilities that might be necessary should the Company be unable to continue as a going concern.

## 2. Significant Accounting Policies

(a) Basis of Presentation

The financial statements and the related notes of the Company are prepared in accordance with generally accepted accounting principles in the United States and are expressed in Canadian dollars. The Company's fiscal year-end is January 31.

(b) Use of Estimates

The preparation of these financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company regularly evaluates estimates and assumptions related to the useful life and recoverability of long-lived assets, valuation of convertible debentures, assumptions used to determine the fair values of stock-based compensation and derivative liabilities, and deferred income tax asset valuation allowances. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

(c) Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents. As at January 31, 2015 and 2014, the Company had no cash equivalents.

(d) Property and Equipment

Property and equipment is comprised of office equipment and is recorded at cost. The Company amortizes the cost of equipment on a straight-line basis over their estimated useful life of five years.

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

**2. Significant Accounting Policies** (continued)

(e) Long-lived Assets

In accordance with ASC 360, "Property, Plant and Equipment", the Company tests long-lived assets or asset groups for recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that the asset will more likely than not be sold or disposed significantly before the end of its estimated useful life. Recoverability is assessed based on the carrying amount of the asset and its fair value, which is generally determined based on the sum of the undiscounted cash flows expected to result from the use and the eventual disposal of the asset, as well as specific appraisal in certain instances. An impairment loss is recognized when the carrying amount is not recoverable and exceeds fair value.

(f) Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC 718, Compensation – Stock-Based Compensation, using the fair value method. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

(g) Derivative Financial Instruments

Derivative financial instruments that are not classified as equity and are not used in hedging relationships are measured at fair value. Subsequent changes to fair value are recorded in the statement of operations.

(h) Loss Per Share

The Company computes net loss per share in accordance with ASC 260, Earnings Per Share. ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the income statement. Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible preferred stock using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Diluted EPS excludes all dilutive potential shares if their effect is anti dilutive. As at January 31, 2015, the Company has 460,000 (2014 – 2,714,289) potentially dilutive shares.

(i) Comprehensive Loss

ASC 220, *Comprehensive Income*, establishes standards for the reporting and display of comprehensive loss and its components in the financial statements. As at January 31, 2015 and 2014, the Company had no items representing comprehensive income or loss.

(j) Research and Development Costs

Research costs are expensed in the period that they are incurred.

**2. Significant Accounting Policies** (continued)

(k) Income Taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, "Income Taxes". The asset and liability method provides that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized. As of January 31, 2015 and 2014, the Company did not have any amounts recorded pertaining to uncertain tax positions.

The Company files federal and provincial income tax returns in Canada. The Company may be subject to a reassessment of federal and provincial income taxes by Canadian tax authorities for a period of three years from the date of the original notice of assessment in respect of any particular taxation year. For Canadian tax returns, the open taxation years range from 2003 to 2014. Tax authorities of Canada have not audited any of the Company's income tax returns for the open taxation years noted above.

The Company recognizes interest and penalties related to uncertain tax positions in tax expense. During the years ended January 31, 2015 and 2014, there were no charges for interest or penalties.

(l) Financial Instruments and Fair Value Measures

ASC 820, Fair Value Measurements, requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. ASC 820 prioritizes the inputs into three levels that may be used to measure fair value:

*Level 1*

Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.

*Level 2*

Level 2 applies to assets or liabilities for which there are inputs other than quoted prices that are observable for the asset or liability such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

*Level 3*

Level 3 applies to assets or liabilities for which there are unobservable inputs to

the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

The Company's financial instruments consist principally of cash, amounts receivable, accounts payable and accrued liabilities, loan payable, due to related parties and convertible debentures. Pursuant to ASC 820, the fair value of our cash is determined based on "Level 1" inputs, which consist of quoted prices in active markets for identical assets. The recorded values of all other financial instruments approximate their current fair values because of their nature and respective maturity dates or durations.

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

**2. Significant Accounting Policies** (continued)

(m) Foreign Currency Translation

The Company's functional currency and its reporting currency is the Canadian dollar and foreign currency transactions are primarily undertaken in United States dollars. Monetary assets and liabilities are translated using the exchange rate prevailing at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are translated at rates of exchange in effect at the date of the transaction. Expenses are translated at average rates for the period. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in the determination of income.

(n) Recent Accounting Pronouncements

In June 2014, the FASB issued ASU 2014-10, "Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation". The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. GAAP for development or exploration stage entities, primarily presentation of inception to date financial information. The provisions of the amendments are effective for annual reporting periods beginning after December 15, 2014, and the interim periods therein. However, early adoption is permitted. Accordingly, the Company has adopted this standard as of January 31, 2015.

The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

(o) Comparative Figures

During the period, the Company determined that certain transactions affecting stockholders' equity had inadvertently been recorded using a par value of $0.01 in the fiscal year ended January 31, 2014.

The Company has determined that its previously filed Form 10-K included a misclassification of $523,000 related to equity. After taking the reclassification into account, the balances of common shares and additional paid-in capital as of January 31, 2014, are $1,674,148 and $264,586, respectively.

**3. Property and Equipment**

| | Cost<br>$ | Accumulated amortization<br>$ | January 31, 2015 Net carrying value<br>$ | January 31, 2014 Net carrying value<br>$ |
|---|---|---|---|---|
| Office furniture and equipment | 2,276 | 1,859 | 417 | 872 |

Depreciation expense included as a charge to income was $455 and $455 for the years ended January 31,

2015 and 2014, respectively.

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

## 4. Loans Payable

On March 30, 2012, the Company issued a promissory note to a non-related party for $30,000. The loan was secured by 3,000,000 shares of common stock of the Company, to be delivered to the lender if principal and interest are not repaid on maturity, due interest at 24% per annum, and matured on March 30, 2013.

On September 19, 2013, the Company issued a promissory note to a non-related party for US$10,000. The loan was secured by 1,000,000 shares of common stock of the Company, to be delivered to the lender if principal and interest are not repaid on maturity, due interest at 24% per annum, and matured on September 19, 2014.

On January 31, 2015, these promissory notes, together with accrued interest, were settled through the issuance of 5,604,285 shares of common stock of the Company (Note 7(e)).

