INNOVUS PHARMACEUTICALS, INC.
Form 10-K
March 19, 2013

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, 2012

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.)

4275 Executive Square, Suite 200, La Jolla CA 92037
(Address of principal executive offices)(Zip code)

Registrant's telephone number: 858-964-5123

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

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.

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 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

The market value of the registrant's common stock held by non-affiliates as of the last business day of the registrant's most recently completed second quarter was $22,291,020, based on 8,195,228 shares being then held by non-affiliates and a closing trading price of $2.72 per share on the OTCBB on June 29, 2012.

Outstanding Shares

As of March 4, 2013, the registrant had 16,298,292 shares of common stock outstanding.

Documents Incorporated by Reference

None.

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PART I

In this report, references to “Innovus Pharma,” the “Company,” “we,” “us,” “our,” and words of similar import and meaning re to Innovus Pharmaceuticals, Inc.

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,” “should,” “could,” “would,” “expects,” “plans,” “believes,” “anticipates,” “intends,” “estimates,” “appro “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.

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. Risk Factors” below and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission, or the SEC. Except as required by applicable law, we do not intend to update any of the forward-looking statement to conform these statement to actual results.

Item 1. Business.

Overview

We are an emerging pharmaceutical company engaged in the commercialization, licensing, and development of prescription and non-prescription pharmaceutical products with unique packaging and presentation. Our products are focused in the respiratory, dermatology and autoimmune therapeutic categories and will be marketed to primary care physicians, pediatricians, dermatologists and rheumatologists. Our business model leverages our ability to acquire and in-license commercial products, to further develop acquired products, to find markets and drive demand for such products, and to establish physician relationships. Our future success is dependent on these ongoing efforts.

Innovus Pharma Strategy

Our corporate strategy focuses on two primary objectives:

· Developing a diversified product portfolio of exclusive branded products through:

o acquisition of marketable and late stage drug candidates awaiting approval from the U.S. Food and Drug Administration, or FDA;

o acquisition of proven brands;

o packaging our products in a kit format designed for better patient compliance and results;

- o introduction of line extensions, reformulations; and
- o strategic development of our own products.

- Building an innovative, global sales and marketing model through commercial partnerships with established complimentary partners that:
  - o generate revenue; and
  - o lower costs compared to traditional pharmaceutical companies.

Our strategy is underway, but we have not yet generated revenue from any of our products.

We believe that our ability to market, license, acquire and develop brand name prescription products will uniquely position us to commercialize our products and grow in this market in a differentiated way. The following are additional details about our strategy:

- Focusing on acquisition of low-risk product opportunities that can reach the market within a relatively short time frame and that are well aligned with current therapeutic forces. In general, we seek pharmaceutical products that are already approved or otherwise marketable, although not on the market, or that are anticipated to be approved by the FDA within one year, or that are currently on the market. Ideal target products typically have market exclusivity and reputation in the medical community and are available for acquisition or license. We seek to combine such drugs with patented reformulation, unique dosage forms, drug delivery, and/or other technologies in an effort to produce unique product profiles with distinct market and/or clinical advantages over others. These proprietary and potentially patented products can then be re-introduced to the market by leveraging the existing market opportunity and patient base of the original product to extend the product lifecycle. Our pending acquisitions of nine products from Prospector Capital Partners II and one product from Centric Research Institute, or CRI, described below, are examples of this strategy. Using this strategy, and except for the CIRCUMSerum products being acquired, we will be working on manufacturing agreements for the acquired products in preparation of first launch in 2014.

- ***Seeking in-license opportunities and co-promotion partnerships***. We intend to in-license other proprietary products that would benefit from our platform.

- Focusing on low-risk and medium-term opportunities that can reach the market at an accelerated pace, by identifying and developing new products utilizing known chemical entities with proprietary delivery technologies for use in new disease areas and/or indications for the chemical entity. Products in this category have been marketed previously, but may be able to be reintroduced to the market by making changes in the delivery route, dosing schedule, or indications

of the drug. By utilizing the regulatory approval pathway authorized by Section 505(b)(2) of the U.S. Food, Drug and Cosmetic Act, or 505(b)(2), which is administered by the FDA, we intend to introduce well-known products, file new drug applications, or NDAs, under 505(b)(2) and, if such NDAs are ultimately approved by the FDA, potentially benefit from a period of market exclusivity for such products. See "—Government Regulation" below. By identifying high value markets with unmet or under-met needs and developing products to serve those needs, we intend to yield significant franchise value through product introduction with both regulatory and intellectual property exclusivity in the market.

- ***Developing a proprietary patent portfolio to protect therapeutic categories we desire to enter***. We are working to file and secure patent claims in the United States and abroad covering product inventions and innovations that we believe are valuable. These patents, if issued and ultimately found to be valid, may enable us to create a barrier to entry for competitors in the United States market (in addition to regulatory exclusivity provided by FDA approval). See "—Government Regulation – Patent Protections" below.

Pharmaceutical Products

Our pharmaceutical product business is divided into prescription products and over-the-counter, or OTC, products.

Prescription Products

We do not currently have any prescription products, but we have entered into a binding term sheet with Prospector Capital Partners II for the acquisition of a portfolio of nine previously marketed prescription products, none of which are currently being marketed. Some of the subject products have been approved by the FDA, and if and when the acquisition of these products is completed, we will need to complete the regulatory transfer of any approvals through the FDA and set up manufacturing, distribution and reimbursement before we can launch any of the products. In addition, some of the products will need to be reformulated to meet current FDA requirements. Reformulation may require additional testing which would delay our launch of the product.

The products subject to the binding term sheet with Prospector are:

1. The Extendryl® product line consists of prescription-only drugs that are generally indicated for treatment and relief of cough, cold and allergy symptoms.

2. The Levall® product line consists of prescription-only drugs that are generally indicated for treatment and relief from coughing, congestion and rhinitis associated with respiratory infections such as the common cold, influenza, bronchitis and sinusitis.

3. Coraz™ Lotion (hydrocortisone lotion USP, 2%), is a convenience kit that also contains Puleré™, a medicated wash. Coraz™ Lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as seborrheic dermatitis. Puleré medicated wash aids in the control of dandruff, seborrhea and itchy flaking scalp.

4. Zytopic™ Cream is a convenience kit that contains Zytopic™ Cream (triamcinolone, USP 0.1%), Cleré™, a non-medicated soap free cleanser, and Emolene™, a non-medicated hypoallergenic moisturizer. Zytopic™ Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as atopic dermatitis. Cleré™ is a hypoallergenic (no perfumes or dyes) cleanser to help manage pruritic conditions.

Many cleansers contain detergents, perfumes, dyes and other allergens that further irritate sensitive skin commonly seen in atopic patients.

5. The Zinx™ family of products consists of four unique prescription products and one over-the-counter product. The base product Zinx™ is an over-the-counter, or "OTC," homeopathic zinc lozenge.

OTC Products

1. As mentioned above, the base product Zinx™ is an OTC homeopathic zinc lozenge.

2. Apeaz™ is an OTC topical cream for the relief of arthritis pain among other inflammatory conditions which contains methylsulfonylmethane and glucosamine.

3. We entered into a binding term sheet with Centric Research Institute, or CRI, to acquire foreign distribution rights to CIRCUMserum™, a non-medicated cream which moisturizes the head of the penis for enhanced feelings of sensation and greater sexual satisfaction. CIRCUMserum is a patent-pending blend of essential oils and ingredients generally recognized as safe that recently commenced marketing in the United States.

