

INNOVUS PHARMACEUTICALS, INC.

Form 10-K

March 30, 2012

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

x] Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2011

or

.. Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-52991

**INNOVUS PHARMACEUTICALS, INC.**

(Name of Registrant as specified in its charter)

NEVADA

(State or other Jurisdiction of Incorporation or organization)

87-0324697

(I.R.S. Employer Identification No.)

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80 West Sierra Madre, Blvd., #392

Sierra Madre, California 91024

(Address of principal executive offices)(Zip code)

Registrant's telephone number: (626) 227-1630

Securities registered under Section 12(b) of the Act: None.

Name of Each exchange on which registered: None.

Securities registered under Section 12 (g) of the Act:

Common Stock (Title of class).

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange 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 Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

(1) Yes  No  (2) 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-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files) Yes  No

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



**Documents Incorporated by Reference**

Documents incorporated by reference: See Part IV, Item 15.

INNOVUS PHARMACEUTICALS, INC.  
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THE SECURITIES AND EXCHANGE COMMISSION  
YEAR ENDED DECEMBER 31, 2011

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## **PART I**

### **FORWARD LOOKING STATEMENTS**

In this Annual Report, references to “Innovus Pharmaceuticals, Inc.,” “Innovus Pharma,” “FasTrack,” the “Company,” “we,” “our,” and words of similar import and meaning refer to Innovus Pharmaceuticals, Inc., the Registrant.

References to “North Horizon”, “North Horizon, Inc.” refer to the pre-transaction public shell.

In this report references to a major related party of the Company – Apricus Biosciences, Inc (Nasdaq: APRI) (“Apricus Bio”), Bio-Quant, Inc. (“Bio-Quant”) and NexMed (U.S.A.), Inc., (“NexMed”) may be used interchangeably, but shall represent the same entity.

#### **Special Note about Forward-Looking Statements**

Certain statements in this report, including information incorporated by reference, are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “believes,” “anticipates,” “intends,” “estimates,” “predicts,” or “projects,” or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements. Forward-looking statements in this report may include statements about:

- future financial and operating results;
- our ability to fund operations and business plans, and the timing of any funding or corporate development transactions we may pursue;
- the timing, conduct and outcome of discussions with regulatory agencies, regulatory submissions and clinical trials;
- our beliefs and opinions about the safety and efficacy of our products and product candidates and the results of our clinical studies and trials;
-

our ability to enter into acceptable relationships with one or more contract manufacturers or other service providers on which we may depend and the ability of such contract manufacturers or other service providers to conduct studies, manufacture biologics or key product components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;

- our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches; our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;

our ability to pursue and effectively develop new product opportunities and acquisitions and to obtain value from such product opportunities and acquisitions;

our ability to gain and maintain the listing of our common stock on a national exchange;

our intellectual property rights and those of others, including actual or potential competitors;

our personnel, consultants and collaborators;

current and future economic and political conditions;

overall industry and market performance;

the impact of accounting pronouncements;

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- management's goals and plans for future operations; and
- other assumptions described in this report underlying or relating to any forward-looking statements

The forward-looking statements in this report speak only as of the date of this report and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be beyond our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Item 1A and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (SEC). 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 statement to conform these statement to actual results.

## **Item 1. Business.**

### **Business of the Company**

Innovus Pharmaceuticals, Inc. (the "Company", "Innovus Pharma", "FasTrack", "we", "us" and "our") is focused on the development and in-licensing/acquisition of new and innovative pharmaceutical product opportunities that offer definable pathways to regulatory approvals, partnering and commercialization. We have a three-pronged approach to our business strategy:

- To internally develop new, 505(b)(2) topical products based on a proven drug delivery technology; and
- To in-license/acquire late stage revenue generating pharmaceutical products; and
- To leverage near term revenue opportunities afforded by our proprietary pipeline comprised of ethical therapeutic ("Rx") and over-the-counter ("OTC") products.

Our business model is designed to create multiple opportunities for success while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our

balance sheet and cash flow with minimal dilution to our shareholders. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products, which we believe would accelerate our shareholders' return on investment and provide us with additional cash flow to fund our own product development.

### **Our Proprietary Product and Technology Portfolios**

In our portfolio of Rx products, we have a partial interest in the potential commercial value of PrevOnco™, a Phase 2/3 second-line Orphan Drug therapy for patients with hepatocellular carcinoma or liver cancer. PrevOnco is based on lansoprazole, a drug widely used to treat gastro-esophageal reflux disease. Preclinical animal data have shown the drug to also be effective in shrinking the tumors commonly associated with liver cancer. In 2010, FasTrack sold the development rights of the product to NexMed (U.S.A.), Inc., ("NexMed") a wholly-owned subsidiary of Apricus Biosciences, Inc. (Nasdaq: APRI) ("Apricus Bio"). In exchange, we are entitled to receive up to 50% of the net commercial value of the product in the event Apricus Bio successfully licenses the product to a commercialization partner. The potential for any returns on PrevOnco is completely dependent on Apricus Bio's efforts. Apricus Bio completely controls the future and progress of the PrevOnco program. There is no assurance that Apricus Bio will continue to develop it, or be successful in its development or licensing efforts.

Pursuant to the overall terms of our Prevonco agreements with Apricus Bio, we have the right to develop two products based on their proprietary NexACT<sup>®</sup> multi-route drug delivery technology. NexACT utilizes patented novel excipients or “penetration enhancers” that when incorporated into drug formulations, may improve their absorption and bioavailability. The technology is incorporated in Vitaros<sup>®</sup>, a topical treatment for erectile dysfunction approved for local marketing in Canada. We have not formally executed any licensing agreement. The terms of the binding Memorandum of Understanding between us and Apricus Bio are described in Footnote 10 of the accompanying consolidated financial statements.

We intend to explore and pursue new product opportunities based on drugs with expired or near-expired patents. Our strategy is to follow the a 505(b)(2) regulatory approval pathway, which typically has a shorter development cycle with less pre-clinical and clinical studies required by the regulatory agencies. In June 2011, we entered into two research agreements with NexMed to conduct feasibility studies on two active drug ingredients identified by us. One study, completed in September 2011, focused on a new minoxidil formulation for treating hair loss. Minoxidil is the active ingredient in Rogaine<sup>®</sup>, a widely marketed topical product for treating male and female hair loss. The study results showed that our proprietary formulation significantly enabled the absorption of minoxidil into the human cadaver skin model. Assuming the availability of financing, we plan to conduct additional studies to optimize our proprietary minoxidil formulation and take it into human clinical trials.

Within our Rx portfolio is a development platform based on SSAO inhibitors. SSAO is known as vascular adhesion protein-1 or VAP-1, and is a dual function molecule with enzymatic and cell adhesion activities. These inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators. A prior owner had developed a treatment for Lupus based on the SSAO platform, but that product failed in late-stage clinical studies. In 2009, FasTrack acquired the SSAO patent portfolio because of the possibility that the SSAO platform had potential for other developers to identify the right medical indication. Because the SSAO platform has unproven safety and efficacy profiles, to develop a product based on this platform would require significant resources and longer development time. We do not have these resources presently and no assurance can be given that even if proper resources were available, we would seek to develop or if development were pursued, a successful SSAO platform would be accomplished. To facilitate the SSAO development we may seek a partnership relationship.

In our portfolio of OTC products, we have two opportunities for development and/or out-licensing. Apezaz<sup>™</sup> is a treatment for pain relief. It is an arthritis cream that delivers different ingredients to various layers of the skin and muscle.

In addition, we have Regia<sup>™</sup>, which is a plant-derived, anti-microbial agent for reducing the bleeding of gums when used in OTC products such as mouthwash. We have an issued US patent which expires in May 2028 and patent applications pending in selected international markets. Our intention is to out-license the patent portfolio for Regia<sup>™</sup> to potential development partners in the OTC space.

## **Prior Transactions**

Innovus Pharma, formerly known as North Horizon, Inc., was incorporated under the laws of the State of Utah on January 15, 1959. It changed the corporate domicile to the State of Nevada in 2007. Initially, North Horizon had authorized capital of 100,000,000 shares of common stock, par value of \$.001 per share. Years ago it sold 100,000 shares of common stock to the public. The offering was registered with the Utah Division of Securities. It entered the cosmetic business. This venture was unsuccessful. Other ventures ensued. None was successful. For the past several years, there were no active business ventures, however, the management maintained North Horizon as a corporate entity and filed requisite reports with the U.S. Securities and Exchange Commission. Innovus Pharma has authorized capital of 150,000,000 shares of common stock, par value of \$.001 per share as of December 31, 2011.

In December 2011 North Horizon changed its name to Innovus Pharmaceuticals, Inc., and entered into a combination transaction with FasTrack Pharmaceuticals, Inc., whereby FasTrack became a wholly owned subsidiary.

We voluntarily filed a registration statement on Form 10-SB to make information more readily available to the public and to become eligible for listing on the OTCQB sponsored by the National Association of Securities Dealers, Inc. We are obligated to file certain interim and periodic reports including an annual report with audited financial statements. Our trading symbol is "INNV."

The financial statements included in this report are for the combined entity including FasTrack Pharma. Under pertinent rules we are deemed to be a small business issuer. There are certain items in this report to which we are not required to respond.

## **Reverse Merger**

On December 7, 2011, the North Horizon completed a combination transaction with FasTrack Pharmaceuticals, Inc., a Delaware corporation, which became a wholly-owned subsidiary of North Horizon (subsequently Innovus Pharma). FasTrack was a specialty pharmaceutical company with a development pipeline of Rx and OTC products.

The business combination agreement (the “Agreement”), dated December 7, 2011, stipulated that North Horizon and FasTrack would undergo a combination whereby both companies would survive as legal entities, but FasTrack would become a wholly-owned subsidiary of North Horizon. Pursuant to the Agreement, North Horizon changed its name to Innovus Pharmaceuticals, Inc. As a result of the combination, the shareholders of FasTrack have actual and effective operating control of the combined entity after the transaction and the shareholders of former North Horizon continue as passive investors in the combined entity. The FasTrack shareholders would have 15,238,938 shares (portion of which are subject to rescission election discussed in Footnote 1 to the Consolidated Financial Statements) of the combined entities’ post-split common stock (representing 92% ownership of Innovus on a fully diluted basis); the shareholders of North Horizon retained their holdings, totaling 1,325,125 shares (representing 8% ownership of Innovus on a fully diluted basis). The transaction has been accounted for as a reverse merger, whereby North Horizon is the legal acquirer and FasTrack is the legal acquiree and the accounting acquirer.

Following is a summary of the changes and actions that resulted from the Closing of the Agreement.

1. Name Change: The Company changed its name to Innovus Pharmaceuticals, Inc.
2. Capitalization: The Company’s capitalization is 150,000,000 shares of common stock authorized.
3. Directors and Change in Control: Vivian Liu; Henry Esber, Ph.D.; and Ziad Mirza, M.D., became the directors of the Company.

4. Reverse Split: Immediately before the combination, North Horizon's issued and outstanding shares in the amount of 13,251,250 were subject to a reverse split on the basis of ten shares into one share (10:1) The reverse split was effective on December 6, 2011.

The foregoing is a brief summary of the Agreement and the transactions inherent herein. The summary is subject to the detailed provisions of the Agreement which was an Exhibit to the Report on Form 8-K filed on July 20, 2011, and which is incorporated herein by reference.

In February 2012, the Company recognized that certain FasTrack shareholders had not received certain information about the Reverse Merger in advance of the closing in accordance with selected statutes of Delaware law. As a result, the Company offered each FasTrack shareholder of record prior to the closing of the Reverse Merger, which excluded holders of promissory notes, the right to rescind, and sell their shares to the Company at \$.002 per share (post-exchange rate) for a period before April 14, 2012. No shareholders elected to exercise their rescission rights as of the date of this filing. Since the shares were not issued until March 22, 2012 and the rescission election was outside of the Company's control, the potential rescission amount is presented as a liability in the accompanying consolidated balance sheet as of December 31, 2011. In addition, shares related to the convertible notes of Apricus Bio, which were converted on December 21, 2011 but were not yet issued as of December 31, 2011 due to administrative delays, therefore presented as contributed capital as of December 31, 2011. The Apricus Bio shares were issued on March 6, 2012. See Footnote 1 in the accompanying consolidated financial statements.

All references and descriptions of the Agreement and the transactions contemplated thereby are subject to the more detailed provisions stated in the Agreement. All references to the Agreement are qualified in their entirety by the text of the Agreement.

FasTrack was organized by shareholders of Bio-Quant, which was a Utah corporation founded in 2000 and operated as a contract research organization for the pharmaceutical industry. In late 2008, Bio-Quant decided to focus on its core business of pre-clinical testing services, and sold its pharmaceutical assets to FasTrack and Sorrento Pharmaceuticals, Inc. (“Sorrento”), which focused on the development of Rx and OTC products, respectively. The limited funding of both FasTrack and Sorrento severely limited their activities and operations. In March 2011, the shareholders of FasTrack and Sorrento decided to combine operations in an effort to better position the combined entity for new investors. Pursuant to an asset purchase agreement between the two companies, FasTrack acquired Sorrento’s assets and liabilities.