## 5. Convertible Debentures

(a) On December 17, 2010, the Company issued a convertible debenture with a non-related party for $65,079 (US$65,000). The debenture was unsecured, due interest at 8% per annum, and matured on September 17, 2011. The note is convertible into common shares at a conversion price equal to 55% of the average closing market price of the lowest three trading prices of the Company's common stock during the preceding ten days prior to conversion. The Company recorded the conversion feature of the convertible debenture as a derivative liability at an estimated fair value of $65,079 with a corresponding discount to the convertible debenture. On June 23, 2011, the Company issued 14,546 shares of common stock to convert $11,674 (US$12,000). On June 29, 2011, the Company issued 16,970 shares of common stock to convert $13,792 (US$14,000). In January 2015, this convertible debenture, including accrued interest and accrued default penalty, was converted to 6,353,287 shares of common stock of the Company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $22,276 (US$20,000)), plus the accrued default penalty of $nil (2014 - $11,138 (US$10,000)). As of January 31, 2015, the fair value of the conversion option derivative liability was $nil (2014 - $126,868).

(b) On February 23, 2011, the Company issued a convertible debenture with a non-related party for $37,944 (US$40,000). The debenture was unsecured, due interest at 8% per annum, and matured on December 23, 2011. The note is convertible into common shares at a conversion price equal to 55% of the average closing market price of the lowest three trading prices of the Company's common stock during the preceding ten days prior to conversion. The Company recorded the conversion feature of the convertible debenture as a derivative liability at an estimated fair value of $37,944 with a corresponding discount to the convertible debenture. On July 11, 2011, the Company issued 23,030 shares of common stock to convert $18,270 (US$19,000). In January 2015, this convertible debenture, including accrued interest and accrued default penalty, was converted to 3,176,633 shares of common stock of the Company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $44,552 (US$40,000)), plus the accrued default penalty of $nil (2014 – $22,276 (US$20,000)). As of January 31, 2015, the fair value of the conversion option derivative liability was $nil (2014 - $73,133).

(c) On July 4, 2011, the Company issued a note payable with a non-related party for $85,000. The note was unsecured, due interest at 24% per annum and matured on October 4, 2011. On October 4, 2011, the note was extended to January 4, 2012 under the same terms of the original agreement.

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

**5. Convertible Debentures** (continued)

On December 4, 2011, the Company agreed to modify the principal balance owing of $85,000 and accrued interest of $8,551 into a new $101,855 (US$100,000) note payable, which was unsecured, due interest at 24% per annum, and matured on December 3, 2012. In addition, the note became convertible into common shares of the Company at a conversion rate of US$0.01 per share. As part of the conversion to extend the note, the Company issued 1,000,000 common shares with a fair value of $225,000 as a termination fee of the original note agreement.

As the modified debt terms include a beneficial conversion feature, the Company accounted for the modified debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options*. The conversion feature resulted in a discount on the convertible note of US$100,000.

On January 31, 2015, this convertible debenture and accrued interest was converted to 17,384,110 shares of common stock of the Company (Note 7(d)). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $111,380 (US$100,000)), plus accrued interest of $nil (2014 - $57,783 (US$51,879)).

The Company also issued 1,000,000 shares of common stock pursuant to termination fee for the July 4, 2011 note payable.

(d) On April 26, 2013, the Company issued a convertible debenture with a non-related party for $15,254 (US$15,000). The debenture was secured by 1,500,000 shares of common stock of the Company, to be delivered to the lender if principal and interest are not repaid on maturity, due interest at 24% per annum, and matured on April 27, 2014. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

As the convertible debt terms include a beneficial conversion feature, the Company accounted for the debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options*. The conversion feature resulted in a discount on the convertible note of US$15,000.

On January 31, 2015, this convertible debenture and accrued interest was converted to 2,105,589 shares of common stock of the Company (Note 7(d)). During the year ended January 31, 2015, the Company recorded accretion expense of $7,304 (2014 - $7,696). As of January 31, 2015, the carrying value of the convertible debenture is $nil (2014 - $8,572 (US$7,696)), plus accrued interest of $nil (2014 - $2,974 (US$2,670)).

(e) On June 27, 2014, the Company issued a convertible debenture with a non-related party for $7,500. The debenture is unsecured, due interest at 24% per annum and due on June 27, 2015. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

As the convertible debt terms include a beneficial conversion feature, the Company accounted for the debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options*. The conversion feature resulted in a discount on the convertible note of $7,500.

On January 31, 2015, this convertible debenture and accrued interest was converted to 725,988 shares of common stock of the Company (Note 7(d)). During the year ended January 31, 2015, the Company recorded accretion expense of $2,275 (2014 - $nil). As of January 31, 2015 and 2014, the carrying value and accrued interest of the convertible debenture is $nil.

(f) On December 11, 2014, the Company issued a convertible debenture with a non-related party for $2,000. The debenture is unsecured, due interest at 24% per annum and due on December 11, 2015. The note, plus accrued interest, is convertible into common shares at a conversion price of US$0.01 per share at the discretion of the lender and at any time during the term of this debenture.

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

**5. Convertible Debentures** (continued)

As the convertible debt terms include a beneficial conversion feature, the Company accounted for the debt terms in accordance with ASC 470, *Debt – Debt with Conversions and Other Options.* The conversion feature resulted in a discount on the convertible note of $1,200.

On January 31, 2015, this convertible debenture was converted to 174,666 shares of common stock of the Company (Note 7(d)). During the year ended January 31, 2015, the Company recorded accretion expense of $133 (2014 - $nil). As of January 31, 2015 and 2014, the carrying value and accrued interest of the convertible debenture is $nil.

**6. Derivative Liabilities**

Derivative liabilities consist of convertible debentures with variable conversion prices and share purchase warrants originally issued in private placements with conversion/exercise prices denominated in United States dollars, which differs from the Company's functional currency.

In January 2015, the December 2010 and February 2011 convertible debentures were converted into shares of common stock of the Company (Notes 5(a) and 5(b)).

The fair values of these derivative liabilities as at January 31, 2015 and 2014 are as follows:

| | January 31, 2015 $ | January 31, 2014 $ |
|---|---|---|
| December 2010 convertible debenture | – | 81,848 |
| February 2011 convertible debenture | – | 44,072 |
| Default penalty on convertible debenture | – | 74,081 |
| 380,000 warrants expiring on July 30, 2015 | 18,665 | 28,765 |
| | 18,665 | 228,766 |

The fair values of derivative financial liabilities were determined using the Black-Scholes option pricing model, using the following assumptions:

| | Expected Volatility | Risk-free Interest Rate | Expected Dividend Yield | Expected Life (in years) |
|---|---|---|---|---|
| As at issuance date: | | | | |
| December 2010 convertible debenture | 125% | 1.19% | 0% | 0.75 |
| February 2011 convertible debenture | 125% | 1.27% | 0% | 0.75 |
| Default penalty on convertible debenture | 125% | 0.08% | 0% | 0.50 |
| 380,000 warrants expiring on July 30, 2015 | 125% | 1.26% | 0% | 4.50 |
| As at January 31, 2015: | | | | |
| December 2010 convertible debenture | – | – | – | – |
| February 2011 convertible debenture | – | – | – | – |
| Default penalty on convertible debenture | – | – | – | – |

| | | | | |
|---|---|---|---|---|
| 380,000 warrants expiring on July 30, 2015 | 342% | 0.07% | 0% | 0.50 |

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

## 7. Common Shares

During the year ended January 31, 2015:

(a) 1,500,000 shares of common stock were issuable pursuant to a default penalty on a convertible debenture on April 27, 2014 (Note 5(d)).