Development Projects

The most advanced development project is our Semicarbazide-sensitive amine oxidase/vascular adhesion protein-1, or SSAO/VAP-1, program which consists of a series of small molecule antagonists to this adhesion molecule. SSAO/VAP-1 has been linked to diseases such as arthritis in published clinical trials by independent investigators. This asset was acquired from La Jolla Pharmaceuticals, Inc. This is a pre-clinical product which requires clinical development beyond our current logistical and financial capacity. We would need to find a development partner in order to complete clinical trials before filing for FDA approval and ultimately marketing this product.

Sales and Marketing Strategy

Our sales and marketing strategy is based on finding commercial partners in the U.S. and internationally for our products. We will focus on setting up commercial partnerships for distribution, marketing and sales in the U.S. and in the Middle East and North Africa, or MENA, region as our second emerging market. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure enabling us to increase our reach while minimizing the incremental spending impact.

As we attempt to build a broader product portfolio, our executive team intends to develop and seek product opportunities in the dermatology, autoimmune and respiratory areas in order to expand the number of products we can promote through our partners and increase our potential revenues. As we move into additional therapeutic areas, we intend to execute the same organizational structure evolution process and sales and marketing plan for each subsequent therapeutic division.

Manufacturers and Single Source Suppliers

We will use third-party manufacturers for the production of our products for development and commercial purposes. We believe there is currently excess capacity for manufacturing in the marketplace and opportunities to lower manufacturing cost through outsourcing. Some of our products are currently available only from sole or limited suppliers.

We are dependent on third parties for the supply of the raw materials necessary to develop and manufacture our products, including the active and inactive pharmaceutical ingredients used in our products. We are required to identify the supplier of all the raw materials for our products in any drug applications that we file with the FDA, and all FDA-approved products that we acquire from others identity the supplier for raw materials. If raw materials for a

particular product become unavailable from an approved supplier specified in a drug application, we would be required to qualify a substitute supplier with the FDA, which would likely delay or interrupt manufacturing of the affected product. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some raw materials are available only from a single source and, in some of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist.

In addition, we obtain some of our raw materials and products from foreign suppliers. Arrangements with international raw material suppliers are subject to, among other things, FDA regulation, various import duties, foreign currency risk and other government clearances. Acts of governments outside the U.S. may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, any changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for research and development prior to the expiration of the applicable U.S. or foreign patents.

Government Regulation

FDA

The 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 U.S. under the Federal Food, Drug and Cosmetic Act, or the 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, or 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, or 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.

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.

Prescription Drug Wrap-Up

The Federal Food, Drug, and Cosmetic Act of 1938 (the "1938 Act") was the first statute requiring pre-market approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the Act to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval (the "1962 Act"). This amendment also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted with the National Academy of Science/National Research Council ("NAS/NRC") to make an initial evaluation of the effectiveness of many drug products. The FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation ("DESI"). We believe that several of our pharmaceutical products will fall within this category.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, however, spurred by serious adverse reactions to one of these products, Congress urged the FDA to expand the new drug requirements to include all marketed unapproved prescription drugs. The FDA created a program, known as the Prescription Drug Wrap-Up, to address these remaining unapproved drugs. Most of these drugs contain active ingredients that were first marketed prior to the 1938 Act.

The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement discretion because there is an argument that all prescription drugs must be the subject of an approved drug application. There are a couple of narrow exceptions. For example, both the 1938 and 1962 Acts include grandfather provisions exempting certain drugs from the new drug requirements. The 1938 clause exempts drugs that were on the market prior to the passage of the 1938 Act and contain the same representations concerning the conditions of use as they did prior to passage of the Act. The 1962 Act exempts, in certain circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 Act. The agency and the courts have interpreted these two exceptions very narrowly.

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of new drug requirements for unapproved drugs that pose a safety threat, lack evidence of effectiveness and prevent patients from pursuing effective therapies, and are marketed fraudulently. In addition, the FDA has indicated that approval of a NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also file a NDA or ANDA for that same drug in order to continue marketing it in the United States. While the FDA generally provides sponsors a one year grace period, the agency is not statutorily required to do so.

In December 2010, the FDA published a list of unapproved prescription cough, cold, and allergy products that were submitted to FDA's Drug Registration and Listing System ("DRLS"). This list of unapproved products included several of the products in the Extendryl® and Levall® product lines that are covered by the binding term sheet we signed with Prospector Capital Partners II. We may be required to obtain FDA approval for these products before we are able to market them.

OTC Monograph Process

The FDA regulates certain non-prescription drugs using an OTC Monograph which, when final, is published in the Code of Federal Regulations at 21 C.F.R. Parts 330-358. Such products that meet each of the conditions established in the OTC Monograph regulations, as well as all other applicable regulations, may be marketed without prior approval by the FDA.

The general conditions set forth for OTC Monograph products include, among other things:

- the product is manufactured at FDA registered establishments and in accordance with cGMPs;
- the product label meets applicable format and content requirements including permissible "Indications" and all required dosing instructions and limitations, warnings, precautions and contraindications that have been established in an applicable OTC Monograph;
- the product contains only permissible active ingredients in permissible strengths and dosage forms;
- the product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation; and

· the product container and container components meet FDA's requirements.

The advertising for OTC drug products is regulated by the Federal Trade Commission, or FTC, which generally requires that advertising claims be truthful, not misleading, and substantiated by adequate and reliable scientific evidence. False, misleading, or unsubstantiated OTC drug advertising may be subject to FTC enforcement action and may also be challenged in court by competitors or others under the federal Lanham Act or similar state laws. Penalties for false or misleading advertising may include monetary fines or judgments as well as injunctions against further dissemination of such advertising claims.

A product marketed pursuant to an OTC Monograph must be listed with the FDA's DRLS and have a National Drug Code listing which is required for all marketed drug products. After marketing, the FDA may test the product or otherwise investigate the manufacturing and development of the product to ensure compliance with the OTC Monograph. Should the FDA determine that a product is not marketed in compliance with the OTC Monograph or is advertised outside of its regulations, the FDA may require corrective action up to and including market withdrawal and recall.

Patent Protections

We currently have one patent issued for Regia™ in Morocco and one issued in the U.S., and an application allowed in Europe. Our intention is to out-license the patent portfolio for Regia™ to potential development partners. 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, or functional group of a molecule. 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.

Competition

The pharmaceutical market is highly competitive with many established manufacturers, suppliers and distributors that are actively engaged in all phases of the business. We believe that competition in the sale of our products will be based primarily on efficacy, reimbursement coverage, regulatory compliance, brand awareness, availability, product safety and price. Our brand name pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. All of our existing products and products we have agreements to acquire compete with generic and other competitive products in the marketplace.

Competing in the branded product business requires us to identify and quickly bring to market new products embodying technological innovations. Successful marketing of branded products depends primarily on the ability to communicate the efficacy, safety and value to healthcare professionals in private practice, group practices and managed care organizations. We anticipate that our branded product offerings will support our existing lines of

therapeutic focus. Based upon business conditions and other factors, we regularly reexamine our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities.

Some of our existing products and products we have agreements to acquire compete with one or more products marketed by very large pharmaceutical companies that have much greater financial resources for marketing, selling and developing their products. These competitors, as well as others, have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. If we directly compete with them for the same markets and/or products, their financial and market strength could prevent us from capturing a meaningful share of those markets.

We also compete with other pharmaceutical companies for product line acquisitions as well as for new products and acquisitions of other companies.