#### **Agreements with Dawson James Securities, Inc.**

In January 2011 FasTrack entered into a Financial Advisory and Consulting Agreement with Dawson James Securities, Inc., for a 12 month term. If FasTrack were sold or engaged in a merger, Dawson James would receive \$50,000 and warrants to purchase shares of the FasTrack’s common stock equal to 2.5% of the Company’s outstanding common stock, on a fully-diluted basis. The warrants have a term of seven years and have an exercise price of \$0.10 per share. Upon the completion of the merger between North Horizon and FasTrack, Innovus Pharma issued to Dawson James warrants to purchase approximately 380,973 shares of its common stock. The Company issued a promissory note for \$50,000 (the “Dawson Note”) which bears interest at 8% per annum and is payable on or before December 6, 2012 (the “Maturity Date”). In the event the Company successfully closes a financing transaction greater than \$2 million before the Maturity Date, the Company would repay the Dawson Note and accrued interest with the closing of the aforementioned financing.

On December 16, 2011, the Company engaged the services of Dawson James to act as its exclusive Placement Agent on a commercially reasonable best efforts basis in connection with a potential offering. Upon signing, the Company paid \$25,000 to Dawson James for due diligence fees. In addition, the Company agreed to pay: (i) a commission equal to 9% of the aggregate gross proceeds; and (ii) non-accountable expense allowance payable in cash upon closing equal to 3% of the aggregate gross proceeds and (iii) warrants to purchase 8.75% of the maximum number of common stock underlying the securities sold in the potential offering. In addition, the Company would pay a 5% cash commission for warrants exercised, if any. No assurance can be given that any of the Company’s securities will be sold.

#### **Manufacturing**

We anticipate that when we enter into production for any of our products, the raw materials will be readily available in the market. At the present time, we do not have any customers or backlog.

We intend to contract with third parties for the manufacture of our compounds for investigational purposes, for preclinical and clinical testing and for commercial sale of any FDA-approved products. All of our compounds are small molecules, generally constructed using industry standard processes and use readily accessible raw materials.

### **Regulatory Requirements**

On December 12, 2011, we filed a Report on Form 8-K describing and reporting the closing of the Agreement between North Horizon and FasTrack. The report was filed within four business days of the closing of the transaction. (See Item 5.01(a)(8) of Form 8-K.) Amendments to Rule 144 effective on February 15, 2008, limited the resale of most securities of a shell company until one year after the filing of the required information about FasTrack. These requirements may be perceived as limiting or eliminating the advantages of using “reverse” reorganizations or mergers of going public. In these transactions the management and shareholders of the acquired company become the controlling shareholders of the public company. Pursuant to applicable regulations a shell company may not use Form S-8 until 60 days after the company is no longer considered to be a shell company.



Amendments to Rule 144 effective on February 15, 2008, limited the tradeability of securities issued and outstanding of a shell company, including shares issued in any transaction involving an acquisition of another business entity or prospect. Our shareholders are subject to these provisions.

Our shares are also considered penny stocks. Section 15g-2 of the regulations under the Exchange Act requires broker-dealers transacting trades in penny stocks to provide potential investors with a disclosure statement detailing the risks of investing in penny stocks and to have the investor sign a receipt of the disclosure statement before any transactions may occur in the investor's account. Also, broker-dealers must approve the account of an investor purchasing penny stocks. After we make any acquisition, most likely our shares of common stock will still be classified as a "penny stock."

## **Government Regulation**

The U.S. Food and Drug Administration ("FDA") and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the Federal Food, Drug and Cosmetic Act ("FDCA") and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may begin;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a New Drug Application ("NDA");
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Our product pipeline is comprised of candidates in various stages of development. On the Rx side, to develop a product to Phase 2 based on the 505b(2) regulatory path would cost approximately \$4 million and take 18 months per candidate. On the OTC side, we estimate that the cost and process to register Apeaz with the FDA and build-out sufficient inventory for launch would cost approximately \$100,000 and take 3-6 months, respectively. See Clinical Trials and 505(b)(2) NDAs for further clarifications. No assurance can be given that the Company will be successful in any of its development or licensing efforts.

## Clinical Trials

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Each protocol is submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap, or be combined.

Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

Phase 2 clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks.

Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Clinical testing must satisfy extensive FDA regulations. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early stage clinical trials does not assure success in later stage trials. The FDA, an IRB or we may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

## **New Drug Applications**

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality products within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions arise after the product reaches the market.

#### **Section 505(b)(2) NDAs**

There are two types of NDAs: the full NDA and the Section 505(b)(2) NDA. When possible, we intend to file Section 505(b)(2) NDAs that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. A full NDA is submitted under Section 505(b)(1) of the FDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug. A Section 505(b)(2) NDA may be submitted for a drug for which one or more of the investigations relied upon by the applicant were not conducted by or for the applicant and for which the applicant has no right of reference from the person by or for whom the investigations were conducted. A Section 505(b)(2) NDA may be submitted based in whole or in part on published literature or on the FDA's finding of safety and efficacy of one or more previously approved drugs, which are known as reference drugs. Thus, the filing of a Section 505(b)(2) NDA may result in approval of a drug based on fewer clinical or nonclinical studies than would be required under a full NDA. The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant's drug and the reference drug. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval of a Section 505(b)(2) NDA.

Because we may develop new formulations of previously approved chemical entities, our drug approval strategy is to submit Section 505(b)(2) NDAs to the FDA. The FDA may not agree that our product candidates are approvable as Section 505(b)(2) NDAs. If the FDA determines that Section 505(b)(2) NDAs are not appropriate and that full NDAs are required for our product candidates, the time and financial resources required to obtain FDA approval for product candidates could substantially and materially increase, and our products might be less likely to be approved. If the FDA requires full NDAs for product candidates, or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than the product candidates would be adversely impacted.



## Patent Protections

We currently have one patent issued for Regia™ in Morocco and one issued in the U.S., and an application pending in Europe. We also have a series of patent applications pending in the U.S.A. and internationally for our SSAO technology platform.

An applicant submitting a Section 505(b)(2) NDA must certify to the FDA the patent status of the reference drug upon which the applicant relies in support of approval of its drug. With respect to every patent listed in the FDA's Orange Book, which is the FDA's list of approved drug products, as claiming the reference drug or an approved method of use of the reference drug, the Section 505(b)(2) applicant must certify that: (1) there is no patent information listed by the FDA for the reference drug; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date; (4) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product in the Section 505(b)(2) NDA; or (5) if the patent is a use patent, that the applicant does not seek approval for a use claimed by the patent. If the applicant files a certification to the effect of clause (1), (2) or (5), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid, unenforceable, or not infringed, or if a court enters a settlement order or consent decree stating the patent is invalid or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged in court, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit. The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Moreover, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

## Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a Section 505(b)(2) product from entering the market. The FDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active ingredient during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until 7 1/2 years after the NCE approval date. The FDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting a full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the preclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.



Other types of exclusivity in the United States include orphan drug exclusivity and pediatric exclusivity. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Section 505(b)(2) NDAs are similar to full NDAs filed under Section 505(b)(1) in that they are entitled to any of these forms of exclusivity if they meet the qualifying criteria. They also are entitled to the patent protections described above, based on patents that are listed in the FDA's Orange Book in the same manner as patents claiming drugs and uses approved for NDAs submitted as full NDAs.

### **Other Regulatory Requirements**

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- meeting record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
  - reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label or unapproved uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

### **Food and Drug Administration Amendments Act of 2007**

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, became law. This legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, the new law significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

The FDA has not yet implemented many of the provisions of the FDAAA, so we cannot predict the impact of the new legislation on the pharmaceutical industry or our business. However, the requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval for new pharmaceutical products, or to produce, market and distribute existing products. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Our business activities are subject to general governmental regulations. In addition, we are obligated to file periodic reports as required by the Exchange Act. We are deemed to be a "smaller reporting company" as defined in Regulation S-K. The SEC adopted rules which phasing out filings under Regulation SB and smaller reporting companies will file reports under the provisions of Regulation S-K. A "Smaller Reporting Company" is defined as a company which has a public float held by non-affiliated of \$75 million or less. Companies without a calculable equity float will qualify if their revenues were below \$50 million in the previous year.

### **Principal Products or Services**

See previous discussion on Our Business.

## **Competition**

We are engaged in a highly competitive business. We expect competition from numerous companies, including large international enterprises, and others entering the market with product similar to ours. Most of these companies have superior research and development, manufacturing, patent, legal marketing, financial, technological, personnel and managerial resources. Acquisition of competing companies by large pharmaceutical or healthcare companies could further enhance the competitors' financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy significant competitive advantages. Products developed by our competitors may be safer and more effective as compared to our products under development.

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### **Facilities, Equipment and Employees**

We currently have no corporate office. Our one employee operates from her private residence.

### **Effect of Governmental Regulations on Our Business**

See previous discussion on regulatory requirements.

We are a “smaller reporting company” subject to reporting requirements of the SEC. We are subject to the provisions of the Sarbanes-Oxley Act of 2002. It created an accounting oversight board to oversee the conduct of auditors of public companies and to ensure auditor independence. This Act imposes the obligations on management for financial reporting and quality financial disclosures, and to expose possible conflicts of interest. It also creates guidelines for audit committees, oversight of the audits performed by public auditing firms, and requires management to make assessments of internal controls procedures and other matters. Compliance with the provisions of this statute will increase our legal and accounting costs.

We are subject to the rules regarding proxy solicitations including the provisions of Regulation 14A. We may be required to provide to shareholders an information statement complying with the provisions of Schedules 14A or 14C.

### **Research and Development Costs During the Past Two Years**

During the years ended December 31, 2011 and 2010 the Company has incurred research and development costs totaling \$58,960 and \$0, respectively.

### **Cost and Effects of Compliance with Environmental Laws**

Currently we are not subject to material environmental laws, rules, or regulations that would have an adverse impact on our business operations or financial conditions.

## **Inflation**

We believe that inflation has little impact on our business affairs.

## **Employees**

We currently have one employee who serves as our President and Chief Executive Officer. Our one employee is not represented by a labor union, and has good relations with the Company. See “Management” for biographical information on our management team and directors. Subject to the availability of financing our intention is to expand our staff to five employees within 12 months in order to implement our growth strategy.

## **Reports**

You may locate reports on the SEC’s Internet site at [www.sec.gov](http://www.sec.gov). The SEC’s telephone number is 202-551-8090. Materials about us are available through the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549.

**Item 1A Risk Factors.**

**RISK FACTORS**

*Our business endeavors and our common stock involve a high degree of risk. You should carefully consider the risks described below with all of the other information included in this Report. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In that event, the market price of our common stock could decline, and investors could lose part or all of their investment.*

**FACTORS THAT COULD AFFECT OUR FUTURE RESULTS**

**RISKS RELATED TO THE COMPANY**

*We continue to require external financing to fund our operations, which may not be available.*

We will need a positive cash flow to fund our ongoing operations, including the development of our products under development and the annual costs to remain a public company, including legal, audit and listing fees. To-date, the Company has been dependent on loans from its current and former management and directors, and from Apricus Bio. We recognize that we cannot continue to depend on these sources to continue our operations in the long term.

Given our current lack of cash resources, we will not be able to implement our growth strategy unless we raise significant capital, enter into licensing and commercialization agreements, or partnering agreements. If we are unable to accomplish these objectives, we would be unable to advance certain programs and may be forced to curtail our operations.

We have engaged the services of Dawson James to pursue financing for us. However, given the current market conditions, there is no assurance that we will be able to successfully raise any money.

Based on the factors described above there is substantial doubt as to the Company's ability to continue as a going concern, as further discussed in Footnote 2 "Going Concern" to the Consolidated Financial Statements.

***We will continue to incur operating losses.***

We have not marketed or generated sales revenues from our product candidates under development. We have never been profitable and have incurred an accumulated deficit of approximately \$2,750,000 since our inception through December 31, 2011. Our ability to generate revenues and to achieve profitability and positive cash flow will depend on the successful licensing and commercialization of our product candidates currently approved or in human clinical trials and those earlier stage products and technology under development.

Our ability to become profitable will depend, among other things, on our (1) raising sufficient capital to implement our growth strategy, (2) obtaining of regulatory approvals of our proposed product candidates, (3) success in licensing, manufacturing, distributing and marketing our proposed product candidates, if approved, and (4) increasing profitability through acquisitions and growth and development of our operations. If we are unable to accomplish these objectives, we may be unable to achieve profitability and would need to raise additional capital to sustain our operations.