(b) 1,000,000 shares of common stock were issuable pursuant to a default penalty on a loan payable on September 19, 2014 (Note 4).

(c) 16,512,521 shares of common stock were issuable in January 2015 to settle $191,977 of amounts due to a related party.

(d) 250,000 shares of common stock were issued during the year pursuant to default penalties on convertible debentures (Notes 5(a) and 5(b)) and 29,920,253 shares of common stock were issuable in January 2015 on conversion of convertible debentures (Notes 5(a), 5(b), 5(c), 5(d), 5(e) and 5(f)). 1,000,000 shares of common stock were issued during the year pursuant to termination fee on a convertible debenture (Note 5(c)).

(e) 5,604,285 shares of common stock were issuable in January 2015 to settle loans payable (Note 4).

During the year ended January 31, 2014:

(f) 3,000,000 shares of common stock were issuable pursuant to a default penalty on a loan payable on March 24, 2013 (Note 4).

(g) The Company issued 3,500,000 shares of common stock to settle $35,000 of amounts due to related party on September 24, 2013.

## 8. Share Purchase Warrants

The following table summarizes the continuity of share purchase warrants:

| | Number of Warrants | Weighted Average Exercise Price $ |
|---|---|---|
| Balance, January 31, 2013 | 387,500 | 0.08 |
| Expired | (7,500) | 1.50 |
| Balance, January 31, 2015 and 2014 | 380,000 | 0.05 |

As at January 31, 2015, the following share purchase warrants were outstanding:

| Number of Warrants | Exercise Price $ | Expiry Date |
|---|---|---|

| | | | |
|---|---|---|---|
| 380,000 | 0.05 | July 30, 2015 | |

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

## 9. Stock Options

The following table summarizes the continuity of the Company's stock options:

| | Number of Options | Weighted Average Exercise Price (US$) | Weighted Average Remaining Contractual Life (years) | Aggregate Intrinsic Value (US$) |
|---|---|---|---|---|
| Outstanding and exercisable, January 31, 2013 | 80,000 | 0.05 | 2.3 | – |
| Outstanding and exercisable, January 31, 2014 | 80,000 | 0.05 | 1.3 | – |
| Outstanding and exercisable, January 31, 2015 | 80,000 | 0.05 | 0.3 | – |

Additional information regarding stock options as of January 31, 2015, is as follows:

| Number of Options | Exercise Price $ | Expiry Date |
|---|---|---|
| 80,000 | 0.05 | May 25, 2015 |

## 10. Related Party Transactions

(a) As at January 31, 2015, the Company owed $nil (2014 - $151,384) to a director of the Company, which is unsecured, non-interest bearing, and due on demand. 16,512,521 shares of common stock were issuable in January 2015 to settle $191,977 of amounts due to this director.

(b) During the year ended January 31, 2015, the Company's director performed services valued at $3,000 (2014 - $nil) which have been recorded as a contribution to capital.

(c) During the year ended January 31, 2015, a director of the Company forgave amounts owing of $nil (2014 - $75,000), for which $nil (2014 - $52,500) was treated as contributed capital and recorded as additional paid-in capital.

(d) In January 2015, the Company issued 16,512,521 shares of common stock pursuant to settlement of amounts due to a related party.

## 11. Income Taxes

The Company has approximately $3,400,000 of non-capital losses carried forward to offset taxable income in future years which expire beginning in fiscal 2029. The income tax benefit differs from the amount computed by applying the Canadian federal and provincial statutory rates to net loss before income taxes for the years ended January 31, 2015 and 2014, respectively, as a result of the following:

| | 2015 $ | 2014 $ |
|---|---|---|
| Net loss before taxes | 1,257,047 | 753,875 |
| Statutory rate | 26.0% | 25.8% |

| | | |
|---|---|---|
| Expected tax recovery | 326,832 | 194,500 |
| Permanent differences and other | 51,983 | (17,473) |
| Expenses deductible for tax purposes | 54 | – |
| Current period losses not recognized | (378,869) | (177,027) |
| Income tax provision | – | – |

**PIVOT PHARMACEUTICALS INC. (formerly Neurokine Pharmaceuticals Inc.)**
Notes to the Financial Statements
Year ended January 31, 2015
(Expressed in Canadian dollars)

**11. Income Taxes** (continued)

The significant components of deferred income tax assets and liabilities as at January 31, 2015 and 2014, after applying enacted corporate income tax rates, are as follows:

| | 2015 $ | 2014 $ |
|---|---|---|
| Non-capital losses carried forward | 898,187 | 635,312 |
| Valuation allowance | (898,187) | (635,312) |
| Net deferred tax asset | – | – |

The following table lists the fiscal year in which the loss was incurred and the expiration date of the operating loss:

| Expiry Date | Non-Capital Loss $ |
|---|---|
| 2029 | 434,518 |
| 2030 | 77,975 |
| 2031 | 139,450 |
| 2032 | 657,883 |
| 2033 | - |
| 2034 | 687,128 |
| 2035 | 1,457,190 |
| | 3,454,144 |

**12. Subsequent Events**

(a) In March 2015, the Company issued 40,000,000 shares of common stock to directors and an officer. 75% of these shares of common stock are held in escrow to be released one third in 6 months, one third in 12 months and one third in 24 months.

(b) In April 2015, the Company effected a reverse stock split of its issued and outstanding shares of common stock on a 10 for 1 basis and changed its name from Neurokine Pharmaceuticals Inc. to Pivot Pharmaceuticals Inc.

(c) In April 2015, the Company issued 2,500,000 shares of common stock to a service provider and an officer for services provided.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

There were no disagreements related to accounting principles or practices, financial statement disclosure, internal controls or auditing scope or procedure during the two fiscal years and interim periods, including the interim period up through the date the relationship ended.