Research and Development Costs during the Past Two Years

During the years ended December 31, 2012 and 2011, we incurred research and development costs totaling $2,000 and $58,960, respectively.

Employees

We currently have one full time employee, Dr. Bassam Damaj, who serves as our President and Chief Executive Officer. We also rely on a number of consultants. Our one employee is not represented by a labor union or by a collective bargaining agreement. Subject to the availability of financing, we intend to expand our staff to implement our growth strategy.

Corporate Formation

Innovus Pharma was incorporated as North Horizon, Inc. in 1959 as a Utah corporation and changed its domicile in 2007 to the State of Nevada. In December 2011, North Horizon merged with FasTrack Pharmaceuticals, Inc. and changed its name to its current name. North Horizon had no ongoing business at the time of the merger, and FasTrack had a pipeline of one commercial stage product, Apeaz™, and one pre-clinical product candidate, Semicarbazide-sensitive amine oxidase/vascular adhesion protein-1, or SSAO/VAP-1, antagonist intended for psoriasis and arthritis, described above under "—Development Projects."

Available Information

Our website is located at http://innovuspharma.com/index.html. Information found on our website is not incorporated by reference into this report.

We file reports and other documents with the U.S. Securities and Exchange Commission, or SEC, including an annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. The documents we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on or through our website, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of our SEC filings are located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings at http://www.sec.gov.

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.

Risks Related to our Business

We need additional funding from our President and Chief Executive Officer or outside parties or we will be forced to curtail or cease operations. Our current cash will fund our business as currently planned only through March 2013. The funding commitment from our President and Chief Executive Officer is anticipated to sustain operations only through January 1, 2014.

We need immediate and substantial cash to continue our operations. We have entered into an amended and restated 8% convertible debenture with our President and Chief Executive Officer, Bassam Damaj, Ph.D., under which Dr. Damaj may provide up to $500,000 in funding (subject to increase in certain circumstances), $35,000 of which has been provided through the date of this report. Dr. Damaj is required to provide additional funds under such debenture if we have insufficient liquidity to meet any material payment obligations arising in the ordinary course of business as they come due, up to the maximum of $500,000 in funding (subject to increase in certain circumstances). However, Dr. Damaj's funding commitment terminates on the earlier to occur of (i) the consummation of one or more transactions pursuant to which we raise net proceeds of at least $500,000 or (ii) January 1, 2014. We currently have no other funding commitments.

The funding commitment from Dr. Damaj is anticipated to sustain operations only through January 1, 2014. We currently have no other funding commitments. If Dr. Damaj were not to perform on his funding commitment, we may not have the financial resources available to pursue remedies against him, and if we do pursue remedies against him, such actions could significantly impair our relationship with Dr. Damaj, potentially leading to the loss of his services.

We therefore will need additional funding, either through Dr. Damaj's commitment, or other sources of equity or debt financings or partnering arrangements, or we will be forced to curtail or cease operations.

We have relied on capital contributed by related parties and such capital may not be available in the future.

In January 2012, the Company issued a total of $174,668 in 8% convertible debentures to six individuals, three of whom were on our board of directors and one of whom owns more than 5% of our outstanding common stock. $100,000 of these funds were available to fund future operations and were used in 2012. In January 2013, we issued an 8% convertible debenture to a board member for $70,000. In January 2013, we entered into a $250,000 convertible debenture with Dr. Damaj, which provided for requests of funding from time to time by our company, which Dr. Damaj had the right to accept or decline in his discretion. In March 2013, that instrument was amended and restated to increase the limit to $500,000 and provide an obligation for Dr. Damaj to provide funding as described above in the risk factor entitled "We need additional funding from our President and Chief Executive Officer or outside parties ...." Dr. Damaj has funded $35,000 to our company under the convertible debenture through the date of this report. For more information about these transactions, see "Part II, Item 7. Management's Discussion and Analysis of Results of Operation and Financial Condition—Results of Operations—Liquidity and Capital Resources," below.

We may not be able to obtain capital from related persons in the future. Except for Dr. Damaj as described above, none of the related persons referenced above, nor any of our other officers, directors, or other stockholders, is under any obligation to continue to provide cash to meet our future liquidity needs.

We may not be able to generate revenue and we will continue to incur operating losses.

We have not marketed or generated sales revenues from our product candidates under development or from our product candidates for which we have agreements to acquire. We have never been profitable and have incurred an accumulated deficit of approximately $2,449,000 since our inception through December 31, 2012. Our ability to generate revenues and become profitable will depend, among other things, on (1) the successful acquisition of our product candidates for which we have agreements to acquire, (2) raising capital to implement our growth strategy, (3) obtaining regulatory approvals of our proposed product candidates, (4) licensing and commercialization of our currently proposed product candidates, and (5) acquisitions of new products and product candidates and growth and development of our operations. If we are unable to accomplish these objectives, we may be unable to generate revenues or achieve profitability and we would need to raise additional capital to sustain our operations.

If we cease to continue as a going concern, due to lack of funding or otherwise, you may lose your entire investment in the company.

Our current plans indicate we will need substantial additional capital for research and development, including costs associated with developing our technology and conducting pre-clinical testing and clinical trials of our product candidates, before we have any anticipated revenue generating products. The funding commitment from Dr. Damaj described in the risk factor entitled “We need additional funding from our President and Chief Executive Officer or outside parties ....” is anticipated to sustain operations only through the end of 2013.

When we require additional funds, general market conditions or the then-current market price of our common stock may not support capital raising transaction such as additional public or private offerings of our common stock or strategic alliances with third parties on acceptable terms to us, or at all. If we require additional funds and we are unable to obtain them on a timely basis or on terms favorable to us, we may be required to scale back our development of new products, sell or license some or all of our technology or assets, or curtail or cease 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 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 Bassam Damaj, Ph.D., our President and Chief Executive Officer. Although we have an employment agreement with Dr. Damaj, he may terminate his agreement at

will at any time, and, therefore, we may not be able to retain his services as expected. The loss of the services of Dr. Damaj 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 presently have no scientific employees.

We may not complete the acquisitions of products from Prospector Capital Partners II and from Centric Research Institute. If we do acquire such products, we will have very limited recourse against Prospector or CRI.

We have binding term sheets with each of Prospector Capital Partners II and Centric Research Institute. Each such binding term sheet contemplates the entry into a definitive agreement prior to consummation of the acquisition. We may not be able to reach acceptable terms with Prospector or CRI on definitive agreements, and if we are not able to do so, we may not be able to consummate such acquisitions.

The binding term sheets with Prospector and CRI contemplate that we will acquire the products “as is.” Accordingly, our ability to pursue remedies against Prospector or CRI should the products not meet our expectations will be severely constrained.

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

In order to successfully develop new products based on generic drugs on the market, 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

Our sales and marketing function is currently very limited. We will need, but may not be able, to attract sales and marketing partners or afford qualified or experienced marketing and sales personnel for our product candidates.

We have no internal sales and marketing capabilities. In order to market our OTC and our prescription product candidates (including candidates we have agreements to acquire) 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 one of our current product candidates (including products we have agreements to acquire), we will realize no revenue from that drug.

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.

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.

We are dependent upon third party contract research organizations, or CROs.

We currently do not have our own research and development infrastructure. To date, our studies have been conducted by outside CROs. 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 have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products.

We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products. These third-party contract manufacturers are also subject to current good manufacturing practice, or cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements, we may incur added costs and delays in identifying and qualifying any such replacements. In addition, a new manufacturer would have to develop processes for production of our drug candidates.

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.