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully operate our business.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop and maintain important relationships with healthcare providers, clinicians and scientists. We are highly dependent upon our management, particularly Vivian Liu, our President and Chief Executive Officer. Although we have an employment agreement with Ms. Liu, these types of agreements are generally terminable at will at any time, and, therefore, we may not be able to retain her services as expected. The loss of the services of Ms. Liu could delay or prevent us from obtaining financing and implementing our business strategy. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We may need to hire additional personnel as we expand our commercial activities. We may not be able to attract and retain qualified personnel on acceptable terms.



Our ability to maintain, expand or renew our business and to get business from new clients, particularly in the drug development sector, also depends on our ability to subcontract and retain scientific staff with the skills necessary to keep pace with continuing changes in drug development technologies.

***We do not have our own proprietary technology and will have to license NexACT or another technology for our own product development programs.***

In order to successfully develop new products based on generic drugs on the market such as minoxidil, we will need to license in a delivery technology, which would enable us to differentiate our product from its generic counterparts. We may not be able to obtain the right to a suitable technology to develop our targeted drug candidates.

Consummation of licensing arrangements is subject to the negotiation of complex contractual relationships and we may be unable to negotiate such agreements on a timely basis, if at all, or on terms acceptable to us.

***We face significant competition and have limited resources compared to our competitors.***

We are engaged in a highly competitive industry. We can expect competition from numerous companies, including large international enterprises, and others entering the market for products similar to ours. Most of these companies have greater research and development, manufacturing, patent, legal, marketing, financial, technological, personnel and managerial resources. Acquisitions of competing companies by large pharmaceutical or healthcare companies could further enhance such competitors' financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy a significant competitive advantage. Products developed by our competitors may be more effective than our product candidates

***We currently have no sales force or marketing organization and will need, but may not be able, to attract marketing partners or afford qualified or experienced marketing and sales personnel for our product candidates under development.***

We have no internal sales and marketing capabilities. In order to market our OTC product candidate directly to customers, we will need to build a sales and marketing infrastructure and/or attract marketing partners that will need to spend significant funds to inform potential customers, including third-party distributors, of the distinctive characteristics and benefits of our product candidates. Our operating results and long term success will depend, among other things, on our ability to establish (1) successful arrangements with domestic and additional international

distributors and marketing partners and (2) if we cannot find such partners or choose to market and sell the product directly to customers, an effective internal marketing and sales organization. Consummation of partnering arrangements is subject to the negotiation of complex contractual relationships, and we may not be able to negotiate such agreements on a timely basis, if at all, or on terms acceptable to us. If we enter into third party arrangements, our revenues would be lower as we would share the revenues with our licensing, commercialization and development partners. If we are unable to launch a drug, we may realize little or no revenue from sales in the OTC market.

***Pre-clinical and clinical trials are inherently unpredictable. If we or our partners do not successfully conduct these trials or gain regulatory approval, we or our partners may be unable to market our product candidates.***

Through pre-clinical studies and clinical trials, our product candidates must be demonstrated to be safe and effective for the indicated uses. Results from pre-clinical studies and early clinical trials may not be indicative of, or allow for prediction of results in later-stage testing. Many of the pre-clinical studies that we have conducted are in animals with “models” of human disease states. Although these tests are widely used as screening mechanisms for drug candidates before being advanced to human clinical studies, results in animal studies are less reliable predictors of safety and efficacy than results of human clinical studies. Future clinical trials may not demonstrate the safety and effectiveness of our product candidates or may not result in regulatory approval to market our product candidates. Commercial sales in the United States of our product candidates cannot begin until final FDA approval is received. The failure of the FDA to approve our product candidates for commercial sales will have a material adverse effect on our prospects and could have a negative effect on the Company’s stock price.

***Patents and intellectual property rights are important to us but could be challenged.***

Proprietary protection for our pharmaceutical products and products under development is of material importance to our business in the U.S. and most other countries. We have sought and will continue to seek proprietary protection for our product candidates to attempt to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. Our success may depend on our ability to (1) obtain effective patent protection within the U.S. and internationally for our proprietary technologies and products, (2) defend patents we own, (3) preserve our trade secrets, and (4) operate without infringing upon the proprietary rights of others. In addition, we have agreed to indemnify our partners for certain liabilities with respect to the defense, protection and/or validity of our patents and would also be required to incur costs or forego revenue if it is necessary for our partners to acquire third party patent licenses in order for them to exercise the licenses acquired from us.

While we have obtained patents and have many patent applications pending, the extent of effective patent protection in the U.S. and other countries is highly uncertain and involves complex legal and factual questions. No consistent policy addresses the breadth of claims allowed in or the degree of protection afforded under patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad enough to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

While we believe that our patents would prevail in any potential litigation, the holders of competing patents could determine to commence a lawsuit against us and even prevail in any such lawsuit.

***We are dependent upon third party contract research organizations (“CROs”).***

We currently do not have our own research and development infrastructure. . To-date, our studies have been conducted by Apricus Bio, for a fee. Assuming we successfully raise sufficient capital to implement our product

development programs, we intend to contract the studies to third party CROs. If the CRO fails to conduct the contracted studies on a timely and satisfactory basis, we would experience and encounter costs and delays in identifying new CROs.

*We are dependent upon third party manufacturers for chemical manufacturing supplies.*

We are dependent on third party chemical manufacturers. Any products must be supplied on a timely basis and at satisfactory quality levels. If our validated third party chemical manufacturers fail to produce quality products on time and in sufficient quantities, our results would suffer, as we would encounter costs and delays in validating new third party suppliers.

*We may be subject to potential product liability and other claims, creating risks and expense.*

We are also exposed to potential product liability risks inherent in the development, testing, manufacturing, marketing and sale of human therapeutic products. Product liability insurance for the pharmaceutical industry is extremely expensive, difficult to obtain and may not be available on acceptable terms, if at all. We may need to acquire such insurance coverage prior to the commercial introduction of our product candidates. If we obtain coverage, we have no guarantee that the coverage limits of such insurance policies will be adequate. A successful claim against us if we are uninsured, or which is in excess of our insurance coverage, if any, could have a material adverse effect upon us and on our financial condition.

## **INDUSTRY RISKS**

*We are vulnerable to volatile stock market conditions.*

The market prices for securities of biopharmaceutical and biotechnology companies, including ours, have been highly volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, future announcements, such as the results of testing and clinical trials, the status of our relationships with third-party collaborators, technological innovations or new therapeutic products, governmental regulation, developments in patent or other proprietary rights, litigation or public concern as to the safety of products developed by us or others and general market conditions, concerning us, our competitors or other biopharmaceutical companies, may have a significant effect on the market price of our common stock.

*Instability and volatility in the financial markets and the global economic recession are likely to have a negative impact on our ability to raise necessary funds and on our business, financial condition, results of operations and cash flows.*

During the past several years, there has been substantial volatility and a decline in financial markets due in part to the lethargic global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. These conditions are likely to have an adverse effect on our industry, licensing partners, and business, including our financial condition, results of operations and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to raise capital through equity sales and/or incur indebtedness, if available, to finance operations. However, recent turmoil in the capital markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through sales of capital stock or through borrowings, under either existing or newly created

instruments in the public or private markets on terms that we believe to be reasonable, if at all.

***Changes in trends in the pharmaceutical and biotechnology industries, including difficult market conditions, could adversely affect our operating results.***

The biotechnology, pharmaceutical and medical device industries generally and drug discovery and development more specifically are subject to increasingly rapid technological changes. Our competitors and others might develop technologies or products that are more effective or commercially attractive than our current or future technologies or products, or that render our technologies or products less competitive or obsolete. If competitors introduce superior technologies or products and we cannot make enhancements to our technologies or products to remain competitive, our competitive position, and in turn our business, revenue and financial condition, would be materially and adversely affected.

***We and any potential licensees are subject to numerous and complex government regulations which could result in delay and expense.***

Governmental authorities in the U.S. and other countries heavily regulate the testing, manufacture, labeling, distribution, advertising and marketing of our proposed product candidates. Before any products we develop are marketed, FDA and comparable foreign agency approval must be obtained through an extensive clinical study and approval process.

The failure to obtain requisite governmental approvals for our product candidates under development in a timely manner or at all would delay or preclude us and our licensees from marketing our product candidates or limit the commercial use of our product candidates, which could adversely affect our business, financial condition and results of operations.

Any failure on our part to comply with applicable regulations could result in the termination of on-going research, discovery and development activities or the disqualification of data for submission to regulatory authorities.

Because we intend that our product candidates will be sold and marketed outside the U.S., we and/or our potential licensees will be subject to foreign regulatory requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements. These requirements vary widely from country to country. The failure to meet each foreign country's requirements could delay the introduction of our proposed product candidates in the respective foreign country and limit our revenues from sales of our proposed product candidates in foreign markets.

Successful commercialization of our product candidates may depend on the availability of reimbursement to the consumer from third-party healthcare payers, such as government and private insurance plans. Even if one or more products is successfully brought to market, reimbursement to consumers may not be available or sufficient to allow the realization of an appropriate return on our investment in product development or to sell our product candidates on a competitive basis. In addition, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to governmental controls. In the U.S., federal and state agencies have proposed similar governmental control and the U.S. Congress has recently adopted regulatory reforms that affect companies engaged in the healthcare industry. Pricing constraints on our product candidates in foreign markets and possibly in the U.S. could adversely affect our business and limit our revenues.

***We face uncertainty related to healthcare reform, pricing and reimbursement which could reduce our revenue potential.***

In 2009 and 2010, the U.S. Congress adopted legislation regarding health insurance, which has been signed into law. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Recently, there have been efforts in the U.S. Congress to defund the health insurance program described above. As a result of the political uncertainty surrounding the implementation of the health care legislation, it is unclear as to what laws, regulations, procedures and funding will be put into place in the near future. Such uncertainty may impact the reimbursement for certain prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. As described above, if reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.



Sales of our product candidates, if approved for commercialization, will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products, if commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Adoption of our product candidates, if approved, by the medical community may be limited if third-party payers will not offer coverage. Cost control initiatives may decrease coverage and payment levels for drugs, which in turn would negatively affect the price that we will be able to charge. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers to any drug candidate we have in development. Any denial of private or government payer coverage or inadequate reimbursement for procedures performed using our drug candidates, if commercialized, could harm our business and reduce our revenue.

## **RISKS RELATED TO OWNING OUR COMMON STOCK**

### ***Our stock could become ineligible to be listed on the OTCQB.***

Currently, our common stock trades on the OTCQB. We received notification from FINRA regarding a “three-strike rule”. In the past we filed two periodic reports late. If we file untimely again any time before May 2012 we most likely will not have our shares quoted on the OTCQB. It is possible that we could fall out of compliance again in the future. If we fail to maintain compliance with any listing requirements, we could be ineligible for the OTCQB, and have to trade our stock on the Pink Sheets.

### ***Our stock is considered a penny stock under SEC regulations and may have limited market liquidity.***

Our stock is considered a penny stock under regulations of the Securities and Exchange Commission and is subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from effecting transactions in our common stock, which may severely limit the market liquidity of the common stock and the ability of our shareholders to sell our securities in the secondary market.

***We do not expect to pay dividends on our common stock in the foreseeable future.***

Although our stockholders may receive dividends if, as and when declared by our board of directors, we do not intend to declare dividends on our common stock in the foreseeable future. Therefore, investors may not purchase our common stock if they need immediate or future income by way of dividends from their investment.

***We may issue additional shares of our capital stock that could dilute the value of your shares of common stock.***

We are authorized to issue 150,000,000 shares of our common stock. In light of our possible future need for additional financing, we may issue additional shares of common stock below current market prices that could dilute the earnings per share and book value of your shares of our common stock. These issuances would dilute existing stockholders and could depress the value of our common stock.

The stock granted to Ms. Liu contains anti-dilution provision, as follows (as amended): if additional shares of stock will be issued during the vesting period of 36 months since the grant date, Ms. Liu will also be issued additional shares in such a way, that she would retain 2%, 4% and 6% ownership of the Company at December 31, of 2011, 2012 and 2013 respectively. No additional shares were issued through December 31, 2011 as Ms. Liu's ownership at 12/31/2011 exceeded 2%.

In addition to provisions providing for proportionate adjustments in the event of stock splits, stock dividends, reverse stock splits and similar events, outstanding warrants representing the right to acquire shares of common stock may cause an adjustment of the exercise or conversion price if we issue shares of common stock at prices lower than the then exercise or conversion price or the then prevailing market price. This means that if we need to raise equity financing at a time when the market price for our common stock is lower than the exercise or conversion price, or if we need to provide a new equity investor with a discount from the then prevailing market price, then the exercise price will be reduced and the dilution to stockholders increased.