**Item 9A. Controls and Procedures**

***Management's Report on Disclosure Controls and Procedures***

As required by Rule 13a-15 under the Exchange Act, our management evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of January 31, 2015.

Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our president (our principal executive officer) and our chief financial officer (our principal financial officer and principal accounting officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our 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, and management is required to apply its judgment in evaluating and implementing possible controls and procedures.

***Management's Annual Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision and with the participation of our management, including our president (our principal executive officer) and our chief financial officer (our principal financial officer and principal accounting officer), we conducted an evaluation of the effectiveness of our internal control over financial reporting as of January 31, 2015 using the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our company's annual or interim financial statements will not be prevented or detected on a timely basis. In its assessment of the effecti veness of internal control over financial reporting as of January 31, 2015, our company determined that there were control deficiencies that constituted material weaknesses, as described below:

> *1. We did not maintain appropriate financial reporting controls* – As of January 31, 2015, our company has not maintained sufficient internal controls over financial reporting for the financial reporting process. As at January 31, 2015, our company did not have sufficient financial reporting controls with respect to timely financial reporting and the ability to process complex accounting issues such as debt conversions. Subsequent to January 31, 2015, our company has obtained the necessary assistance to ensure that the performance of complex accounting issues can be performed accurately and on a timely basis.

Accordingly, our company concluded that these control deficiencies resulted in a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls.

As a result of the material weaknesses described above, management has concluded that our company did not maintain effective internal control over financial reporting as of January 31, 2015 based on criteria established in *Internal Control—Integrated Framework* issued by COSO.

Sadler Gibb & Associates, LLC, our independent registered public auditors, was not required to and has not issued an attestation report concerning the effectiveness of our internal control over financial reporting as of January 31, 2015 pursuant to temporary rules of the Securities and Exchange Commission that permit our company to provide only management's report in this annual report.

***Changes in Internal Controls***

During the period ended January 31, 2015, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

On July 24, 2014, Maziar Badii and Richard Azani resigned as directors of our company. The resignations of Maziar Badii and Richard Aazani were not the result of any disagreements with our company regarding our operations, policies, practices or otherwise. In addition, Hamid Doroudian resigned as our president, chief executive officer and secretary.

On July 24, 2014, we appointed Dr. Patrick Frankham and Dr. Hamid Doroudian as directors of our company and appointed Dr. Ahmad Doroudian, a director of our company, as president, chief executive officer and secretary.

On February 5, 2015, we accepted the resignation of Dr. Ahmad Doroudian as our president and chief executive officer of our company. Dr. Ahmad Doroudian remains a director and serves as chairman of the board. In addition, Dr. Hamid Doroudian resigned as a director of our company. The resignations of Dr. Ahmad Doroudian and Dr. Hamid Doroudian were not the result of any disagreements with our company regarding our operations, policies, practices or otherwise.

Also on February 5, 2015, Dr. Barbara-Jean Bormann-Kennedy (BJ Bormann) and Dr. Wolfgang Renz were appointed directors of our company. Concurrently with Dr. Ahmad Doroudian's resignation, we appointed Dr. Bormann as chief executive officer of our company.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

All directors of our company hold office until the next annual meeting of the security holders or until their successors have been elected and qualified. The officers of our company are appointed by our board of directors and hold office until their death, resignation or removal from office. Our directors and executive officers, their ages, positions held, and duration as such, are as follows:

| Name | Position Held with the Company | Age | Date First Elected or Appointed |
|---|---|---|---|
| Dr. Ahmad Doroudian | Chairman, Secretary and Director | 54 | September 17, 2007 |
| Moira Ong | Chief Financial Officer | 40 | December 26, 2010 |
| Dr. Patrick Frankham | Vice-President Business Development and Director | 43 | July 24, 2014 |
| Dr. Barbara-Jean Bormann-Kennedy *(BJ Bormann)* | Chief Executive Officer and Director | 56 | February 5, 2015 |
| Dr. Wolfgang Renz | Director | 46 | February 5, 2015 |

**Business Experience**

The following is a brief account of the education and business experience during at least the past five years of each director, executive officer and key employee of our company, indicating the person's principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

***Dr. Ahmad Doroudian – Chairman, Secretary and Director***

Dr. Ahmad Doroudian was as our appointed president, chief executive officer and director on September 17, 2007 and as chief executive officer and secretary on March 30, 2011. He resigned as president, chief executive officer and secretary on August 30, 2011 and was re-appointed as president, chief executive officer and secretary on July 24, 2014. Dr. Doroudian subsequently resigned as president and chief executive officer on February 5, 2015 and was appointed as chairman on that date. Currently, Dr. Ahmad Doroudian acts as our company's chairman, secretary and director.

Prior to joining us, Dr. Doroudian was involved in early stage financing and management of private and publicly listed companies. From 1997 to 2004, he acted as the chief executive officer, chairman, vice chairman and director of PanGeo Pharma, Inc. (now PendoPharm, a division of Pharmascience Inc.), a TSX-listed company founded by Dr. Doroudian which received over $100 million dollars in financing. From 2004 through 2007, Dr. Doroudian also served as the president of, Rayan Pharma Inc., an exporter of pharmaceuticals to Eastern Europe. From 2006 to 2008, Dr. Doroudian was owner and chief executive officer of ABF Pharmacy, a group of successful retail pharmacies. Dr. Doroudian is also the chief executive officer of Merus Labs International Inc., a specialty pharmaceutical company engaged in the acquisition and licensing of pharmaceutical products.

***Moira Ong – Chief Financial Officer***

Moira Ong was appointed as our chief financial officer on December 26, 2010. Ms. Ong has more than 18 years of experience in public company accounting and audit reporting. From 2010 through 2012, Ms. Ong was also the vice president of finance of Merus Labs International Inc., a specialty pharmaceutical company engaged in the acquisition and licensing of pharmaceutical products. From 2005 until 2010, Ms. Ong was senior manager at a global accounting firm in charge of completion of financial statements for Canadian publicly listed companies. From 2003 to 2005 she served as financial consultant for a private financial planning company. Ms. Ong was a manager in the banking and securities group at a global accounting firm in

New York from 2000 to 2003. Ms. Ong obtained her CA designation in 1999 and her CFA designation in 2003.