Material weaknesses or deficiencies in our internal control over financial reporting could harm stockholder and business confidence on our financial reporting, our ability to obtain financing and other aspects of our business.

Maintaining an effective system of internal control over financial reporting is necessary for us to provide reliable financial reports. As of December 31, 2012, we concluded that we had a material weakness in our internal control related to lack of segregation of duties in our accounting function. The existence of a material weakness is an indication that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected.

As a result of this material weakness, management’s assessment as of December 31, 2012 concluded that our internal control over financial reporting was not effective, and our principal executive and financial officer concluded that our disclosure controls and procedures were not effective as of December 31, 2012.

Because we have concluded that our internal control over financial reporting is not effective, and to the extent we identify future weaknesses or deficiencies, there could be material misstatements in our financial statements and we could fail to meet our financial reporting obligations. As a result, our ability to obtain additional financing, or obtain additional financing on favorable terms, could be materially and adversely affected which, in turn, could materially and adversely affect our business, our financial condition and the market value of our securities. In addition, perceptions of us could also be adversely affected among investors, business partners, customers and others.

Risks Related to our Industry

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 companies 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 may not obtain required FDA or foreign regulatory approvals. The FDA and foreign regulatory approval processes are time-consuming and expensive.

The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive.

We may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of an NDA the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. The Prescription Drug User Fee Act, or PDUFA, sets time standards for the FDA's review of NDA's. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we desire and could affect the marketability of our products.

Even if we comply with all the FDA regulatory requirements, we may never obtain regulatory approval for any of our product candidates in development. Even if regulatory approval of our products in development is received, such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. Such events would have a material adverse effect on our operations and financial condition. We may market certain of our products without the prior application to and approval by the FDA. For example, some of the product candidates to be acquired through the binding term sheet we signed with Prospector Capital Partners II may potentially be marketed under an over-the-counter, or OTC, monograph, or a determination of the Drug Efficacy Study Implementation, or DESI, review. The FDA may subsequently require us to withdraw such products and submit NDA's for approval prior to re-marketing. For example, several of the products in the Extendryl® and Levall® product lines that are covered by the binding term sheet we signed with Prospector Capital Partners II are identified in a list of unapproved prescription cough, cold, and allergy products published by FDA in December 2010. We may be required to obtain FDA approval for these products before we are able to market them.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current cGMP and to stop shipments of allegedly violative products. In the event the FDA takes any such action relating to our products (if any are approved by the FDA), such actions would have a material adverse effect on our operations and financial condition.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our products. It is possible that the FDA or other governmental authorities will issue additional regulations further restricting the sale of our proposed products. Any change in legislation or regulations that govern the review and approval process relating to our future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute those products.

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 are 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.

Instability and volatility in the financial markets and the global economic recession may have a negative impact on our ability to do business in our industry.

During the past several years, there has been substantial volatility in financial markets and a global recession. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. These conditions may have an adverse effect not only on us, but also on our suppliers, manufacturers, contract research organizations, licensing partners and potential end users of our products.

Risks Related to Owning our Common Stock

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.

Our stock could become ineligible to be quoted on the OTCBB or the OTCQB.

Currently, our common stock trades are reported on the OTCBB and the OTCQB. Continued quotation on the OTCBB and the OTCQB requires that we continue to timely file all of the reports required under Exchange Act. We have in the past been untimely on the filing of reports. If we fail to file these reports timely, our stock could be ineligible for quotation on the OTCBB or the OTCQB. Other quotation services that could report quotes in our stock are associated with less liquidity and transparency than the OTCBB or the OTCQB, and if our common stock ceases to be quoted on the OTCBB or the OTCQB, our stock price could decline and your ability to sell our common stock could become significantly constrained.

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. Generally, a penny stock is defined as any equity security that has a market price of less than $5.00 per share and that does not trade on a national securities exchange, subject to certain limited exceptions. Securities that are deemed to be a penny stock are subject to additional rules relating to sales practices for broker-dealers who sell penny stocks to persons other than established customers and accredited investors. 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 stockholders to sell their shares.

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.

If the ownership of our common stock continues to be highly concentrated it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

As of March 4, 2013, our executive officers, our directors and their affiliates beneficially owned or controlled approximately 50.6% of the outstanding shares of our common stock. Bassam Damaj, our President and Chief Executive Officer, beneficially owns 29.2% of the outstanding shares of common stock, Henry Esber, Ph.D., our Chairman, beneficially owns 13.9% of the outstanding shares of common stock, and Vivian Liu, a director and our former President and Chief Executive Officer, beneficially owns 5.1% of the outstanding shares of common stock. Accordingly, a limited number of stockholders will have substantial control over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets, or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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 need for additional financing, we may issue significant amounts of additional shares of common stock. Some or all of these issuances may be at or below current market prices, and investors may receive additional dilutive rights, such as tandem warrants and anti-dilution protection.

We have issued convertible debentures representing aggregate principal of up to $732,668. In the event these debentures are not converted into a subsequent PIPE financing or repaid on or before January 13, 2014, each holder will have the right to convert the unpaid principal and accrued interest the right to convert the principal and accrued interest into shares of our common stock at $0.05 per share.

We may also issue shares of our common stock for services and for rights to product candidates. We have reserved 10,000,000 shares for issuance under our 2013 Equity Incentive Plan, and 6,000,000 of those shares are reserved under the award to Dr. Damaj described below under Part III, Item 11. Executive Compensation—Employment Agreements. Our binding term sheets with Prospector Capital Partners II and CRI each contemplate the issuance of shares of our common stock.

Any or all of these issuances would dilute existing stockholders and could depress the value of our common stock.

We may have liability for shares of our common stock issued in the reverse merger.

Questions arose as to whether we complied with federal and applicable state securities laws in connection with the issuance of shares of our common stock to the FasTrack stockholders in connection with the December 2011 business combination transaction pursuant to which FasTrack became our wholly owned subsidiary. We made a rescission offer and provided detailed information to the FasTrack stockholders. The offer expired and no FasTrack stockholder accepted the offer. The rescission offer may not have been effective to extinguish liabilities we may have to the former FasTrack stockholders under federal or applicable state securities laws. Accordingly, liability may not lapse until all applicable statutes of limitation run. The former FasTrack stockholders reside in different jurisdictions and the statutes of limitation in those jurisdictions have different terms, the longest being four years. In some cases, claims may not be extinguished at the expiration of such limitation periods. We are unable to predict if any former FasTrack stockholder will make a claim or if pursued what the outcome may be. Any successful claim, or even the possibility of such claims, could have a material adverse effect on our financial condition and ability to raise capital.

Nevada law and provisions in our charter documents may delay or prevent a potential takeover bid that would be beneficial to common stockholders.

Our articles of incorporation and our bylaws contain provisions that may enable our board of directors to discourage, delay, or prevent a change in our ownership or in our management. In addition these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock. These provisions include the following:

- our board of directors may increase the size of the board of directors up to nine directors and fill vacancies on the board of directors; and
- our board of directors is expressly authorized to make, alter, or repeal our bylaws.