***Due to our limited public float, a large influx of free and tradable shares could negatively impact our stock price***

We have limited public float in the trading market for our shares of common stock. Previously the Company was designated as a shell company as defined by the SEC. Rule 144 states that the provisions of Rule 144 are unavailable to shareholders of a shell company until 12 months have expired after a former shell company files information that includes disclosures similar to information provided in a Form 10 filed with the SEC. On December 12, 2011, we filed a report on Form 8-K, which we believe included disclosures that would be included in a Form 10. Thus, on December 12, 2012, the provisions of Rule 144 should become available to shareholders of the Company. On March 22, 2012, the Company issued 14,722,571 shares to complete the exchange of FasTrack shares for Innovus Pharma shares.

Shares held by Apricus Bio and others holding large positions influence the public float. These parties' investment objectives may differ from other shareholders. If large shareholders decide to sell all or part of their shares, their selling may cause the market price of our shares to decrease significantly.

***Certain common shares are subject to rescission rights.***

On February 29, 2012, the Company made an offer for rescission to former FasTrack shareholders of the record date for the approval of the Reverse Merger. The Reverse Merger had been approved by the written consent of FasTrack shareholders holding a majority of the shares outstanding. Because FasTrack had not solicited any proxies from its shareholders for approval of the Reverse Merger, limited or no information had been provided to the FasTrack shareholders who had not signed the written consent. The Company sent to the former FasTrack shareholders the

North Horizon Information Statement dated September 27, 2012 and a report on Form 8-K dated December 12, 2011, which provided information about North Horizon and FasTrack including a description of the business, future plans, risk factors, financial information, description of the transactions, biographical summaries of the new officer and directors, financial statements and pro-forma financial statement for North Horizon and FasTrack as of September 30, 2011. Former holders of FasTrack shares prior to consummation of the Reverse Merger must reject the rescission offer of \$6 per share (\$.002 after effect of conversion ratio) within thirty days of the date of receipt of the information, or at the latest April 14, 2012. The rescission offer is limited to the FasTrack shareholders who were shareholders as of the record date.

**Item 2. Properties.**

None.

**Item 3. Legal Proceedings.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Part II.**

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

There is a public trading market for our common equity. Our trading symbol is "INNV." Our public market is limited and not active. We have approximately 500 shareholders of record.

We are approved to list our stock on the OTCQB. The application consisted of corporate information, financial statements and other documents as required by Rule 15c2-11 of the Securities Exchange Act of 1934, as amended, and by FINRA. It is anticipated that a listing on the OTCQB will permit price quotations for our shares to be published by such service and any trades that may occur. Our share prices may be volatile and subject to broad price movements.

Further, our equity shares are subject to the provisions of Section 15(g) and Rule 15g-9 of the Exchange Act, commonly referred to as the “Penny Stock” rules. Section 15(g) states certain requirements for transactions in penny stocks and Rule 15g-9(d)(1) incorporates the definition of penny stock as used in Rule 3a51-1 of the Exchange Act.

Generally a penny stock is defined as any equity security that has a market price of less than \$5.00 per share, subject to certain limited exceptions. Rule 3a51-1 provides that any equity security is considered to be a penny stock unless that security is registered and traded on a national securities exchange meeting certain criteria set by the Commission; issued by a registered investment company; excluded from the definition on the basis of price (at least \$5.00 per share) or the issuer’s net tangible assets; or exempted from the definition by the Commission. Once shares are deemed to be a penny stock, trading in the shares then becomes subject to additional rules relating to sales practices for broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor has assets in excess of \$1,000,000 or annual income exceeding \$200,000, or with spouse annual income of \$300,000. In calculating the net assets of an accredited investor a personal residence is excluded unless the indebtedness on the residence exceeds its value then the excess indebtedness is deducted from the net assets.

For transactions covered by these rules, broker-dealers must make a special suitability determination for the purchase of such securities and must have received prior to the purchase the purchaser’s written consent for the transaction. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery of a risk disclosure document relating to the penny stock market prior to the first transaction. A broker-dealer must also disclose the commissions payable to both the broker-dealer and the registered representative, and current quotations for the security. Finally, monthly statements must be sent disclosing recent price information for the penny stocks held in the account and information on the limited market in penny stocks. These rules may restrict the ability of broker-dealers to trade and/or maintain our common stock and may affect the ability of shareholders to sell their shares.

**Dividend Policy.**

We have not declared nor paid cash dividends nor made distributions in the past. We do not anticipate that we will pay cash dividends or make distributions in the foreseeable future.

**Prior reverse splits.**

In 1978, North Horizon's shares of common stock were subject to a reverse split on the basis of ten shares into one share. In 1980, North Horizon's shares of common stock were subject to a second reverse split of ten shares into one share. In December 2011, North Horizon completed a third reverse split of ten shares into one share.

**Securities Authorized for Issuance Under Equity Compensation Plans.**

We have no equity compensation plans.

**Item 6. Selected Financial Data.**

No information is required for smaller reporting companies.

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

*The following information should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in the Form 10-K.*

We, Innovus Pharmaceuticals, Inc., as an entity continuing the business operations of FasTrack, are a development stage company as we have limited assets, operations and income. For the next twelve months, additional capital will be required to maintain our corporate operations, which will include filing appropriate reports with the Securities and Exchange Commission and we will need to seek additional funding for our product selection and development. If we

are unable to obtain significant financing, our ability to continue as a going concern is doubtful.

We are focused on the development and in-licensing/acquisition of new and innovative pharmaceutical product opportunities that offer definable pathways to regulatory approvals, partnering and commercialization. We have a three-pronged approach in our business strategy:

- To internally develop new, 505(b)(2) topical products based on a proven drug delivery technology; and
- To in-license/acquire late stage revenue generating pharmaceutical products; and
- To leverage near term revenue opportunities afforded by our proprietary pipeline comprised of ethical therapeutic (“Rx”) and over-the-counter (“OTC”) products.

Our business model is designed to create multiple opportunities for success while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our balance sheet and cash flow with minimal dilution to our shareholders. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products, which we believe would accelerate our shareholders’ return on investment and provide us with additional cash flow to fund our own product development.



We believe that inflation has not and will not have a material effect on our operations. If we are involved in a merger or acquisition, management will evaluate the possible effects of inflation on operations and our business.

## **Liquidity and Capital Resources**

At December 31, 2011, the Company had \$25,014 in cash. On January 13, 2012, the Board of Directors authorized a total of \$174,667 in promissory notes (the "January Notes") to six individuals. One January Note for \$74,667 was issued to an accredited investor for liabilities assumed from North Horizon and therefore this did not result in any cash inflow for us. Five January Notes for a total of \$100,000 in a new cash infusion were issued to five individuals, three of who are members of the Company's Board of Directors. The January Notes bear an annual interest rate of 8% and are payable in cash at the earlier of January 13, 2013, or when the Company completes a financing of a minimum of \$4 million (the "Financing"). The holders of the January Notes have the right to convert their principal and interest accrued into the Company's securities on the same terms as investors in the Financing. In the event the Company defaults on repayment, the annual interest rate would increase to 13% and the holders of the January Notes would have the right to convert at \$.05 per share.

## **Results of Operations**

For the years ended December 31, 2011 and 2010

Revenues – for the years ended December 31, 2011 and 2010 the Company earned no revenues, and consequently, no cost of sales. Gross profits for the 2011 and 2010 years was \$0.

Operating Expenses – Operating expenses for the years ended December 31, 2011 and 2010 totaled \$2,188,535 and \$53,601, respectively, marking a \$2,134,934 increase. This increase was primarily the result of increases in research and development costs (\$58,960), professional fees (\$131,276), and investment banking fees (\$1,954,029), including fair value of warrants issued of \$1,904,865.

Other Income – The Company recognized interest expense of \$67,717 and \$16,322 for the years ended December 31, 2011 and 2010, respectively, resulting in a change of \$51,395. This change is primarily the result of increased level of debt during 2011 compared to 2010 and \$48,920 discount recorded on the conversion of convertible notes.

Net Loss – The Company recognized net losses in the amount of \$2,256,252 and \$69,923, for the years ended December 31, 2011 and 2010, respectively. This increased net loss results primarily from increased operating expenses and interest expense.

### **Off-Balance Sheet Arrangements**

We have no such arrangements to discuss.

### **Recent Accounting Pronouncements**

See Footnote 2 to our consolidated financial statements for the periods ended December 31, 2011 and 2010. The adoption of recently implemented accounting rules and policies did not have any impact on the Company's financial position, results of operations or cash flows.

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

Not required for smaller reporting companies.

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

See the consolidated financial statements commencing at page F-1 of this filing.

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

In December 2011, North Horizon dismissed its previous auditing firm of Pritchett Siler and Hardy. FasTrack engaged EisnerAmper LLP, as its independent registered public accounting firm. On February 2, 2012, we filed a report on Form 8-K advising of this change. The change became effective for the audit of our financial statements for the period ended December 31, 2011.

We have had no disagreements with our current or our prior auditors.

**Item 9A. Controls and Procedures.**

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by the annual report management performed with the participation of our Chief Executive Officer and Chief Financial Officer an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms, and the such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on the evaluation and

identification of the material weakness in internal control over financial reporting described below our Chief Executive Officer and our Chief Financial Officer concluded that as of December 31, 2011, our disclosure controls and procedures are not effective.

#### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13(a)-15(f) and Rule 15d-15(f) promulgated under the Exchange Act as a process designed by or under the supervision of the company's principal executive officer and principal financial officer and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States and include those policies and procedures that:

Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the Company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditure of the Company are being made in accordance with authorization of management and directors of the Company;

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

As of December 31, 2011, we conducted an assessment, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer of the effectiveness of our internal control over financial reporting based on the criteria of internal control over financial reporting established in “*Internal Control -- Integrated Framework*,” issued by the Committee of Sponsoring Organization (COSO) of the Treadway Commission. Based upon this assessment we determined that there is a material weakness affecting our internal control over financial reporting and have concluded that our internal control over financial reporting was not effective as of the end of the period covered by our Form 10K for the period ended December 31, 2011.

We have one employee, and she is responsible for all matters surrounding accounting and business transactions. Management believes that the material weakness of the lack of segregation of responsibilities can impact our financial statements. The existence of any material weakness precludes an effective determination.

#### Changes in Internal Controls

We observed in the fourth quarter of 2011 that we had no significant changes in our internal controls in that period. We made no significant changes during the fourth quarter of 2011. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events and there is no certainty that any design will succeed in achieving its stated goal under all potential future considerations regardless of how remote.

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

#### **Item 9B. Other Information.**

On January 13, 2012, the Board of Directors authorized a total of \$174,667 in promissory notes (the “January Notes”) to six individuals. One January Note for \$74,667 was issued to one accredited investor for the liabilities assumed from North Horizon, Inc. Five January Notes for a total of \$100,000 in new cash infusion were issued to five individuals,

three of whom are members of the Company's Board of Directors. The January Notes bear an annual interest rate of 8% and payable in cash at the earlier of January 13, 2012, or when the Company completes a financing of a minimum of \$4 million (the "Financing"). The holders of the January Notes have the right to convert their principal and interest accrued into the Company's securities at the same terms as the investors in the Financing. In the event the Company defaults on repayment, the annual interest rate would increase to 13% and the holders of the January Notes would have the right to convert at \$0.05 per share.

### **Part III**

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

The Company currently has one officer. Ms. Vivian Liu has served as our President & Chief Executive Officer since the acquisition of FasTrack Pharma on December 7, 2011. See her biographical information below.

The Company currently has three directors. They are Vivian Liu, Dr. Ziad Mirza, and Dr. Henry Esber. Their biographical information is as follows.

Vivian Liu, 50, is a director, President and Chief Executive Officer. Ms. Liu became our President and Chief Executive Officer effective with the acquisition of FasTrack on December 7, 2011. Prior to that, she served as the President and Chief Executive Officer of FasTrack Pharma from January - December 2011. In 1995, Ms. Liu co-founded NexMed, Inc., which in 2010 was renamed to Apricus BioSciences, Inc., (Nasdaq: APRI). Ms. Liu was NexMed's President and Chief Executive Officer from 2007 to 2009. Prior to her appointment as President, Ms Liu served in several executive capacities, including Executive Vice President, Chief Operating Officer, Chief Financial Officer, and Vice President of Corporate Affairs. She was appointed as a director of NexMed in 2007 and served as Chairman of the Board from 2009 to 2010. Ms. Liu has an M.P.A. from the University of Southern California, and has a B.A. from the University of California, Berkeley.

Henry Esber, Ph.D, 73, has served as a Director of FasTrack since January 2011. In 2000 Dr. Esber co-founded Bio-Quant, Inc., the largest pre-clinical discovery contract research organization in San Diego, California. From 2000 to 2010 he served as its Senior Vice President and Chief Business Development Officer. Dr. Esber has more than thirty-five years experience in the pharmaceutical service industry. Dr. Esber currently serves on the Board of Directors of Apricus and several private pharmaceutical companies. In the event that a potential conflict of interest arises between FasTrack and Apricus, Mr. Esber will abstain from participating in the decision involving the conflict.