***Dr. Patrick Frankham – Vice-President Business Development and Director***

Dr. Patrick Frankham was appointed as vice-president business development and director of our company on July 24, 2014. Dr. Frankham has over 20 years of experience in the biopharmaceutical and services industries. Prior to joining Pivot Pharmaceuticals he was Executive Director, Healthcare Innovation, Boehringer-Ingelheim GmbH. He has also founded several multinational healthcare startup enterprises including healthcare information technology, services and pharmaceuticals companies. His professional experience includes public and private companies as well as multinational corporations. He has developed pharmaceutical products in several therapeutic areas and interacted with global regulatory authorities. Notable prior organizations where he held increasing leadership roles include, Phoenix International Life Sciences (MDS Pharma Services), Endoceutics Inc., AeternaZentaris, BioAxone Biosciences, & ICON Clinical Research. Dr Frankham obtained his PhD in molecular endocrinology (Université Laval, Canada), and holds an MBA in Finance (University of Liverpool, UK). We appointed Dr. Frankham to our board due to his background in the biopharmaceutical industry.

***Dr. Barbara-Jean Bormann-Kennedy (BJ Bormann) – Chief Executive Officer and Director***

Dr. Bormann was appointed as chief executive officer and director of our company on February 5, 2015. Dr. Bormann is a professional with almost 30 years of experience in academic and pharmaceutical science and biotech and pharmaceutical business development. Dr. Bormann also serves as the interim chief executive officer of Supportive Therapeutics, LLC, a company that is developing a drug for the treatment of oral mucositis, a severe side effect to radiation and chemotherapy treatment in oncology patients. Dr. Bormann has previously been the chief executive officer of Harbour Antibodies based in the Netherlands, licensing transgenic mice that make human antibodies, and the chief business advisor for NanoMedical Systems, Inc. of Austin, Texas that licenses a unique implantable drug delivery device. Prior to these engagements, Dr. Bormann was senior vice president responsible for world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. from 2007 to 2013. From 1996 to 2007, she served in a number of positions at Pfizer, Inc., the last one being vice president of Pfizer Global Research and Development and the world-wide Head of Strategic Alliances. Dr. Bormann currently serves on the board of directors of various companies, including Supportive Therapeutics, LLC, the Institute for Pediatric Innovation and Bioline RX (BLRX:NASDAQ). Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology.

***Dr. Wolfgang Renz - Director***

Dr. Wolfgang Renz was appointed as a director of our company on February 5, 2015. Dr. Wolfgang Renz is president of international business at Physicians Interactive. Formerly, he served as corporate vice president of business model & healthcare innovation at Boehringer Ingelheim, one of the world's largest pharmaceutical companies. For over a decade, he has been involved in developing medicines and technology to help people lead healthier, more productive lives. At Boehringer Ingelheim, he led a team of specialists to find, test, and develop the disruptive technologies that will shape the way health care will be delivered in the future. In addition, he also serves as adjunct professor of surgery at McGill University's Faculty of Medicine in Montreal, Canada. Dr. Renz holds a medical degree and a Ph.D. from Freiburg University and is board certified in Germany in emergency medicine.

**Family Relationships**

There are no other family relationships between any of our directors, executive officers and proposed directors or executive officers.

**Conflicts of Interest**

Dr. Bormann serves as the interim chief executive officer of Supportive Therapeutics, LLC, a company that is developing a drug for the treatment of oral mucositis, a severe side effect to radiation and chemotherapy treatment in oncology patients. Dr. Bormann currently serves on the board of directors of various companies, including Supportive Therapeutics, LLC, the Institute for Pediatric Innovation and Bioline RX (BLRX:NASDAQ).

Dr. Renz is president of international business at Physicians Interactive and also serves as adjunct professor of surgery at McGill University's Faculty of Medicine in Montreal, Canada.

While we do not anticipate that these activities will compete with our business, Dr. Bormann and Dr. Renz may have pre-existing fiduciary duties with one or more organizations and may not agree to present business opportunities or research data to us unless other entities have first declined to accept them or consented to their release. Accordingly, they may have a conflict of interest in determining to which entity a particular business opportunity should be presented.

Our directors are not obligated to commit their time and attention exclusively to our business and, accordingly, they may encounter a conflict of interest in allocating their time between our operations and those of other businesses. Our directors devote their time on an as needed basis. All of our directors, in the course of their other business activities, may become aware of investment and business opportunities which may be appropriate for presentation to us as well as other entities to which they owe a fiduciary duty. As a result, they may have conflicts of interest in determining to which entity a particular business opportunity should be presented. They may also in the future become affiliated with entities engaged in business activities similar to those we intend to conduct.

In general, officers and directors of a corporation are required to present business opportunities to a corporation if:

- the corporation could financially undertake the opportunity;
- the opportunity is within the corporation's line of business; and
- it would be unfair to the corporation and its stockholders not to bring the opportunity to the attention of the corporation.

**Involvement in Certain Legal Proceedings**

To the best of our knowledge, none of our directors or executive officers has, during the past ten years:

1. been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offences);

2. had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

3. been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

4. been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

5. been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

6. been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

**Compliance with Section 16(a) of the Securities Exchange Act of 1934**

Our common stock is not registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Accordingly, our officers, directors, and principal stockholders are not subject to the beneficial ownership reporting requirements of Section 16(a) of the Exchange Act.

**Code of Ethics**

Effective April 20, 2011, our company's board of directors adopted a code of business conduct and ethics that applies to, among other persons, members of our board of directors, our company's officers including our president, chief executive officer and chief financial officer, employees, consultants and advisors. As adopted, our code of business conduct and ethics sets forth written standards that are designed to deter wrongdoing and to promote:

1. honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

2. full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the Securities and Exchange Commission and in other public communications made by us;

3. compliance with applicable governmental laws, rules and regulations;

4. the prompt internal reporting of violations of the code of business conduct and ethics to an appropriate person or persons identified in the code of business conduct and ethics; and

5. accountability for adherence to the code of business conduct and ethics.

Our code of business conduct and ethics requires, among other things, that all of our company's senior officers commit to timely, accurate and consistent disclosure of information; that they maintain confidential information; and that they act with honesty and integrity.

In addition, our code of business conduct and ethics emphasizes that all employees, and particularly senior officers, have a responsibility for maintaining financial integrity within our company, consistent with generally accepted accounting principles, and federal and state securities laws. Any senior officer who becomes aware of any incidents involving financial or accounting manipulation or other irregularities, whether by witnessing the incident or being told of it, must report it to our company. Any failure to report such inappropriate or irregular conduct of others is to be treated as a severe disciplinary matter. It is against our company policy to retaliate against any individual who reports in good faith the violation or potential violation of our company's code of business conduct and ethics by another.

