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	87-0324697
(State or other Jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)

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 x

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 x

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 x No ¨ (2) Yes x 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 x No ¨

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company:

Large accelerated filer	¨	Accelerated filed	¨
Non-accelerated filer	¨	Smaller reporting company	x

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

Market Value of Non-Affiliate Holdings

State the aggregate market value of the voting and non-voting common stock held by non-affiliates computed by reference to the price at which the common stock was last sold, or the average bid and asked price of such common stock, as of the last business day of the Registrant's most recently completed second quarter.

The market value of our voting and non-voting common stock (we have only common voting stock outstanding) was $12,490, based on 168,786 shares being then held by non-affiliates and a closing trading price of such common stock of $0.074 per share on the OTCBB on June 30, 2011.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Exchange Act subsequent to the distribution of securities under a plan confirmed by a court. N/A Yes ¨ No ¨.

Outstanding Shares

As of March 28, 2012, we had 16,183,600 shares of our common stock outstanding.

Documents Incorporated by Reference

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

INNOVUS PHARMACEUTICALS, INC.
INDEX TO ANNUAL REPORT ON FORM 10-K FILED WITH
THE SECURITIES AND EXCHANGE COMMISSION
YEAR ENDED DECEMBER 31, 2011

ITEMS IN FORM 10-K

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;
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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;

- 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. The 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® 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®, 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®, 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. Apeaz™ 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™, 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™ 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 ("FFDCA") 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 FFDCA, 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.

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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 FFDCA 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 FFDCA 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 FFDCA 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.

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. 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