Ziad Mirza, M.D., 49, is a director of FasTrack and has served as Chairman of the Board of Directors since March 2010. He also served as FasTrack's Acting Chief Executive Officer from March 2010 to December 2010. He is the President and co-founder of Baltimore Medical and Surgical Associates. He is a Certified Medical Director of long term care through the American Medical Directors Association. He is as well a Certified Physician Executive from the American College of Physician Executives. He consults for pharmaceutical companies on clinical trial design. He has a medical degree from the American University of Beirut and completed his residency at Good Samaritan Hospital in Baltimore. He received an MBA from the University of Massachusetts. Dr. Mirza is a first cousin of Dr. Bassam Damaj, our largest shareholder.

All directors hold office until the next annual meeting of stockholders or until their successors have been duly elected and qualified. There are no agreements with respect to the election of directors. We have no standing committees.

None of our officers or directors has during the past ten years has been involved in any events, such as petitions in bankruptcy, receivership or insolvency, criminal convictions, or proceedings relating to securities violations.

#### Director Compensation

Our directors are not compensated for attending meetings of the Board of Directors. In the future the directors may be compensated for their services. No decision has been made as to the manner or type of future compensation.

#### Section 16(a) Beneficial Ownership Reporting Compliance

All reports required to be filed under Section 16(a) were filed.

#### **Item 11. Executive Compensation.**

On January 21, 2011, FasTrack appointed Ms. Vivian Liu to serve on its Board of Directors, and also approved her appointment as its President and Chief Executive Officer. Ms. Liu and the Board of Directors agreed that Ms. Liu would forego collecting salary until the Company has raised an aggregate of \$500,000 or more in cash, excluding the \$250,000 cash infusion from Apricus Bio. As part of her compensation, Ms. Liu received 6% of FasTrack's outstanding equity shares in the form of 273 shares of restricted stock (the "Restricted Stock"). Commencing on the first day of employment, and thereafter on the first of each month for a total of thirty-six months, the restriction on 1/36 of the Restricted Stock would be removed, so long as Ms. Liu remained employed as the Company's Chief Executive Officer. In the event Ms. Liu's employment is terminated prior to the last restriction removal, Ms. Liu would immediately forfeit the remaining Restricted Stock. In the event the Company was acquired before the last restriction removal, the Company agreed to immediately remove the restriction on the remaining Restricted Stock. Upon the completion of the Merger between North Horizon and FasTrack Pharma on December 7, 2011, all of Ms. Liu's remaining Restricted Stock vested. Ms. Liu's 273 FasTrack shares were exchanged for 833,668 shares of Innovus Pharma shares.



The stock granted to Ms. Liu contains anti-dilution provision, as follows: if additional shares of stock will be issued during the vesting period, Ms. Liu will also be issued additional shares in such a way, that she would retain 2%, 4% and 6% ownership of the Company at December 31, 2011, 2012 and 2013, respectively. No additional shares were issued through December 31, 2011.

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

### Security Ownership of Certain Beneficial Owners.

All reports for officers, directors and 10% holders required under Section 16(a) were filed. The following table sets forth information, to the best of our knowledge, as of December 31, 2011, with respect to each person known to own beneficially more than 5% of the issued and outstanding common stock, each director and all directors and officers as a group.

Name	Number of Shares Owned Beneficially (2)	Percentage of Company (3)	
Vivian Liu	841,367	5.07	Officer and Director (1)
Henry Esber	2,272,924	13.72	Director (1)
Ziad Mirza	407,071	2.46	Director (1)
Wallace Boyack	840,579	5.07	
Ramon Jadra	989,198	5.97	
Bassam Damaj (4) & Family	4,555,093	27.68	

(1). The officers and directors own 3,521,362 shares of common stock, which is 21% of the outstanding shares as of December 31, 2011.

(2). The number of shares owned, include direct and beneficial ownership. The percentages are based on 16,564,063 shares of common stock being on a fully diluted basis, including shares which were subject to rescission at December 31, 2011 (none of which were rescinded as of the date of this filing)

(3). Based on information from our shareholder records. We made no independent verification of this information.

(4). Dr. Damaj is Chairman, President & CEO of Apricus Bio.

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

In January 2010 FasTrack's Board of Directors approved \$7,000 in payment to Dr. Bassam Damaj, who is our largest shareholder and serves as Chairman of the Board, President & Chief Executive Officer of Apricus Bio. The payment was for overhead expenses. The agreement included a provision that if FasTrack was unable to pay cash, Dr. Damaj would receive 1% of Fastrack's outstanding equity based on its outstanding shares as of January 15, 2011. On February 7, 2011, FasTrack issued 134,364 shares (as converted post combination) of common stock to Dr. Damaj to satisfy the obligation.

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In January 2010 the Sorrento Board of Directors approved a payment of \$7,000 to Dr. Bassam Damaj for 2010 overhead expenses. The agreement had a similar provision as the FasTrack agreement. Sorrento paid cash of \$7,000 to satisfy the obligation.

From October 2009 to 2011, Directors and Officers of the Company advanced cash or incurred FasTrack's expenses. The amounts varied from \$600 to \$5,000. Substantially all such advances have been repaid.

Since October 2009 FasTrack and Sorrento entered into agreements with others that are deemed to be related parties. In October 2009 FasTrack acquired the right to PrevOnco from Bio-Quant for \$276,020 paid for by 13,372,384 shares of FasTrack common stock (as converted post combination) and the issuance of a promissory note in the amount of \$250,000. In October 2009 Sorrento purchased from Bio-Quant the rights of Apez and Regia for a purchase price of \$120,858 paid for with 4,379 shares of Sorrento's common stock valued at \$11,000 and a promissory note.

In March 2010 FasTrack entered into an Agreement with NexMed in which FasTrack sold the development rights of PrevOnco to NexMed for cancellation of \$204,896 of the FasTrack Promissory Note and a right to 50% of the net proceeds defined as gross proceeds less 115% of the aggregate development expenses incurred by NexMed.

In March 2011 FasTrack acquired Sorrento's over-the-counter products. FasTrack assumed Sorrento's liabilities in the amount of \$142,808.

Because the three foregoing transactions are considered transaction with entities under common control, they have been recorded at historical carrying value (nil) and as equity transactions - deemed contributions or distribution.

In April 2011 FasTrack entered into an Agreement with Apricus Bio described herein.

The notes and accrued interest at the date of conversion (as described below) to Apricus Bio aggregated to \$489,061, bore per annum interest of 4.25% and were due on April 4, 2013. These notes were secured by a first priority security interest in the assets of the Company. The notes are convertible upon the happening of either financing of more than \$2,000,000 or a merger or acquisition transaction prior to the maturity date. Any outstanding amount will convert on the date of closing of the financing or the merger or acquisition at a price per share equal to ninety per cent (90%) of the price of the shares sold in the financing or exchange in the merger or acquisition. On December 22, 2011, the notes were convertible into 135,888 shares of the Company's common stock, pursuant to the terms of the note agreement. The shares which have trading restrictions until December 12, 2012, were physically delivered to Apricus Bio in March 2012.

In the past, the principal shareholder of North Horizon, who was also one of its directors and its president advanced funds to pay in the amount of \$26,601 for expenses North Horizon incurred in 2011. See “Related Party Transactions” Footnote 8 in the Consolidated Financial Statements for further information.

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

The following is a summary of the fees billed to the Company and its subsidiary by its principal accountants during the fiscal years ended December 31, 2011, and 2010. The accounting firm of (“Pritchett”) was the principal auditor for North Horizon, Inc., during 2011 and EisnerAmper LLC was the principal auditor for FasTrack Pharmaceuticals, Inc. The fees were as follows for the years 2011 and 2010.

	2011	2010
Audit fees		
EisnerAmper LLP	\$27,000	\$15,000 <sup>1</sup>
Pritchett Siler & Hardy	0	\$3,800

Other fees

EisnerAmper	\$6,000	2	\$7,000	3
Pritchett Siler & Hardy	\$3,900	4	\$3,600	4

Total fees

EisnerAmper LLP	\$33,000	\$22,000
Pritchett Siler & Hardy	\$3,900	\$3,600

1. For the audit of FasTrack financial statements from inception to December 31, 2010.
2. For the preparation of the Company's tax returns for 2011.
3. For the preparation of FasTrack tax returns from inception to December 31, 2010.
4. For the review of the North Horizon quarter statements.

**Item. 15 Exhibits, Financial Statement Schedules.**

(a)(1)(2) Financial statements. See the audited financial statements for the years ended December 31, 2011, and 2010, presented in Item 8.

(a)(3) Exhibits. The following exhibits are filed as part of this Annual Report:

**No. Description**

2.1	Merger Agreement and Plan of Merger - previously filed on July 20, 2011	
3.1	Articles of Incorporation	Previously filed
3.2	Bylaws	Previously filed
3.3	Ethics Policy	Previously filed
3.4	Amendments to Articles of Incorporation - Nevada	Previously filed on December 12, 2011
3.5	Certificate of Merger - Delaware	Previously filed on December 12, 2011
3.6	Articles of Merger - Utah	Previously filed on December 12, 2011
10.1	Financial Advisory and Consulting Agreement with Dawson James Securities, Inc., - previously filed on December 12, 2011	
10.2	Placement Agent Agreement with Dawson James Securities, Inc., dated December 16, 2011	
10.3	Addendum to Placement Agent Agreement with Dawson James Securities, Inc., dated March 22, 2012.	
10.4	Vivian Liu Employment Offer, dated March 7, 2012.	
21.2	List of subsidiaries	

Previously filed on  
December 12, 2011

31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act  
31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act  
32.1 Certification  
32.2 Certification

Exhibits 1.1, 3.4, 3.5 and 3.6 have been re-designated in this report.

We filed a Report on Form 8-K on December 12, 2011, which was filed during the last quarter of calendar year ended December 31, 2011. On February 2, 2012, we filed a Report on Form 8-K regarding the change in auditors.

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## Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

Innovus Pharmaceuticals, Inc. Registrant

s/Vivian Liu

Vivian Liu, President, Chief Executive Officer and Chief Financial Officer

Date: March 30, 2012.

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.

s/ Ziad Mirza

Ziad Mirza, MD, Chairman of the Board

Date: March 30, 2012.

s/ Henry Esber

Henry Esber, Ph.D. Director

Date: March 30, 2012.

s/Vivian Liu

Vivian Liu, Director.

Date: March 30, 2012.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Innovus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Innovus Pharmaceuticals, Inc. (the “Company”), Inc. as of December 31, 2011 and December 31, 2010 and the related consolidated statements of operations, changes in stockholders’ deficit and cash flows for the years then ended and for period from inception (October 31, 2008) to December 31, 2011. 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 audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Innovus Pharmaceuticals, Inc. (the “Company”) as of December 31, 2011 and 2010, and the results of their operations and their cash flows for the years then ended and for period from inception (October 31, 2008) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has limited liquidity, all of which have raised substantial doubt about its ability to continue as a going concern. Management’s plans regarding those matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

March 30, 2012

Edison, New Jersey

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**INNOVUS PHARMACEUTICALS, INC.**

(Formerly North Horizon, Inc.)

(A Development Stage Company)

## Consolidated Statements of Operations

	For the Years Ended		From
	December 31,		October 31,
	2011	2010	2008
			(Inception)
			through
			December
			31,
			2011
			\$-
REVENUES	\$-	\$-	\$-
OPERATING EXPENSES			
Research and development	58,960	-	78,960
Professional fees	131,276	-	131,276
Investment banking fees	1,954,865	-	1,954,865
(including fair value of warrant - \$1,904,865)			
General and administrative	43,434	53,601	97,159
Total Operating Expenses	2,188,535	53,601	2,262,260
LOSS FROM OPERATIONS	(2,188,535 )	(53,601 )	(2,262,260)
OTHER EXPENSES			
INTEREST EXPENSE	(67,717 )	(16,322 )	(91,285 )
TOTAL INTEREST EXPENSE	(67,717 )	(16,322 )	(91,285 )
LOSS BEFORE INCOME TAXES	(2,256,252 )	(69,923 )	(2,353,545)
PROVISION FOR INCOME TAXES	-	-	-
NET LOSS	\$(2,256,252 )	\$(69,923 )	\$(2,353,545)
BASIC AND DILUTED			
LOSS PER SHARE	\$(0.16 )	\$(0.01 )	
WEIGHTED AVERAGE			
NUMBER OF SHARES			
OUTSTANDING - BASIC AND DILUTED	13,785,487	13,681,876	

The accompanying notes are an integral part of these financial statements.

**INNOVUS PHARMACEUTICALS, INC.**

(Formerly North Horizon, Inc.)