Our code of business conduct and ethics was included as an exhibit to our annual report on Form 10-K filed with the SEC on May 11, 2011. We will provide a copy of the code of business conduct and ethics to any person without charge, upon request. Requests can be sent to: Pivot Pharmaceuticals Inc., 1275 West 6th Avenue, Vancouver, British Columbia V6H 1A6.

**Committees of the Board**

All proceedings of our board of directors were conducted by resolutions consented to in writing by all the directors and filed with the minutes of the proceedings of the directors. Such resolutions consented to in writing by the directors entitled to vote on that resolution at a meeting of the directors are, according to the corporate laws of the state of Nevada and the bylaws of our company, as valid and effective as if they had been passed at a meeting of the directors duly called and held.

Our company currently does not have nominating, compensation committees or committees performing similar functions nor does our company have a written nominating, compensation or audit committee charter. Our board of directors does not believe that it is necessary to have such committees because it believes that the functions of such committees can be adequately performed by our directors.

Our company does not have any defined policy or procedure requirements for shareholders to submit recommendations or nominations for directors. The directors believe that, given the early stage of our development, a specific nominating policy would be premature and of little assistance until our business operations develop to a more advanced level. Our company does not currently have any specific or minimum criteria for the election of nominees to the board of directors and we do not have any specific process or procedure for evaluating such nominees. Our directors assess all candidates, whether submitted by management or shareholders, and make recommendations for election or appointment.

A shareholder who wishes to communicate with our board of directors may do so by directing a written request addressed to our president, at the address appearing on the first page of this annual report.

**Audit Committee and Audit Committee Financial Expert**

Our board of directors has determined that none of our the members of our audit committee qualifies as an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. Dr. Wolfgang Renz is "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Securities Exchange Act of 1934, as amended.

Our company has a formal audit committee which was formed in May 2010, but currently does not have a financial expert. Our audit committee consists of Dr. Ahmad Doroudian and Dr. Patrick Frankham. Financial information relating to quarterly reports was disseminated to all board members for review. The audited financial statements for the years ended January 31, 2015 and 2014 were provided to each member of the board in which any concerns by the members were directed to management and the auditors.

We believe that the members of our board of audit committee and our entire board of directors are collectively capable of analyzing and evaluating our financial statements and understanding internal controls and procedures for financial reporting. We believe that retaining an independent director who would qualify as an "audit committee financial expert" would be overly costly and burdensome and is not warranted in our circumstances given the early stages of our development and the fact that we have not generated any material revenues to date. In addition, we currently do not have nominating, compensation or audit committees or committees performing similar functions nor do we have a written nominating, compensation or audit committee charter. Our board of directors does not believe that it is necessary to have such committees because it believes the functions of such committees can be adequately performed by our board of directors.

Our company has an audit committee charter which was adopted and approved by our board of directors on May 25, 2010. A copy of our audit committee charter is included as an exhibit to this annual report.

**Item 11. Executive Compensation**

The particulars of the compensation paid to the following persons:

(a) our principal executive officer;

(b) each of our two most highly compensated executive officers who were serving as executive officers at the end of the years ended January 31, 2015 and 2014; and

(c) up to two additional individuals for whom disclosure would have been provided under (b) but for the fact that the individual was not serving as our executive officer at the end of the years ended January 31, 2015 and 2014,

who we will collectively refer to as the named executive officers of our company, are set out in the following

summary compensation table, except that no disclosure is provided for any named executive officer, other than our principal executive officers, whose total compensation did not exceed $100,000 for the respective fiscal year:

| SUMMARY COMPENSATION TABLE | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Name and Principal Position** | **Year** | **Salary ($)** | **Bonus ($)** | **Stock Awards ($)** | **Option Awards ($)** | **Non-Equity Incentive Plan Compensa-tion ($)** | **Change in Pension Value and Nonqualified Deferred Compensa-tion Earnings ($)** | **All Other Compensa-tion ($)** | **Total ($)** |
| Dr. Barbara-Jean Bormann-Kennedy(BJ Bormann) (1) *President and Director* | 2015<br>2014 | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A | N/A<br>N/A |
| Moira Ong (2) *Chief Financial Officer* | 2015<br>2014 | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | 4,128<br>3,218 | 4,128<br>3,218 |
| Dr. Ahmad Doroudian (3) *Chairman, Secretary and Director* | 2015<br>2014 | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil |
| Dr. Hamid Doroudian (4) *Former President, Chief Executive Officer, Secretary and Director* | 2015<br>2014 | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil | Nil<br>Nil |

(1) Dr. Bormann was appointed as our president and director on February 5, 2015.

(2) Ms. Ong was appointed as our chief financial officer on December 26, 2010.

(3) Dr. Ahmad Doroudian was as our appointed president, chief executive officer and director on September 17, 2007 and as chief executive officer and secretary on March 30, 2011. He resigned as president, chief executive officer and secretary on August 30, 2011 and was re-appointed as president, chief executive officer and secretary on July 24, 2014. Dr. Doroudian subsequently resigned as president and chief executive officer on February 5, 2015 and was appointed as chairman on that date. Currently Dr. Ahmad Doroudian acts as our company's chairman, secretary and director.

(4) Dr. Hamid Doroudian was appointed president, chief executive officer and secretary of our company on August 30, 2011. On July 24, 2014, Dr. Hamid Doroudian was appointed as a director of our company and resigned as president, chief executive officer and secretary. Dr. Hamid Doroudian resigned as a director of our company on February 5, 2015.

Other than as set out below, there are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers. Our directors and executive officers may receive share options at the discretion of our board of directors in the future. We do not have any material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers, except that share options may be granted at the discretion of our board of directors.

**Stock Option Plan**

We do not currently have a stock option plan.

**Stock Options/SAR Grants**

During our fiscal year ended January 31, 2015 there were no grants of plan based awards to our named officers or directors.

**Outstanding Equity Awards at Fiscal Year End**

The particulars of unexercised options, stock that has not vested and equity incentive plan awards for our named executive officers are set out in the following table:

| | Options Awards | | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of That Have Not Vested ($) | Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Stock Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Unitsor Other Rights That Have Not Vested ($) |
| Dr. Ahmad Doroudian (1) | 80,000 | Nil | 80,000 | 0.05 | May 25, 2015 | Nil | N/A | N/A | N/A |

(1) Dr. Ahmad Doroudian was as our appointed president, chief executive officer and director on September 17, 2007 and as chief executive officer and secretary on March 30, 2011. He resigned as president, chief executive officer and secretary on August 30, 2011 and was re-appointed as president, chief executive officer and secretary on July 24, 2014. Dr. Doroudian subsequently resigned as president and chief executive officer on February 5, 2015 and was appointed as chairman on that date. Currently Dr. Ahmad Doroudian acts as our company's chairman, secretary and director.