In addition Chapter 78 of the Nevada Revised Statutes contains provisions that may enable our board of directors to discourage, delay, or prevent a change in our ownership or in our management. The combinations with interested stockholders provisions of the Nevada Revised Statutes, subject to certain exceptions, restrict the ability of our company to engage in any combination with an interested stockholder for three years after the date a stockholder becomes an interested stockholder, unless, prior to the stockholder becoming an interested stockholder, our board of directors gave approval for the combination or the acquisition of shares which caused the stockholder to become an interested stockholder. If the combination or acquisition was not so approved prior to the stockholder becoming an interested stockholder, the interested stockholder may effect a combination after the three-year period only if either the stockholder receives approval from a majority of the outstanding voting shares, excluding shares beneficially owned by the interested stockholder or its affiliates or associates, or the consideration to be paid by the interested stockholder exceeds certain thresholds set forth in the statute. For purposes of the foregoing provisions, "interested stockholder" means either a person, other than our company or our subsidiaries, who directly or indirectly beneficially owns 10% or more of the voting power of our outstanding voting shares, or one of our affiliates or associates which at any time within three years immediately before the date in question directly or indirectly beneficially owned 10% or more of the voting power of our outstanding shares.

In addition the acquisition of controlling interest provisions of the Nevada Revised Statutes provide that a stockholder acquiring a controlling interest in our company, and those acting in association with that stockholder, obtain no voting rights in the control shares unless voting rights are conferred by stockholders holding a majority of our voting power (exclusive of the control shares). For purposes of these provisions, "controlling interest" means the ownership of outstanding voting shares enabling the acquiring person to exercise (either directly or indirectly or in association with others) one-fifth or more but less than one-third, one-third or more but less than a majority, or a majority or more of the voting power in the election of our directors, and "control shares" means those shares the stockholder acquired on the date it obtained a controlling interest or in the 90-day period preceding that date.

Accordingly, the provisions could require multiple votes with respect to voting rights in share acquisitions effected in separate stages, and the effect of these provisions may be to discourage, delay, or prevent a change in control of our company.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We own no real property. We lease approximately 750 square feet of office space in La Jolla, California at a current rental rate of approximately $1,200 per month. The lease expires on July 14, 2013. We are in discussions to extend the term of the lease. This space is adequate for our current requirements but we will require a larger, more permanent space as we add personnel consistent with our business plan.

Item 3. Legal Proceedings.

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. We are not currently a party to any material pending litigation or other material legal proceeding.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the OTCQB and the OTCBB and its trading symbol is "INNV." The market for our common stock is limited. The prices at which our common stock may trade may be volatile and subject to broad price movements.

The following table sets forth the high and low bid prices per share of our common stock by the OTCQB for the periods indicated as reported on the OTCQB. The quotes represent inter-dealer prices, without adjustment for retail mark-up, markdown or commission and may not represent actual transactions. The trading volume of our securities fluctuates and may be limited during certain periods. As a result of these volume fluctuations, the liquidity of an investment in our securities may be adversely affected.

	2012		2011	
	High	Low	High	Low
First Quarter	$4.00	$2.00	$0.50	$0.15

Second Quarter	$3.60	$2.01	$0.50	$0.50
Third Quarter	$3.60	$2.00	$5.00	$0.30
Fourth Quarter	$2.00	$0.15	$7.50	$2.40

As of March 4, 2013, we had 503 record holders of our common stock. The number of record holders does not include holders who hold their stock in “street name” inside bank or brokerage accounts.

Our common stock is considered a “penny stock” and is subject to the provisions of Section 15(g) and Rule 15g-9 of the Exchange Act, commonly referred to as the “Penny Stock” rules. Generally, a penny stock is defined as any equity security that has a market price of less than $5.00 per share and that does not trade on a national securities exchange, subject to certain limited exceptions. Securities that are deemed to be a penny stock are subject to additional rules relating to sales practices for broker-dealers who sell penny stocks to persons other than established customers and accredited investors. 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 stockholders to sell their shares.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. We expect to retain all available funds and any future earnings to support operations and fund the development and growth of our business. Our board of directors will determine whether we pay and the amount of future dividends (including cash dividends), if any.

December 2011 Reverse Split

Unless otherwise noted, the share amounts, price per share and other similar references used in this report have been adjusted to reflect retrospective application of the 10-for-1 reverse split of our common stock effected in December 2011.

Recent Sales of Unregistered Securities

During the fiscal year ended December 31, 2012, the following securities were sold without registration under the Securities Act and not previously reported as sales of unregistered securities on Form 10-Q or Form 8-K:

On January 13, 2012, we sold a total of $174,668 in 8% convertible debentures to six individuals. One convertible debenture in the principal amount of $74,668 was issued to an accredited investor to settle liabilities assumed from North Horizon and therefore this did not result in any cash inflow for us. Convertible debentures in an aggregate principal amount of $100,000 were issued to five accredited investors, three of whom are members of our board of directors—Dr. Henry Esber, Vivian Liu and Dr. Ziad Mirza. The convertible debentures bear an annual interest rate of 8% and were payable in cash at the earlier of January 13, 2013 and when our company completes a financing with minimum proceeds of $4 million. The holders have the option to convert the outstanding principal and interest accrued under their convertible debentures into securities that we issue in any future financing with minimum proceeds of $4 million. If we defaulted on repayment, or if we failed to complete such financing within one year of the date the convertible debentures were issued, the annual interest rate would increase to 13% and the holders would have the right to convert the principal and accrued interest into shares of our common stock at $0.05 per share. Through December 31, 2012, $12,000 (plus accrued interest of $435) of the convertible debentures were converted into 16,580 shares of common stock, leaving a balance of $162,668 in aggregate principal amount outstanding under the convertible debentures at December 31, 2012. In January 2013, the holders of the convertible debentures agreed to extend the January 13, 2013 maturity date to January 13, 2014 at the same interest rate of 8% per annum6. We do not have the right to pre-pay these convertible debentures.

The convertible debentures (and the shares of common stock issued upon their conversion) were offered and sold without registration under the Securities Act to individuals who were accredited investors and who, by reason of their business or financial experience were capable of evaluating the merits and risks of an investment in the convertible debentures and of protecting their own interests in connection with the acquisition of the convertible debentures, and in reliance upon the exemption from registration in Regulation D, Rule 506 of the Securities Act. The convertible debentures may not be offered or sold in the United States in the absence of an effective registration statement or exemption from the registration requirements under the Securities Act, and the convertible debentures bear an appropriate restrictive legend.

Item 6. Selected Financial Data.

Not applicable.

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 this report.

Overview

We are an emerging pharmaceutical company engaged in the commercialization, licensing, and development of prescription and non-prescription pharmaceutical products with a unique packaging and presentation. Our products are focused in the respiratory, dermatology and autoimmune therapeutic categories and will be marketed to primary care physicians, pediatricians, dermatologists and rheumatologists. Our business model leverages our ability to acquire and in-license commercial products, ongoing product development, business development and established physician relationships, to drive strong growth in demand for our core products. Our future success is very dependent on these ongoing efforts.

Our corporate strategy focuses on two primary objectives:

- Developing a diversified product portfolio of exclusive branded products through:
  - acquisition of approved or late stage drug candidates awaiting approval from the U.S. Food and Drug Administration, or FDA;
  - acquisition of proven brands;
  - packaging our products in a kit format designed for better patient compliance and results;
  - introduction of line extensions, reformulations; and
  - strategic development of our own products.
- Building an innovative, global sales and marketing model through commercial partnerships with established complimentary partners that:
  - generate revenue; and
  - lower costs compared to traditional pharmaceutical companies.

Our strategy is underway, but we are a development stage company, and we have not yet generated revenue from any of our products. We have signed two binding term sheets to acquire presecription and non-prescription products. See "Part I. Business—Pharmaceutical Products." We have limited assets and operations and we are dependent on our President and Chief Executive Officer for operating capital through the end of 2013. Additional capital will be required to maintain our corporate operations and we will need to seek additional funding for our product selection and development.