(A Development Stage Company)

Consolidated Balance Sheets

December 31

	2011	2010
<b><u>ASSETS</u></b>		
<b>CURRENT ASSETS</b>		
Cash	\$25,014	\$1,650
<b>TOTAL ASSETS</b>	<b>\$25,014</b>	<b>\$1,650</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$1,687	\$10,034
Convertible notes payable	-	200,952
Promissory notes - Dawson James	50,000	-
Accrued interest payable	-	23,569
Related-party payables	87,168	18,600
Total Current Liabilities	138,855	253,155
Contingent liability related to common shares, subject to recission rights, issuable to FasTrack shareholders arising from Merger (14,722,077 shares )	28,926	
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Common stock; 150,000,000 shares authorized, at \$0.001 par value, 1,325,125 and 13,754,045 shares issued and outstanding, respectively	1,325	13,754
Additional paid-in capital	2,606,331	228,912
Deficit accumulated during the development stage	(2,750,423)	(494,171)
Total Stockholders' Equity (Deficit)	(142,767 )	(251,505)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$25,014</b>	<b>\$1,650</b>

The accompanying notes are an integral part of these financial statements.

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**INNOVUS PHARMACEUTICALS, INC.**

(Formerly North Horizon, Inc.)

(A Development Stage Company)

## Statements of Stockholders' Deficit

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Deficit Accumulated During The Development Stage	Total Stockholders' Deficit
Balance at October 31, 2008 (Inception)	-	\$0	\$0	\$0	\$0
Balance on December 31, 2008	-	-	-	-	-
Issuance of common stock - FasTrack asset purchase	13,372,284	13,372	12,648	-	26,020
Issuance of common stock - Sorrento business combination	-	-	11,000	-	11,000
Deemed distribution for the value of assets acquired from Apricus Bio	-	-	-	(396,878 )	(396,878 )
Net loss for the year ended December 31, 2009	-	-	-	(27,370 )	(27,370 )
Balance at December 31, 2009	13,372,284	\$ 13,372	\$ 23,648	\$ (424,248 )	\$ (387,228 )
Issuance of common stock for compensation of board members (Mirza and Nasser)	381,761	382	368	-	750
Deemed contribution for the value of assets sold to Apricus Bio	-	-	204,896	-	204,896
Net loss for the year ended December 31, 2010	-	-	-	(69,923 )	(69,923 )
Balance at December 31, 2010	13,754,045	\$ 13,754	\$ 228,912	\$ (494,171 )	\$ (251,505 )
Issuance of common stock for services rendered	134,364	134	6,866	-	7,000

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Issuance of common stock for compensation of officer	833,668	834	804	-	1,638
Forgiveness of interest by Apricus Bio	-	-	4,021	-	4,021
Contribution to capital arising from the conversion of the convertible promissory notes held by Apricus Bio at the date of the Merger and pursuant to the terms of the convertible note, which will result in the issuance of 135,888 shares of common stock in March 2012 to Apricus Bio	-	-	538,117	-	538,117
Issuance of shares for net liabilities assumed in the Merger	1,325,125	1,325	(63,050 )	-	(61,725 )
Issuance of warrants to investment banker for services	-	-	1,904,865	-	1,904,865
Reclassification of shares issuable to FasTrack shareholders pursuant to rescission offer	(14,722,077)	(14,722 )	(14,204 )	-	(28,926 )
Net loss for the year ended December 31, 2011	-	-	-	(2,256,252 )	(2,256,252 )
Balance at December 31, 2011	1,325,125	\$ 1,325	\$2,606,331	\$(2,750,423 )	\$(142,767 )

The accompanying notes are an integral part of these financial statements.

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**INNOVUS PHARMACEUTICALS, INC.**

(Formerly North Horizon, Inc.)

(A Development Stage Company)

## Consolidated Statements of Cash Flows

	For the Year Ended		From October 31, 2008 (Inception) through December 31, 2011
	December 31, 2011	2010	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (2,256,252)	\$ (69,923)	\$ (2,353,545)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued for services	8,638	750	9,388
Value of warrants granted to investment banker	1,904,865	-	1,904,865
Non-cash interest expense (including a discount on conversion of Apricus Bio convertible notes of \$48,920)	67,717	16,323	91,461
Promissory note issued for services rendered	50,000	-	50,000
Research and development expense recognized upon purchase of SSAO inhibitor assets	-	-	20,000
Expenses paid on behalf of the Company by Apricus Bio	-	25,990	25,990
Changes in operating assets and liabilities			
Change in related-party payable	25,168	-	25,168
Accounts payable	(8,172 )	10,034	1,687
Net Cash Used in Operating Activities	(208,036 )	(16,826)	(224,986 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
	-	-	-
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of loans from officers	5,003	17,500	23,603
Repayments of loans from officers	(23,603 )	-	(23,603 )
Proceeds from convertible notes payable	250,000	-	250,000
Net Cash Provided by Financing Activities	231,400	17,500	250,000

NET CHANGE IN CASH	23,364	674	25,014
CASH AT BEGINNING OF PERIOD	1,650	976	-
CASH AT END OF PERIOD	\$25,014	\$1,650	\$25,014
Interest paid	\$nil	\$nil	\$nil
Taxes paid	\$nil	\$nil	\$nil

*See note 9 for supplemental information on non-cash financing activities*

The accompanying notes are an integral part of these financial statements.

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**INNOVUS PHARMACEUTICALS, INC.**

**(Formerly North Horizon, Inc.)**

(A Development Stage Company)

Notes to the Consolidated Financial Statements

December 31, 2011 and 2010

1. COMPANY INFORMATION AND HISTORY

Nature of Business

Innovus Pharmaceuticals, Inc. (formerly North Horizon, Inc.) (“the Company”), a corporation organized under the laws of the State of Utah, entered into a combination with FasTrack Pharmaceuticals, Inc. (“FasTrack”), a corporation organized under the laws of the State of Delaware. The combination was effective on December 7, 2011.

Innovus Pharmaceuticals, Inc. was organized as a Utah corporation in 1959. In 2007, it changed its domicile to Nevada, and from 2007 through September 30, 2011, maintained the Company as a corporate entity and filed requisite reports with the U.S. Securities and Exchange Commission. Prior to the business combination the Company was considered a non-operating public shell corporation.

FasTrack Pharmaceuticals, Inc., (“FasTrack”) was incorporated in the State of Delaware on October 31, 2008 and commenced operations on October 1, 2009. FasTrack is a specialty pharmaceutical company focusing on the development of innovative pharmaceutical products. FasTrack develops ethical therapeutic drugs based on its unique delivery platforms and knowhow. Upon its acquisition of the Sorrento Pharmaceuticals Inc. (“Sorrento”) assets and liabilities in March 2011, the FasTrack also began to focus on OTC opportunities. Sorrento was incorporated in the state of Delaware on October 31, 2008 and commenced operations on October 1, 2009.

FasTrack and Sorrento were formed by the shareholders of Bio-Quant, Inc. (“Bio-Quant”), a contract research organization for the pharmaceutical industry that has been in existence since 2000. In 2008, Bio-Quant decided to focus on its core business of pre-clinical testing services and therefore formed FasTrack and Sorrento, and, in 2009, sold its pharmaceutical assets to the two companies, for FasTrack to focus on the development of ethical therapeutic (“Rx”) and for Sorrento on Over-the Counter (“OTC”) products. Both FasTrack and Sorrento had limited operations during 2009 and 2010, as their funding was severely limited. In March 2011, the shareholders of FasTrack and Sorrento elected to combine operations in an effort to better position the combined entity for new investors. Pursuant to an asset purchase agreement between the two companies, FasTrack acquired Sorrento’s assets and liabilities. All periods of the financial statements of FasTrack have been presented on a combined basis for the combination of FasTrack and Sorrento given the two companies merged as entities under common control.

Bio-Quant was acquired by Apricus Biosciences, Inc. (Nasdaq: APRI) (“Apricus Bio”) in December 2009. NexMed (U.S.A.), Inc., (“NexMed”) is a wholly owned subsidiary of Apricus Bio. As such, throughout the financial statements Bio-Quant, Apricus Bio and NexMed may be used interchangeably, but shall represent the same entity.

Innovus Pharmaceuticals, Inc. (“Innovus Pharma”) is focused on the development and in-licensing/acquisition of new and innovative pharmaceutical product opportunities that offer definable pathways to regulatory approvals, partnering and commercialization. We have a three-pronged approach in our business strategy:

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**INNOVUS PHARMACEUTICALS, INC.**

**(Formerly North Horizon, Inc.)**

(A Development Stage Company)

Notes to the Consolidated Financial Statements

December 31, 2011 and 2010

- To internally develop new, 505(b)(2) topical pharmaceutical; and
- To in-license/acquire late stage revenue generating pharmaceutical products; and
- To leverage near term revenue opportunities afforded by our proprietary pipeline comprised of ethical therapeutic (“Rx”) and over-the-counter (“OTC”) products.

Our business model is designed to create multiple opportunities for success while minimizing the risks associated with reliance on any single technology platform or product type, and to bridge the critical gap between promising new product candidates and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

In parallel, as our business strategy advances and corresponding valuations are established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential. Our long-term goal is to improve our balance sheet and cash flow with minimal dilution to our shareholders. This strategy may include debt financing and/or acquisitions of small revenue generating companies and products, which we believe would accelerate our shareholders’ return on investment and provide us with additional cash flow to fund our own product development.

Our Proprietary Product and Technology Portfolios

In our portfolio of Rx products, we have a partial interest in the potential commercial value of PrevOnco™, a Phase 2/3 second-line Orphan Drug therapy for patients with hepatocellular carcinoma or liver cancer. PrevOnco is based on lansoprazole, a drug widely used to treat gastro-esophageal reflux disease. Preclinical animal data have shown the drug to also be effective in shrinking the tumors commonly associated with liver cancer. In 2010, FasTrack sold the development rights of the product to NexMed. In exchange, we are entitled to receive up to 50% of the net commercial value of the product in the event Apricus Bio successfully licenses the product to a commercialization partner.

Pursuant to the overall terms of our PrevOnco agreements with Apricus Bio, we have the right to develop two products based on their proprietary NexACT<sup>®</sup> multi-route drug delivery technology. NexACT utilizes patented novel excipients or “penetration enhancers” that when incorporated into drug formulations, may improve their absorption and bioavailability. The technology is incorporated in Vitaros<sup>®</sup>, a topical treatment for erectile dysfunction approved for local marketing by Health Canada in October 2010.

We intend to pursue new product opportunities based on drugs with expired patents. Our strategy is to follow a 505(b)(2) regulatory approval pathway, which typically has a significantly shorter development cycle with less pre-clinical and clinical studies required by the regulatory agencies. We are actively exploring possible topical product candidates in dermatology. In June 2011, we entered into two research agreements with NexMed to conduct feasibility studies on two active drug ingredients identified by us. Assuming the availability of financing, we plan to conduct additional studies to optimize our proprietary minoxidil formulation and take it into human clinical trials.

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**INNOVUS PHARMACEUTICALS, INC.**

**(Formerly North Horizon, Inc.)**

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December 31, 2011 and 2010

Within our Rx portfolio is a development platform based on SSAO inhibitors. SSAO is known as vascular adhesion protein-1 or VAP-1, and is a dual function molecule with enzymatic and cell adhesion activities. These inhibitors are designed to reduce inflammation by blocking the white blood cells and reducing the levels of inflammatory mediators. A prior owner had developed a treatment for Lupus based on the SSAO platform, but that product failed in late-stage clinical studies. In 2009, FasTrack acquired the SSAO patent portfolio because of the possibility that the SSAO platform had potential for other developers to identify the right medical indication. Because the SSAO platform has unproven safety and efficacy profiles, to develop a product based on this platform would require significant resources and longer development time. We do not have these resources presently and no assurance can be given that even if proper resources were available, we would seek to develop or if development were pursued a successful SSAO platform would be accomplished. To facilitate the SSAO development we may seek a partnership relationship.

In our portfolio of OTC products, we have two opportunities for development and/or out-licensing. Apez<sup>TM</sup> is a potential treatment for pain relief. It is an arthritis cream intended to deliver different ingredients to various layers of the skin and muscle.

In addition, we have Regia<sup>TM</sup>, which is a plant-derived, anti-microbial agent for reducing the bleeding of gums when used in OTC products such as mouthwash. We have an issued US patent which expires on May 9, 2028 for Regia<sup>TM</sup> and applications pending in selected international markets. Our intention is to out-license the patent portfolio for Regia<sup>TM</sup> to potential development partners in the OTC space.

Merger between the Innovus and FasTrack

The merger agreement (the "Agreement"), dated December 7, 2011, stipulated that Innovus and FasTrack would undergo a combination whereby both companies would survive as legal entities, but FasTrack would become a wholly-owned subsidiary of Innovus. Pursuant to the Agreement, Innovus changed its name from North Horizon, Inc. to Innovus Pharmaceuticals, Inc.