**Option Exercises**

During our fiscal year ended January 31, 2015 there were no options exercised by our named officers.

**Compensation of Directors**

Other than set out below, we do not have any agreements for compensating our directors for their services in their capacity as directors, although such directors are expected in the future to receive stock options to purchase shares of our common stock as awarded by our board of directors.

We have determined that Dr. Wolfgang Renz is an independent director, as that term is used in Item 7(d)(3)(iv)(B) of Schedule 14A under the *Securities Exchange Act of 1934*, as amended, and as defined by Rule 4200(a)(15) of the NASDAQ Marketplace Rules.

Effective March 19, 2015, we entered into director services agreements with our chief executive officer and director, BJ Bormann, and our directors, Dr. Wolfgang Renz and Dr. Patrick Frankham. Pursuant to the agreements each director shall provide director services to our company for a period of 24 months in consideration for 100,000,000 shares of our common stock payable in installments of 25,000,000 upon execution of the agreement, 25,000,000 after 6 months, 25,000,000 after 12 months, and 25,000,000 after 24 months. Each agreement may be terminated by our company without notice for cause, or by any party with 30 days prior notice.

**Pension, Retirement or Similar Benefit Plans**

There are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers. We have no material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers, except that stock options may be granted at the discretion of the board of directors or a committee thereof.

**Indebtedness of Directors, Senior Officers, Executive Officers and Other Management**

None of our directors or executive officers or any associate or affiliate of our company during the last two fiscal years, is or has been indebted to our company by way of guarantee, support agreement, letter of credit or other similar agreement or understanding currently outstanding.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The following table sets forth, as of May 15, 2015, certain information with respect to the beneficial ownership of our common shares by each shareholder known by us to be the beneficial owner of more than 5% of our common shares, as well as by each of our current directors and executive officers as a group. Each person has sole voting and investment power with respect to the shares of common stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common stock, except as otherwise indicated.

| Name and Address of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percentage of Class (1) |
|---|---|---|
| Dr. Ahmad Doroudian (2) 4172 Doncaster Way Vancouver BC V6S 1V9 | 20,659,501(3) Common Shares | 19.06% |
| Moira Ong (4 )2392 Lawson AvenueWest Vancouver, BC V7V 2E6 | 2,000,000 Common Shares | 1.85% |
| Dr. Patrick Frankham (5)<br>388 De La Vauvette<br>Rosemere, QC, J7A 4J7 | 10,000,000 Common Shares | 9.23% |
| Dr. Barbara-Jean Bormann-Kennedy(BJ Bormann) (6)<br>#306 – 1188 BroadwaySomerville, MA 02144 | 10,000,000 Common Shares | 9.23% |
| Dr. Wolfgang Renz (7)<br>Am Hochgericht 31Rheinfelden, Germany 79618 | 10,000,000 Common Shares | 9.23% |
| ***Directors and Officers as a Group(1)*** | ***52,659,501 Common Shares*** | ***48.60%*** |
| Devan Dass4093 W. 40th AvenueVancouver BC V6C 3B9 | 8,608,950Common Shares | 7.94% |
| Dr. Giora Davidai21 Hampton LaneNew Canaan CT 06840 | 10,000,000Common | |

| | | |
|---|---|---|
| | Shares | 9.23% |
| Stanley Papp and Sharon Papp JTTEN1315 Dempsey RoadNorth Vancouver BC V7K 1S7 | 7,953,644Common Shares | 7.34% |
| Teya Kamille Sellan<br>PO Box 166<br>Dewdney, BC V0M 1H0 | 6,953,644Common Shares | 6.42% |
| Vintage Capital Group Inc. 36945 Lougheed HigwayMission BC V0M 1H0 | 8,243,352Common Shares | 7.61% |
| ***Over 5% Shareholders as a Group*** | ***41,759,590Common Shares*** | ***38.54%*** |

(1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding on May 15, 2015. As of May 15, 2015, there were 108,363,784 shares of our company's common stock issued and outstanding.

(2) Dr. Ahmad Doroudian was as our appointed president, chief executive officer and director on September 17, 2007 and as chief executive officer and secretary on March 30, 2011. He resigned as president, chief executive officer and secretary on August 30, 2011 and was re-appointed as president, chief executive officer and secretary on July 24, 2014. Dr. Doroudian subsequently resigned as president and chief executive officer on February 5, 2015 and was appointed as chairman on that date. Currently Dr. Ahmad Doroudian acts as our company's chairman, secretary and director.

(3) Includes 20,259,501 shares owned by Dr. Ahmad Doroudian, 200,000 shares owned by Khadija Zerouali, the spouse of Dr. Ahmad Doroudian, and 200,000 shares owned by Kinwa Pharma International Company Ltd., a company over which Dr. Ahmad Doroudian and Ms. Zerouali have shared voting and investment power and 80,000 options to purchase shares at $0.05 for a period of five years from May 25, 2010 and 50,000 warrants to purchase shares at $0.05 for a period of five years from July 30, 2010.

(4) Ms. Ong was appointed as our chief financial officer on December 26, 2010.

(5) Dr. Patrick Frankham was appointed as vice-president business development and director of our company on July 24, 2014.

(6) Dr. Bormann was appointed as chief executive officer and director of our company on February 5, 2015.

(7) Dr. Renz was appointed as a director of our company on February 5, 2015.

**Changes in Control**

We are unaware of any contract or other arrangement or provisions of our Articles or Bylaws the operation of which may at a subsequent date result in a change of control of our company. There are not any provisions in our Articles or Bylaws, the operation of which would delay, defer, or prevent a change in control of our company.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Except as disclosed herein, no director, executive officer, shareholder holding at least 5% of shares of our common stock, or any family member thereof, had any material interest, direct or indirect, in any transaction, or proposed transaction since the year ended January 31, 2015, in which the amount involved in the transaction exceeded or exceeds the lesser of $120,000 or one percent of the average of our total assets at the year-end for the last three completed fiscal years.

**Director Independence**

We currently act with four directors, consisting of Dr. Ahmad Doroudian, Dr. Patrick Frankham, Dr. BJ Bormann and Dr. Wolfgang Renz. Dr. Wolfgang Renz is an independent director.

Our audit committee consists of Dr. Ahmad Doroudian and Dr. Patrick Frankham.

We do not have a standing compensation or nominating committee, but our entire board of directors acts in such capacities.