Financial Transactions

Reverse Merger

In December 2011, our company, then known as North Horizon, Inc., entered into a business combination transaction with FasTrack Pharmaceuticals, Inc. pursuant to which FasTrack became a wholly owned subsidiary of North Horizon. FasTrack was a specialty pharmaceutical company with a development pipeline of one prescription and one OTC product. The transaction closed on December 7, 2011. 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.

Immediately before the closing of the transaction, North Horizon's issued and outstanding shares of common stock (an aggregate 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.

In connection with the transaction, we changed our name from North Horizon, Inc. to Innovus Pharmaceuticals, Inc.

In connection with the transaction, we issued to the former FasTrack stockholders an aggregate of 15,238,938 shares of our common stock. Immediately following the closing of the transaction, the former FasTrack stockholders held in the aggregate 92% of our common stock on a fully diluted basis.

Upon the completion of this transaction, we issued warrants to purchase approximately 380,973 shares of our common stock with a term of seven years and an exercise price of $0.10 per share to designees of the placement agent. We also issued a promissory note, bearing interest at 8% per annum, to the placement agent in the original principal amount of $50,000. Such note was due and payable on December 6, 2012, and in January 2013, we paid $54,548 to fully discharge such note.

Questions arose as to whether we complied with federal and applicable state securities laws in connection with the issuance of shares of our common stock to the FasTrack stockholders in connection with the transaction. In February 2012, we made a rescission offer and provided detailed information to the FasTrack stockholders. The offer expired and no FasTrack stockholder accepted the offer. The rescission offer may not have been effective to extinguish liabilities we may have to the former FasTrack stockholders under federal or applicable state securities laws. Accordingly, liability may not lapse until all applicable statutes of limitation run. The former FasTrack stockholders reside in different jurisdictions and the statutes of limitation in those jurisdictions have different terms, the longest being four years. In some cases, claims may not be extinguished at the expiration of such limitation periods. We are unable to predict if any former FasTrack stockholder will make a claim or if pursued what the outcome may be. Any successful claim, or even the possibility of such claims, could have a material adverse effect on our financial condition and ability to raise capital. The potential amount payable to the former FasTrack stockholders in respect of the rescission offer was presented as a liability in the accompanying consolidated balance sheet as of December 31, 2011. Management concluded that the potential liability after the rescission offer is neither probable nor reasonably estimable, and accordingly, upon expiration of the rescission offer, the amount of such liabilitiy was reclassified to stockholders' deficit, and no liability is recorded for this contingency in the accompanying consolidated balance sheet as of December 31, 2012.

Results of Operations

For the years ended December 31, 2012 and 2011

Overview

For the years ended December 31, 2012 and 2011, we had no revenues, and consequently, no cost of sales or gross profits. During 2012, we had little resources available to develop or acquire products.

Operating Expenses

Operating expenses for the years ended December 31, 2012 and 2011 totaled $219,484 and $2,188,535, respectively, a $1,969,051 (90%) decrease year-over-year. 2011 expenses include the fair value of warrants issued to a placement agent for services valued at $1,904,865. We did not issue any warrants for services in 2012. Research and development expenses decreased from $58,960 in 2011 to $2,000 in 2012, a difference of $56,960, as a result of not conducting any proof of concept formulation studies in 2012. The reduction in research and development expenses also contributed to the overall decrease in operating expenses.

Other Income

We recognized interest expense of $17,031 and $67,717 for the years ended December 31, 2012 and 2011, respectively, a decrease of $50,686 year-over-year. This decrease was primarily the result of a decrease in the amount of debt during 2012 compared to 2011 and a $48,920 discount recorded in 2011 relating to the conversion of convertible notes.

Net Loss

We recognized a net loss in the amount of $236,515 and $2,256,252 for the years ended December 31, 2012 and 2011, respectively. The decrease in net loss results primarily from the decrease in operating expenses.

Liquidity and Capital Resources

At December 31, 2012, we had $18,445 in cash. At December 31, 2012, we had no other sources of liquidity.

Since December 31, 2012, we have received additional debt financing. In January 2013, we issued an 8% convertible debenture to Henry Esber, Ph.D., a board member, in the amount of $70,000 and entered into a $250,000 convertible debenture with Bassam Damaj, Ph.D., our President and Chief Executive Officer, which provided for requests of funding from time to time by our company, which Dr. Damaj had the right to accept or decline in his discretion. In March 2013, that instrument was amended and restated to increase the maximum principal amount to $500,000, $35,000 of which has been funded through the date of this report. Dr. Damaj is required to provide additional funds under such debenture if we have insufficient liquidity to meet any material payment obligations arising in the ordinary course of business as they come due, up to the maximum of $500,000 in funding. The funding commitment increases by the gross amount of any cash salary, bonus or severance payments provided to Dr. Damaj under his employment agreement with our company. Dr. Damaj's salary has been accrued and not paid under the provision of such employment agreement stating that salary payments will be accrued and not paid for so long as payment of such salary would jeopardize our ability to continue as a going concern. We have the right to pre-pay interest and principal under Dr. Damaj's convertible debenture. We anticipate that Dr. Damaj's salary will continue to be so accrued at least until we have received at least $500,000 in external funding. See "Part III, Item 11. Executive Compensation—Employment Agreements," below. Dr. Damaj's funding commitment terminates on the earlier to occur of (i) the consummation of one or more transactions pursuant to which we raise net proceeds of at least $500,000 or (ii) January 1, 2014.

Each of these convertible debentures bear an annual interest rate of 8% and are payable in cash at the earlier of January 13, 2014, or when we complete a financing with minimum proceeds of $4 million. The holders of the convertible debentures have the option to convert their principal and interest accrued into securities that issued in any future financing of our company with minimum proceeds of $4 million. In the event of a default on repayment, the annual interest rate would increase to 13% and the holders of the convertible debentures would have the option to convert to common stock at a value of $0.05 per share. With the exception of Dr. Damaj's convertible debenture, we do not have the right to pre-pay the convertible debentures.

Also in January 2013, we and each holder of the 8% convertible debentures we issued in January 2012 (totaling $162,668 in principal amount) agreed to extend the maturity date of such notes to January 13, 2014 at the same

interest rate of 8% per annum. See “Part II, Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchase of Equity Securities—Recent Sales of Unregistered Securities,” above, for more information on the 8% convertible debentures issued in January 2012.

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

We have experienced net losses and negative cash flows from operations each year since its inception. Through December 31, 2012, we had an accumulated deficit of approximately $2,449,000. Our operations have been financed through advances from officers and directors and related parties and to a lesser extent from outside capital. We have not yet had sufficient funds to significantly develop or commercialize our technologies.

In February 2013 we signed two binding term sheet for the acquisition of portfolios of products. The initial purchase price for these portfolios will be in the form of our common stock, with subsequent milestone and/or royalty payments in cash.

Management anticipates that we will continue to incur significant losses at least until successful commercialization of one or more of our products. Management has projected that cash on hand, plus the funds available from Dr. Damaj, will be sufficient to allow us to continue our operations and commence the product development process for selected products through January 1, 2014. We may not be successful in commercializing products or raising outside capital to allow us to continue as a going concern beyond that date. We have flexibility to slow down or defer our product development activities if necessary.

Over the next few years, we will require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. When we require additional funds, general market conditions or the then-current market price of our common stock may not support capital raising transaction such as additional public or private offerings of our common stock or strategic alliances with third parties on acceptable terms to us, or at all. If we require additional funds and we are unable to obtain them on a timely basis or on terms favorable to us, we may be required to scale back our development of new products, sell or license some or all of our technology or assets, or curtail or cease operations.