As a result of the merger, the shareholders of FasTrack have actual and effective operating control of the consolidated entity after the transaction and the shareholders of former North Horizon continue as passive investors in the consolidated entity.

The transaction was accounted as a reverse acquisition under provisions of ASC Topic 805 "Business Combinations." As a result, the accompanying consolidated financial statements are issued under the name of the "legal acquirer" – Innovus Pharmaceuticals, Inc. However, these financial statements are continuation of the "accounting acquirer" – FasTrack for all periods presented. Due to the fact that prior to the transaction Innovus Pharmaceuticals, Inc. had only nominal net assets and did not constitute a "business," the transaction was deemed an equivalent of issuance of stock by

the private company (FasTrack) for the net assets of the shell corporation (Innovus Pharmaceutical Inc.), accompanied by recapitalization. No goodwill or other intangible assets were recorded under recapitalization accounting. As a result of recapitalization, the historical equity of the accounting acquirer (FasTrack) prior to the transaction has been retroactively restated using the share exchange ratio determined in the transaction: 1 share of FasTrack was exchanged for 3,054 shares of Innovus.

As a result of the combination the shareholders of FasTrack received 15,238,938 shares of the combined entity's post-split common stock (representing 92% ownership of Innovus on a fully diluted basis); the shareholders of North Horizon retained their holdings, totaling 1,325,125 shares (representing 8% ownership of Innovus).

On February 29, 2012, the Company made an offer for rescission to former FasTrack shareholders of the record date for the approval of the Reverse Merger. The Reverse Merger had been approved by the written consent of FasTrack shareholders holding a majority of the shares outstanding. Because FasTrack had not solicited any proxies from its shareholders for approval of the Reverse Merger, limited or no information had been provided to the FasTrack shareholders who had not signed the written consent. The Company sent to the former FasTrack shareholders the North Horizon Information Statement dated September 27, 2012 and a report on Form 8-K dated December 12, 2011, which provided information about North Horizon and FasTrack including a description of the business, future plans, risk factors, financial information, description of the transactions, biographical summaries of the new officer and directors, financial statements and pro-forma financial statement for North Horizon and FasTrack as of September 30, 2011. Former holders of FasTrack shares prior to consummation of the Reverse Merger must reject the rescission offer of \$6 per share (\$.002 after effect of conversion ratio) within thirty days of the date of receipt of the information, or at the latest April 14, 2012. The rescission offer is limited to the FasTrack shareholders who were shareholders as of the record date.

In addition, shares related to the convertible note of Apricus Bio, which was converted on December 21, 2011 were not yet issued as of December 31, 2011 due to administrative delays.

Shares subject to rescission rights and shares issuable to Apricus Bio were issued as of the date of this filing. As of the date of this filing no shareholders exercised their rescission rights.

**INNOVUS PHARMACEUTICALS, INC.**

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Notes to the Consolidated Financial Statements

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The following table presents selected information as of December 31, 2011 as if all shares under the rescission rights and shares to Apricus Bio upon conversion of the notes payable were issued and outstanding as of December 31, 2011:

	December 31, 2011
Shares issued and outstanding	1,325,125
Potential shares subject to rescission rights (1)	14,722,077
Shares issuable for conversion of Apricus Bio notes (1)	135,888
Shares, which would have been issued and outstanding, as if rescission rights were not granted and Apricus Bio shares were issued at the date of the Merger	16,183,090

(1) Issued in March 2012

2.

GOING CONCERN

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company has experienced net losses and negative cash flows from operations each year since its inception. Through December 31, 2011, the Company had an accumulated deficit of approximately \$2,750,000. The Company's operations have been financed through advances from officers and directors and related parties. The Company has not yet had sufficient funds to significantly develop its technologies.

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**INNOVUS PHARMACEUTICALS, INC.**

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As a result of its losses to date, expected losses in the future, limited capital resources and accumulated deficit, there is substantial doubt as to the Company's ability to continue as a going concern. The Company's continuation is based on the Company's ability to generate or obtain sufficient cash to meet our obligations on a timely basis and ultimately to attain profitable operations. The Company anticipates that it will continue to incur significant losses at least until successful commercialization of one or more of its products. In light of management's efforts, there are no assurances that the Company will be successful in this or any of its endeavors or become financially viable and continue as a going concern.

As noted in Note 9 the company received funding of \$100,000 in January 2012 in the form of promissory notes, principally from related parties. The Company has also engaged Dawson James Securities, an investment banking firm, to attempt to secure financing on behalf of the Company. The timing, form and amount of financing, if any, is uncertain.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### Basic Loss per Common Share

Basic loss per share is calculated by dividing the Company's net loss applicable to common shareholders by the weighted average number of common shares during the period. Diluted earnings per share is calculated by dividing the Company's net income available to common shareholders by the diluted weighted average number of shares outstanding during the year. Due to net losses at December 31, 2011 and 2010, the effect of the potential common shares resulting from warrants was excluded, as the effect would have been anti-dilutive.

The diluted share amount for 2011 assumes that the shares issuable to Apricus Bio upon conversion of the notes payable are not outstanding, and that the shares subject to rescission rights are not outstanding as of December 31, 2011.



	For the Year Ended December 31, 2011	For the Year Ended December 31, 2010
Net Loss (numerator)	\$(2,256,252 )	\$(69,923 )
Common Shares (denominator)	13,785,487	13,681,876
Net loss per share amount	\$(0.16 )	\$(0.01 )

Revenue Recognition

The Company will develop an appropriate revenue recognition policy when planned principle operations commence.

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**INNOVUS PHARMACEUTICALS, INC.**

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Notes to the Consolidated Financial Statements

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Advertising Costs

The Company's policy regarding advertising is to expense advertising costs when incurred. The Company did not incur any advertising expense during the years ended December 31, 2011 and 2010.

Cash and Cash Equivalents

For purposes of financial statement presentation the Company considers all highly liquid instruments purchased with a maturity of three months or less to be cash equivalents to the extent the funds are not being held for investment purposes.

Fair value measurements

The Company adopted the standard issued by the FASB, which clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

Level 1-Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2-Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3-Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

Fair value measurements

The carrying amounts reported in the balance sheets for cash, notes payable, and accounts payable and accrued expenses, approximate their fair market value based on the short-term maturity of these instruments.

Research and development

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents. Such costs also include the \$20,000 purchase price of the acquired intellectual property assets for the SSAO inhibitor indication, which did not meet the definition of an asset. Research and development costs totaled \$58,960 and \$-0- during the fiscal years ended December 31, 2011 and 2010, respectively.

Income Taxes

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates.

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**INNOVUS PHARMACEUTICALS, INC.**

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Notes to the Consolidated Financial Statements

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At December 31, 2011, the Company had net operating loss carry forwards of approximately \$374,000 that may be offset against future taxable income through 2031. Deferred tax assets amounted to approximately \$1,167,000 have been fully reserved. No tax benefit has been reported in 2011 and 2010, financial statements since the potential tax benefit is offset by a valuation allowance of the same amount.

The Company has undergone ownership change that will significantly impair the Company's ability to utilize these losses before their expiration due to Section 382 of Internal Revenue Code of 1986, as amended. Pursuant to Section 382 of the Internal Revenue Code of 1986, the annual utilization of a company's net operating loss carryforwards may be limited if the Company experiences a change in ownership of more than 50 percentage points within a three-year period. An ownership change occurs with respect to a corporation if it is a loss corporation on a testing date and, immediately after the close of the testing date, the percentage of stock of the corporation owned by one or more five-percent shareholders has increased by more than 50 percentage points over the lowest percentage of stock of such corporation owned by such shareholders at any time during the testing period.

The Company adopted the provisions of ASC 740-10 and has analyzed its filing positions in all open tax years in jurisdictions where it may be obligated to file returns. The Company believes that its income tax filing position and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded. The Company's policy is to recognize interest and/or penalties related to income tax matter in income tax expense. The Company had no accrual for interest or penalties at December 31, 2011. In addition, future changes in unrecognized tax benefits will have no impact on the effective tax rate due to the existence of the valuation.

A reconciliation of the statutory federal income tax rate to the effective tax rate is as follows:

Expected Federal Tax	34.0	%
State Tax (Net of Federal Benefit)	5.9	%
Intangibles	(-0.1)	%
Valuation Allowance	(-39.8)	%
Total	0.0	%

Stock based compensation

The Company's share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

Recent Accounting Pronouncements

Management has considered all recent accounting pronouncements issued since the last audit of our financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's financial statements.

4. ASSET PURCHASE AGREEMENTS WITH APRICUS BIO

In 2009, FasTrack purchased SSAO inhibitors compound technology from La Jolla Pharmaceutical Company ("La Jolla") (a non-related entity) for approximately \$20,000. The purchase was paid for by Bio-Quant and thus FasTrack issued a demand note to Bio-Quant for the same face amount. The purchase price was recorded as an expense pursuant to our accounting policy for research and development costs.

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**INNOVUS PHARMACEUTICALS, INC.**

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On October 1, 2009, FasTrack entered into an Asset Purchase Agreement with Bio-Quant (“the FasTrack-BQ Agreement”). Pursuant to the terms of the FasTrack-BQ Agreement, FasTrack acquired the rights to PrevOnco™ and another early stage cancer product candidate. The total purchase price was \$276,020, which was paid in 13,372,284 shares of FasTrack’s common stock valued at \$26,020 and the issuance of the \$250,000 FasTrack Promissory Note.

On October 1, 2009, Sorrento entered into an Asset Purchase Agreement with Bio-Quant (the Sorrento-BQ Agreement”). Pursuant to the terms of the Sorrento-BQ Agreement, Sorrento acquired the rights of Apeaz™ and Regia™. The total purchase price was \$120,858, which was paid in 4,379 shares of Sorrento’s common stock, valued at \$11,000 and the issuance of the Sorrento Promissory Note in the amount of \$109,858.

The aggregate purchase price of the October 1, 2009 transaction was \$398,878 and is recorded as a deemed distribution for the value of the net assets acquired from Apricus Bio.

On March 10, 2010, FasTrack entered into an Asset Purchase Agreement with NexMed (the “FasTrack-NexMed Agreement”). Pursuant to the terms of the FasTrack-NexMed Agreement, FasTrack sold the development rights of PrevOnco™ to NexMed in exchange for cancellation of \$204,896 of a FasTrack promissory note and in the event NexMed successfully licenses the product, 50% of the net proceeds, which is defined as the gross proceeds less 115% of the aggregate development expenses incurred by NexMed.

On March 16, 2011, FasTrack and Sorrento entered into an Asset Purchase Agreement, (the “FasTrack-Sorrento Agreement”). According to the terms of the FasTrack-Sorrento Agreement, the Company acquired the development and commercialization rights to ApeazT and Regia. In consideration for these rights, FasTrack agreed to assume the liabilities of Sorrento, comprised of immediately payable expenses of \$22,600 and \$120,208 for the interest and principal, respectively, due on Sorrento promissory notes. Since these two entities were considered entities under common control, the combination was accounted for at historical costs.

On April 4, 2011, FasTrack entered into an Asset Purchase Agreement with Apricus Bio (the FasTrack-Apricus Bio Agreement”). According to the terms of the FasTrack-Apricus Bio Agreement, FasTrack sold the patent rights for the backup compound for PrevOnco™, in exchange for Apricus Bio providing FasTrack with a) a fully funded loan of \$250,000 evidenced by a secured convertible promissory note, b) a second secured convertible promissory note in the amount of \$224,520, which consolidated the \$200,952 of various outstanding demand notes payable to Apricus Bio (see Footnote 5) and related accrued interest in the amount of \$23,568 (together the “Apricus Bio Notes”, and c) the right to develop two products using the NexACT technology. The issuance of \$224,520 note was considered debt restructuring. The restructuring did not result in any material gains or losses.

Since all of the above transactions are considered transactions with entities under common control, they have been reflected at historical carrying value (nil) and as equity transactions - deemed contributions or distributions.

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**INNOVUS PHARMACEUTICALS, INC.**  
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5. NOTES PAYABLE

Apricus Bio Note

The following summarizes the promissory note activities with Apricus Bio.

Borrowing from Bio-Quant pursuant to the FasTrack-BQ Agreement- October 2009	\$250,000
Borrowing from Bio-Quant for purchase of SSAO inhibitors from an unrelated third party- October 2009	20,000
Borrowing pursuant to Sorrento-Bio-Quant Agreement- October 2009	109,858
Balance at December 31, 2009	\$379,858
Cancellation of note pursuant to FasTrack-NexMed Agreement- March 2010	(204,896)
Demand note issued for payment of certain legal expenses By Apricus Bio on behalf of FasTrack	25,990
Balance at December 31, 2010	\$200,952
Issuance of fully-funded convertible note to Apricus Bio	250,000
Conversion of convertible notes payable to Apricus Bio pursuant to reverse-merger with Innovus	(450,952)
Balance, December 31, 2011	\$-0-

Interest expense recorded to Apricus Bio amounted to \$18,797 and \$16,322, for the years ended December 31, 2011 and 2010, respectively. On April 4, 2011, pursuant to the terms of the FasTrack-Apricus Bio Agreement, the above demand notes payable to Apricus Bio were combined into one secured convertible note plus accrued interest in the amount of \$224,500.