**Item 14. Principal Accounting Fees and Services**

The aggregate fees billed for the most recently completed fiscal year ended January 31, 2015 and for the fiscal year ended January 31, 2014 for professional services rendered by the principal accountant for the audit of our annual financial statements and review of the financial statements included in our quarterly reports on Form 10-Q and services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for these fiscal periods were as follows:

| | Year Ended | |
|---|---|---|
| | January 31, 2015 $ | January 31, 2014 $ |
| Audit Fees | 16,500 | 15,200 |
| Audit Related Fees | Nil | Nil |
| Tax Fees | Nil | Nil |
| All Other Fees | Nil | Nil |
| Total | 16,500 | 15,200 |

Our board of directors pre-approves all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the board of directors either before or after the respective services were rendered.

Our board of directors has considered the nature and amount of fees billed by our independent auditors and believes that the provision of services for activities unrelated to the audit is compatible with maintaining our independent auditors' independence.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements

(1) Financial statements for our company are listed in the index under Item 8 of this document.

(2) All financial statement schedules are omitted because they are not applicable, not material or the required information is shown in the financial statements or notes thereto.

(b) Exhibits

| Exhibit Number | Description |
|---|---|
| **(3)** | **Articles of Incorporation and Bylaws** |
| 3.1 | Articles of Incorporation 649186 B.C. Ltd. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.2 | "Company Act" Memorandum of 649186 B.C. Ltd. Certificate of Amendment (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.3 | Certificate of Filing of 649186 B.C. Ltd. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.4 | Certificate of Incorporation of 649186 B.C. Ltd. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.5 | Certificate of Name Change of 649186 B.C. Ltd. to Xerxes Health Corp. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.6 | Transition Application of Xerxes Health Corp. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.7 | Certificate of Name Change of Xerxes Health Corp. to Neurokine Pharmaceuticals Inc. (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.8 | Notice of Alteration to Authorized Share Structure (incorporated by reference from our Registration Statement on Form S-1 filed on August 7, 2009) |
| 3.9 | Notice of Alteration to Authorized Share Structure (incorporated by reference to our Current Report on Form 8-K filed on June 4, 2014) |
| 3.10 | Notice of Alteration removing Pre-Existing Company Provisions (incorporated by reference to our Current Report on Form 8-K filed on October 9, 2014) |
| 3.11 | Articles (incorporated by reference to our Current Report on Form 8-K filed on October 9, 2014) |
| 3.12 | Notice of Alteration changing name to Pivot Pharmaceuticals Inc. (incorporated by reference to our Current Report on Form 8-K filed on April 17, 2015) |
| 3.13* | Certificate of Name Change of Neurokine Pharmaceuticals Inc. to Pivot Pharmaceuticals Inc. |
| **(10)** | **Material Contracts** |
| 10.1 | Non-Exclusive License Agreement with Globe Laboratories Inc. dated June 17, 2008 (incorporated by reference to our Registration Statement on Form S-1/A filed on December 3, 2009) |
| 10.2 | Clinical Trial Services Agreement with Virtus Clinical Development (Pty) Limited dated March 1, 2009 (incorporated by reference to our Registration Statement on Form S-1/A filed on March 4, 2010) |

| | |
|---|---|
| 10.3 | Master Service Agreement with Northern Lipids Inc. dated October 2, 2007 (incorporated by reference to our Registration Statement on Form S-1/A filed on December 3, 2009) |
| 10.4 | Assignment of Invention (NK-001) dated January 30, 2008 (incorporated by reference to our Registration Statement on Form S-1/A filed on December 3, 2009) |
| 10.5 | Assignment of Invention (NK-002) dated April 18, 2008 (incorporated by reference to our Registration Statement on Form S-1/A filed on December 3, 2009) |
| 10.6 | Subscription Agreement with Ahmad Doroudian (incorporated by reference to our Form 8-K filed on August 12, 2010) |
| 10.7 | Debt Settlement Subscription Agreement dated September 26, 2013 with Ahmad Doroudian (incorporated by reference to our Quarterly Report on Form 10-Q filed on December 16, 2013) |
| 10.8 | Director Services Agreement dated February 25, 2015 with Barbara-Jean Bormann-Kennedy (incorporated by reference to our Current Report on Form 8-K filed on March 26, 2015) |
| 10.9 | Director Services Agreement dated February 25, 2015 with Dr. Patrick Frankham (incorporated by reference to our Current Report on Form 8-K filed on March 26, 2015) |
| 10.10 | Director Services Agreement dated February 26, 2015 with Dr. Wolfgang Renz (incorporated by reference to our Current Report on Form 8-K filed on March 26, 2015) |
| 10.11 | Consulting Services Agreement dated February 25, 2015 with Dr. Giora Davidai (incorporated by reference to our Current Report on Form 8-K filed on March 26, 2015) |
| **(31)** | **Rule 13a-14(d)/15d-14(d) Certifications** |
| 31.1* | Section 302 Certification under the Sarbanes-Oxley Act of 2002 of Principal Executive Officer |
| 31.2* | Section 302 Certification under the Sarbanes-Oxley Act of 2002 of Principal Financial Officer |
| **(32)** | **Section 1350 Certifications** |
| 32.1* | Section 906 Certification under the Sarbanes-Oxley Act of 2002 of Principal Executive Officer |
| 32.2* | Section 906 Certification under the Sarbanes-Oxley Act of 2002 of Principal Financial Officer |
| **99** | **Additional Exhibits** |
| 99.1* | Audit Committee Charter |
| **101*** | **Interactive Data Files** |
| 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.*

## 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.

**PIVOT PHARMACEUTICALS INC.**
(Registrant)

Dated: June 17, 2015

By: */s/ Dr. BJ Bormann*
Dr. BJ Bormann
Chief Executive Officer and Director
(Principal Executive Officer)

Dated: June 17, 2015

By: */s/ Moira Ong*
Moira Ong
Chief Financial Officer
(Principal Financial Officer and Principal
Accounting Officer)

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

Dated: June 17, 2015

By: */s/ Dr. BJ Bormann*
Dr. BJ Bormann
Chief Executive Officer and Director
(Principal Executive Officer)

Dated: June 17, 2015

By: */s/ Dr. Ahmad Doroudian*
Dr. Ahmad Doroudian
Chairman, Secretary and Director

Dated: June 17, 2015

By: */s/ Dr. Patrick Frankham*
Dr. Patrick Frankham
Vice-President Business Development
and Director

Dated: June 17, 2015

By: */s/ Dr. Wolfgang Renz*
Dr. Wolfgang Renz
Director