Recent Accounting Pronouncements

See Footnote 2 to our consolidated financial statements for the periods ended December 31, 2012 and 2011. The adoption of recently implemented accounting rules and policies did not have any impact on our financial position, results of operations or cash flows.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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

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

Not applicable.

Item 9A. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)) as of December 31, 2012. Based on that evaluation, our principal executive officer and principal financial officer has concluded that as of December 31, 2012, these disclosure controls and procedures were not effective as the result of the material weakness described below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control — Integrated Framework, our management concluded that our internal control over financial reporting was not effective as of December 31, 2012 and determined that there is a material weakness affecting our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. During 2012, we had only one employee, who was responsible for all matters surrounding accounting and business transactions. As a result, we had a material weakness due to the lack of segregation of duties in our accounting function.

Notwithstanding the identified material weaknesses described above, management believes that the financial statements and other financial information included in this report present fairly in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with accounting principles generally accepted in the United States.

We continue to have only one employee responsible for all matters surrounding business transactions. We have implemented various controls involving board approval for expenditures and reimbursements in order to mitigate this material weakness. We intend to hire additional accounting personnel, including a Chief Financial Officer when we have the financial resources to do so, and in connection with such hires, implement appropriate segregation of duties.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Exchange Act Rules 13a-15(d) and 15d-15(d) that occurred during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting. Management's report on internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to the rules of

the SEC because we are an emerging growth company and a smaller reporting company.

Item 9B. Other Information.

On March 18, 2013, we amended and restated the 8% convertible debenture issued to Dr. Damaj in January 2013 to increase the maximum principal amount from $250,000 to $500,000, $35,000 of which has been funded through the date of this report. The amended and restated 8% convertible debenture requires Dr. Damaj to provide additional funds under such debenture if we have insufficient liquidity to meet any material payment obligations arising in the ordinary course of business as they come due, up to the maximum of $500,000 in funding. The funding commitment increases by the gross amount of any cash salary, bonus or severance payments provided to Dr. Damaj under his employment agreement with our company. The amendment and restatement also provides that we have the right to pre-pay interest and principal under Dr. Damaj's convertible debenture. Dr. Damaj's funding commitment terminates on the earlier to occur of (i) the consummation of one or more transactions pursuant to which we raise net proceeds of at least $500,000 or (ii) January 1, 2014.

For additional terms of the amended and restated 8% convertible debenture with Dr. Damaj, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources," above.

On February 15, 2013, our board of directors unanimously adopted the Innovus Pharmaceuticals, Inc. 2013 Equity Incentive Plan, or the 2013 Equity Plan, and approved forms of award agreements under the 2013 Equity Plan, including the forms of restricted stock agreement, stock unit agreement, nonstatutory stock option agreement and incentive stock option agreement. The 2013 Equity Plan and the types of awards we may issue under such plan are described in more detail in "Part III. Item 11. Executive Compensation—2013 Equity Incentive Plan" below.

PART III

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

We currently have one employee, Dr. Bassam Damaj, who was appointed as our President and Chief Executive Officer on January 22, 2013. Prior to Dr. Damaj's appointment, Vivian Liu served as our President and Chief Executive Officer.

We currently have four directors: Dr. Damaj, Dr. Henry Esber, Ziad Mirza and Ms. Liu.

Bassam Damaj, Ph.D., 45, has served on our Board of Directors since January 22, 2013 and as our President and Chief Executive Officer, and our principal financial officer, since January 22, 2013. Before joining Innovus Pharma, Dr. Damaj served as President and Chief Executive Officer of Apricus Biosciences, Inc. (NASDAQ: APRI) from December 2009 until November 2012, during which time Apricus Bio obtained approval of its lead drug, Vitaros, a treatment for erectile dysfunction in Canada and licensed its rights to multiple large pharmaceutical companies such as Novartis-Sandoz, Abbott, Takeda, Bracco and others. Before joining Apricus Bio, Dr. Damaj was a co-founder of Bio-Quant, Inc. and served as the Chief Executive Officer and Chief Scientific Officer and as a member of Bio-Quant's board of directors from its inception in June 2000 until its acquisition by Apricus Bio in June 2011. In addition, Dr. Damaj was the founder, Chairman, President and Chief Executive Officer of R&D Healthcare, and the co-founder of Celltek Biotechnologies. He also served as a member of the Board of Directors of CreAgri, Inc. and was Member of the Scientific Advisory Board of MicroIslet, Inc. He is the author of the Immunological Reagents and Solutions reference book, the inventor of many patents and the author of numerous peer reviewed scientific publications. Dr. Damaj won a US Congressional award for the Anthrax Multiplex Diagnostic Test in 2003. Dr. Damaj holds a Ph.D. degree in Immunology/Microbiology from Laval University and completed a postdoctoral fellowship in molecular oncology at McGill University.

Henry Esber, Ph.D., 74, has served as a member of our Board of Directors since January 2011 and has served as Chairman of the Board since January 18, 2013. In 2000, Dr. Esber co-founded Bio-Quant, Inc., a 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 of experience in the pharmaceutical service industry. Dr. Esber served on the Board of Directors of Apricus Bio from December 2009 to January 2013, and currently serves on the Board of Directors of several private pharmaceutical companies.

Vivian Liu, 51, has served as a member of our Board of Directors since December 2011 and served as our President, Chief Executive Officer and Chief Financial Officer from December 2011 to January 22, 2013. Prior to that, she served as the President and Chief Executive Officer of FasTrack Pharma from January 2011 to 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 its Board of Directors 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.

Ziad Mirza, M.D., 51, has served as a member of our Board of Directors since December 2011, and served as Chairman of our Board of Directors from December 2011 to January 2013. 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 also 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 M.B.A. from the University of Massachusetts.

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Dr. Mirza and Dr. Damaj are cousins. Otherwise, there are no family relationships among any of the members of our board of directors or our executive officers.

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

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers and directors, and persons who own more than 10% of our common stock, to file reports of securities ownership and changes in such ownership with the SEC. Our officers and directors and persons who own more than 10% of our common stock also are required by rules promulgated by the SEC to furnish us with copies of all Section 16(a) reports they file. Based solely upon a review of the copies of such forms furnished to us and written representations from our directors and executive officers, we believe that all Section 16(a) filing requirements were timely met during the fiscal years ended December 31, 2012 and December 31, 2011, except that the Form 3 required to be filed by each of Dr. Damaj, Dr. Esber, Mr. Mirza and Ms. Liu reporting his or her initial ownership of our common stock on December 7, 2011, the date they became 10% owners, directors or executive officers, was filed late. These Form 3s were filed on January 6, 2012.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth information concerning compensation earned for services rendered to us during the years ended December 31, 2012 and December 31, 2011 by our principal executive officer. There were no other executive officers of our company during 2012.

2012 Summary Compensation Table

	Year	Salary	Bonus	Total

Name and Principal Position				Stock Awards	Option Awards	All Other Compensation		
Vivian Liu	2012	--	--	--	--	$ 16,200	(1)	$16,200
Former Chief Executive Officer and President	2011	--	--	$ 1,638 (2)	--	--		$1,638

(1) Represents reimbursement payments for medical and dental insurance.

(2) Represents the total grant date fair value, as determined under FASB ASC Topic 718, Stock Compensation, of restricted stock awards granted during fiscal 2011 by FasTrack to Ms. Liu.