Apricus Bio forgave FasTrack interest charge on the \$200,952 note outstanding for the duration of three month period ended March 31, 2011. The amount of forgiven interest was \$4,021. The Company considers the forgiveness a deemed contribution and recorded the forgiven interest against additional paid in capital for the period ended December 31, 2011.

On December 21, 2011 the total balance due Apricus Bio of \$489,197 comprising of \$450,952 of principle and related accrued interest of \$38,245 was convertible into 135,888 shares of Innovus. As stipulated in a convertible note agreement conversion was automatic upon consummation of the Merger Agreement and the conversion price was



determined at a 10% discount to the fair value of the shares of stock of the Company. The discount resulted in a \$48,920 charge to interest expense in 2011. The price of the stock was determined based upon the over-the-counter quotation system. The shares were issued in March 2012.

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Dawson James Promissory Note

On December 7, 2011 the Company entered into a promissory note with Dawson James Securities, Inc. (“DJS”) whereby, as compensation for consulting services rendered, the Company agreed to pay DJS a sum of \$50,000. The principal is due by December 6, 2012 and accrues interest at a rate of 8.0% per annum. The note is unsecured.

6. RECAPITALIZATION TRANSACTION

On December 7, 2011 the Company consummated a combination wherein FasTrack Pharmaceuticals, Inc. (“FasTrack”), a corporation organized under the laws of the state of Delaware, merged with and into North Horizon, Inc., a Utah corporation.

The combination (the “Agreement”) stipulated that the companies would undergo a combination whereby the surviving entity would be North Horizon. FasTrack then became a wholly-owned subsidiary of North Horizon. North Horizon then changed its name to Innovus Pharmaceuticals, Inc. The transaction has been accounted for as a reverse merger, whereby North Horizon is the legal acquirer and FasTrack is the legal acquiree and the accounting acquirer.

As consideration for the business, the shareholders of FasTrack were allocated 15,238,938 shares (portion of which are subject to rescission election discussed in Note 1) of the Company’s post-split common stock (representing 92% ownership of Innovus on a fully diluted basis); the shareholders of North Horizon held 1,325,125 shares (representing 8% ownership of Innovus). Included in the FasTrack shares are the 135,888 shares issuable to Apricus Bio upon conversion of their note (see Note 4), which were issued in March of 2012. The authorized number of shares in the surviving entity was changed to 150,000,000. All shares were issued to the FasTrack shareholders in March of 2012, due to the time required to gather signatures of each shareholder. See Note 1. As part of the recapitalization transaction, the company assumed a liability of approximately \$60,000 due to an officer of North Horizon.

7. STOCK-BASED COMPENSATION

On March 8, 2010, Dr. Ziad Mirza and Mr. Mohammed Nasser were appointed to serve on the Company's Board of Directors. In addition, Dr. Mirza was appointed to serve as the acting Chief Executive Officer. In consideration for their services to the Company, the Board of Directors approved the issuance of 305,409 and 76,352 shares of common stock to Dr. Mirza and Mr. Nasser, respectively, for their services rendered to the Company. The shares were valued at \$0.002 per share and the Company recorded expense of \$750 for such issuance of shares. Due to absence of contemporaneous third-party transactions and lack of objective business information for an independent appraisal, the fair value per share was equal to the value at which the original issuance of shares to Bio-Quant took place for the purchase of assets by FasTrack in accordance with the FasTrack-BQ agreement.

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On January 21, 2011, the Company appointed Ms. Vivian Liu (appointment was updated on March 7, 2012) to serve on its Board of Directors, and also approved her appointment as its President and Chief Executive Officer. Ms. Liu and the Board of Directors agreed that Ms. Liu would forego collecting salary until the Company has raised an aggregate of \$500,000 or more in cash, excluding the \$250,000 cash infusion from Apricus Bio, at which time her salary will commence at \$150,000 per year, effective retroactively to January 1, 2012. As part of her compensation, Ms. Liu received 6% of the Company's outstanding equity shares in the form of 833,668 shares of restricted stock (the "Restricted Stock"). Due to absence of contemporaneous third-party transactions and lack of objective business information for an independent appraisal, the fair value per share was equal to the value at which the original issuance of shares to Bio-Quant took place for the purchase of assets by FasTrack in accordance with the FasTrack-BQ agreement (\$0.002/per share). The remaining shares issued to Ms. Liu fully vested on the date of the merger – December 7, 2011.

The stock granted to Ms. Liu contains anti-dilution provision, as follows (as updated): if additional shares of stock will be issued during the period ending December 31, 2012, Ms. Liu will also be issued additional shares in such a way, that she would retain at least 2%, 4% and 6% ownership of the Company at December 31, 2011, 2012 and 2013, respectively. No additional shares were issued or issuable through December 31, 2011 as her ownership percentage exceeds 2%. If additional shares are to be issued, a compensatory charge will be recognized.

On December 7, 2011, as compensation for service rendered, the Company granted to DJS warrants to purchase an aggregate of 380,973 shares of the Company's common stock at a strike price of \$0.10. The warrants expire on December 6, 2018. The Company performed an analysis of the warrants granted using the Black-Scholes options pricing model, assuming an annual volatility of 563.19% with a value of common stock of \$5 per share based upon the quoted price on such day, and a risk-free rate of 0.93%. Pursuant to this analysis, the Company valued the warrants granted at an aggregate value of \$1,904,865. This amount is included as compensation expense for the year ended December 31, 2011.

## 8. RELATED-PARTY TRANSACTIONS

At December 31, 2011 the Company owed \$87,168 to a related party. This amount represents advances made by a shareholder of North Horizon over time, including approximately \$60,000 assumed at the merger date, in order to help the Company meet its operating cash requirements. For the year ended December 31, 2011 the Company incurred expenses of approximately \$27,000 to such related party for professional services rendered. The advances are unsecured, non-interest bearing, and are due on demand.

During the year ended 2011 the Company paid approximately \$59,000 to Apricus Bio for feasibility studies in relation to two compounds identified by the Company. The amount was expended in research and development cost in the Consolidated Statement of Operations.

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In January 2010, the FasTrack Board of Directors approved \$7,000 in payment to Dr. Bassam Damaj, the Company's largest shareholder and the CEO of Apricus Bio, to cover the Company's 2010 overhead expenses, which were being incurred by Dr. Damaj. The two parties agreed that in the event the Company could not pay in cash, Dr. Damaj would be entitled to 1% of the Company's outstanding equity based on its shares outstanding as of January 15, 2011. On February 7, 2011, FasTrack issued 134,364 shares to Dr. Damaj in lieu of the \$7,000 cash payment.

In January 2010, the Sorrento Board of Directors approved \$7,000 in payment to Dr. Damaj, to cover Sorrento's 2010 overhead expenses, which were being incurred by Dr. Damaj. The two parties agreed that in the event the Company could not pay in cash, Dr. Damaj would be entitled to 1% of the Company's outstanding equity based on its shares outstanding as of January 15, 2011. In March 2011, Sorrento elected to pay Dr. Damaj in cash. The liability was paid in April 2011.

From October 1, 2009 until 2011 various Board members and officers of the Company either advanced cash loans to the Company or incurred expenses on behalf of the Company. These transactions were necessary to pay for various administrative expenses. Such advances and expenses ranged from \$600 to \$5,000. Substantially all such advances for an aggregate amount of 23,603 were repaid in due course after receipt of cash raised with April 4, 2011 convertible promissory note issued to Apricus Bio.

## 9. NON-CASH FINANCING ACTIVITIES

Non-cash financing activities can be summarized as follows:

### Year ended December 31, 2011:

The Company issued 1,325,125 shares of common stock to settle the \$61,725 net liabilities acquired in the Merger

Deemed contribution from forgiveness of interest by Apricus Bio in the amount of \$4,021

Deemed contribution from the conversion of Apricus Bio notes plus accrued interest (including interest resulting from conversion discount) in the amount of \$538,117

Year ended December 31, 2010:

Cancellation of note payable to Apricus Bio and recognition of deemed contribution for the value of cancelled note of \$204,896.

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10.

COMMITMENTS AND CONTINGENCIES

License

Pursuant to the terms of the FasTrack - Apricus Bio Agreement on April 4, 2011, upon approval by Apricus Bio of a one or both products to be combined with NexACT® drug delivery technology, the individual product Licenses will be granted to the Company. Upon grant of such product License, the Company will:

1. Make a \$500,000 up-front payment per license to Apricus Bio in the form of cash or a Secured Convertible Promissory Note,

2. Make Milestone and Royalty Payments:

(a) For sales of the Licensed Product directly or as a co-marketer:

(i) Milestone Payments:

To be paid on a Licensed Product by Licensed Product basis and payable within 10 days of achievement:

-\$350,000 for dosing of first patient in Phase I clinical trial;

-\$750,000 for dosing of first patient in Phase II clinical trial;

-\$1,250,000 for dosing of first patient in Phase III clinical trial;

-\$2,500,000 for regulatory approval of Licensed Product;

-\$1.5 million upon first reaching Net Sales of at least \$0-\$50 million;

-\$3 million upon first reaching Net Sales of at least \$50-\$200 million;

-\$6 million upon first reaching Net Sales of at least \$200 million to \$500 million; and

-\$12 million upon first reaching Net Sales of above \$500 million.



(ii) Royalties:

4.5% of net sales of Licensed Products invoiced by the Company.

- (b) For Licensed Products that will be licensed by Licensee to third party sub-licensees:

(i) Milestone Payments: The Company shall pay Apricus Bio 33 1/3% of all milestone payments it receives from any third party sublicense relating to any Product, net of its development expenses.

(ii) Royalties: The Company shall pay Apricus Bio with the following royalties on its Net Sales received by The Company from sales of the Licensed Products by third party sublicensees.

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Annual Net Profits in \$	Royalty %	
\$0 to \$5 million	20	%
\$5 to \$10 million	25	%
\$10 to 15 million	30	%
\$15 to 20 million	35	%
Greater than \$20 million	40	%

Royalties in (a) and (b) above will be payable on a country-by-country basis for the longer of (i) the time during which manufacture, use or sale of Licensed Product would infringe any patent rights within the Patents and (ii) 15 years from the first commercial sale of Licensed Product in such country. Thereafter, Apricus Bio shall receive 50% of the royalty payments described above.

As of December 31, 2011, no products have been approved and no milestone payments were triggered.

Agreement with a Placement Agent

On December 16, 2011, the Company engaged the services of Dawson James Securities, Inc. to act as the Company's exclusive Placement Agent on a commercially reasonable best efforts basis in connection with the a potential offering of equity or equity-linked securities of the Company.

The Company shall pay to Dawson James a cash fee payable upon each closing of the transaction contemplated by a. this Agreement ("Closing") equal to nine percent (9%) of the gross proceeds received by the Company (the "Placement Fee").

The Company shall also pay Dawson James a non-accountable expense allowance payable in cash upon each Closing, equal to three percent (3%) of the gross proceeds received by the Company from Investors at each Closing.

b. Upon execution of the Agreement, the Company paid a non-refundable cash deposit of \$25,000, which will be applied to the monies due hereunder at the first closing. The amount was recorded in "Professional Fees" expense in the Consolidated Statement of Operations

c. The Company shall deliver warrants to the Placement Agent or its designees (the "Agent Warrants") to purchase 8.75% of the maximum number of common stock underlying the securities sold in the potential offering.

d. The Company shall reimburse the Placement Agent for legal fees up to \$50,000 and other expenses incurred in connection with the Offering.

The Company shall pay a cash fee equal to five percent (5%) of the gross proceeds received by the Company upon exercise of warrants, if any.

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11. SUBSEQUENT EVENTS

On January 13, 2012, the Board of Directors authorized the issuance of a total of \$174,667 in promissory notes (the "January Notes") to six individuals. One January Note for \$74,667 was issued to one accredited investor for the liabilities assumed from North Horizon, Inc. The five remaining January Notes for a total of \$100,000 in new cash infusion were issued to five individuals, three of whom are members of the Company's Board of Directors. The January Notes bear an annual interest rate of 8% and payable in cash at the earlier of January 13, 2013 or when the Company completes a financing of a minimum of \$4 million (the "Financing"). The holders of the January Notes have the right to convert their principal and interest accrued into the Company's securities at the same terms as the investors in the future financing. In the event the Company defaults on repayment, the annual interest rate would increase to 13% and the holders of the January Notes would have the right to convert at \$0.05 per share.

In accordance with ASC 855-10, Company management reviewed all material events through the date of this report and there are no material subsequent events to report, other than those listed in the previous paragraph.