Employment Agreements

In January 2011, FasTrack appointed Ms. Vivian Liu to serve on its Board of Directors and to serve as its President and Chief Executive Officer. Under the terms of her appointment, Ms. Liu agreed to forego collecting salary until FasTrack 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 shares of common stock in the form of 273 shares of FasTrack 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 FasTrack'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 FasTrack was acquired before the last restriction removal, FasTrack agreed to immediately remove the restriction on the remaining Restricted Stock. Upon the completion of the reverse merger between North Horizon, Inc. and FasTrack in December 2011, all of Ms. Liu's remaining Restricted Stock vested, and Ms. Liu's 273 FasTrack shares were exchanged for 833,668 shares of our common stock.

In March 2012, we entered into an employment letter with Ms. Liu. The employment letter provided that Ms. Liu would be entitled to receive salary of $150,000 per year, which would commence upon us raising an aggregate of $500,000 in investment proceeds and would be retroactive to January 1, 2012. In addition, Ms. Liu was eligible to receive an annual bonus targeted at 30% of her base salary, which was expected to be paid out in the first quarter following the bonus year. Ms. Liu was also entitled to medical and dental coverage and any other benefits offered by our company, and until we set up our own plan, we agreed to reimburse Ms. Liu for her COBRA coverage from her previous employer. Ms. Liu was also entitled to stock compensation to bring her ownership of common stock to 4%, and 6% on December 31, 2012 and December 31, 2013, respectively, calculated on a fully-diluted basis, assuming her continuous employment with our company. Ms. Liu agreed that upon her resignation as President and Chief Executive Officer on January 22, 2013, no cash amounts or stock compensation ever became due to her under her employment letter.

On January 22, 2013, we entered into an employment agreement with Dr. Damaj. Under the terms of the employment agreement, Dr. Damaj will earn a base salary of $375,000 for the first year of the agreement, increasing to $440,000 in the second year and increasing a minimum of 10% per year thereafter. Dr. Damaj's salary will be accrued and not paid for so long as payment of such salary would jeopardize our ability to continue as a going concern. Dr. Damaj will also be entitled to earn an annual cash bonus based on performance objectives approved by our Board of Directors, with an annual target cash bonus of 75% of his base salary. Dr. Damaj was also entitled to receive a grant of restricted stock units covering 6,000,000 shares of common stock, which grant occurred on February 15, 2013. 2,000,000 of such shares vested upon grant, and the remaining 4,000,000 shares will vest in eight equal quarterly installments beginning on April 1, 2013. The vested portion of this restricted stock unit grant will be settled with a like number of common shares on the earliest of (1) the termination of Dr. Damaj's employment, (2) a change in control of our company, or (3) January 22, 2020. Upon any termination of Dr. Damaj's employment, Dr. Damaj will be entitled to all accrued and unpaid salary and benefits, certain personal computer and telecommunications equipment and the continuation of health benefits for a period of 12 months. In the event we terminate Dr. Damaj's employment without cause or Dr. Damaj resigns for good reason, Dr. Damaj will be entitled to a severance payment equal to 1.5 times his then base salary and annual target bonus amount, or 2 times his then base salary and annual target bonus amount if such termination occurs within 24 months of a change of control, and continuation of health benefits for a period of 24 months.

2013 Equity Incentive Plan

In February 2013, our board of directors unanimously adopted the Innovus Pharmaceuticals, Inc. 2013 Equity Incentive Plan, or the 2013 Equity Plan. The 2013 Equity Plan was not contingent upon stockholder approval; though we may seek stockholder approval in the future. Unless terminated earlier, the 2013 Equity Plan will terminate on February 15, 2023.

The 2013 Equity Plan is currently administered by the 2013 Equity Incentive Plan Committee. Our board of directors is the initial 2013 Equity Incentive Plan Committee, which we refer to as the Committee. The Committee's responsibilities and authority include:

- Selecting individuals who are to receive awards;

- Determining the type, number, vesting requirements and other features and conditions of awards and amending such awards;

- Determining any performance goals or other factors included in an award; and

- Interpreting the provisions of, and deciding all questions arising under, the 2013 Equity Incentive Plan.

Any of our employees, directors, non-employee directors and consultants, as determined by the Committee, may be selected to participate in the 2013 Equity Plan. We may award these individuals with one or more of the following types of awards and all awards will be evidenced by an executed agreement between us and the participant:

- stock options;

- stock appreciation rights;

- restricted stock grants;

- stock units;
- other equity awards; and
- cash awards.

Stock options may be granted under the 2013 Equity Plan, including incentive stock options, as defined under Section 422 of the Internal Revenue Code, or the Code, and nonstatutory stock options. A stock option gives the participant the right to buy a specified number of shares of our common stock for a fixed price during a fixed period of time. The exercise price of all stock options granted under the 2013 Equity Plan will be determined by the Committee except that all options must have an exercise price that is not less than 100% of the fair market value of the underlying shares on the date of grant. The Committee may, in its discretion, subsequently reduce the exercise price of an option to the then-fair market value of the underlying shares as of the date of such price reduction. Stock options may be exercised as determined by the Committee, but in no event after the tenth anniversary of the date of grant.

Stock appreciation rights entitle a participant to receive a payment equal in value to the difference between the fair market value of a share of stock on the date of exercise of the stock appreciation right over the exercise price of the stock appreciation rights. We may pay that amount in cash, in shares of our common stock, or in a combination of both. The exercise price of all stock appreciation rights granted under the 2013 Equity Plan will be determined by the Committee, except that all stock appreciation rights must have an exercise price that is not less than 100% of the fair market value of the underlying shares on the date of grant. The Committee may, in its discretion, subsequently reduce the exercise price of a stock appreciation right to the then-fair market value of the underlying shares as of the date of such price reduction.

A restricted stock award is the grant of shares of our common stock at a price determined by the Committee (including zero), and which may be subject to a substantial risk of forfeiture until specific conditions or goals are met. Conditions may be based on continuing employment or achieving performance goals. During the period of vesting, participants holding shares of restricted stock generally will have full voting and dividend rights with respect to such shares.

A stock unit is a bookkeeping entry that represents the equivalent of a share of our common stock. A stock unit is similar to a restricted stock award except that participants holding stock units do not have any stockholder rights until the stock unit is settled with shares. Stock units represent an unfunded and unsecured obligation for us and a holder of a stock unit has no rights other than those of a general creditor.

Subject to certain adjustments in the event of a change in capitalization or similar transaction, as of the February 2013 adoption of the 2013 Equity Plan, we could issue a maximum of 10,000,000 shares of our common stock under the 2013 Equity Plan. Similarly, subject to certain adjustments in the event of a change in capitalization or similar transaction, the maximum aggregate number of shares that may be issued in connection with any type of award, including incentive stock options, under the 2013 Equity Plan was 10,000,000 shares. Shares subject to awards that expire or are canceled will again become available for issuance under the 2010 Stock Plan.

Additionally, no person may receive grants of any award intended to qualify as performance-based compensation under Code Section 162(m) during any fiscal year covering in excess of 3,000,000 common shares. This limit is increased to 4,000,000 shares in connection with either a participant’s commencement of employment with us or becoming a covered employee whose compensation is subject to the tax deduction limits of Code Section 162(m). Furthermore, no person will receive awards in the aggregate (including stock options, stock appreciation rights, restricted stock and stock units) that exceed these limits if such awards are intended to qualify as performance-based compensation under Code Section 162(m).

The 2013 Equity Plan provides that in the event there is a change in control, outstanding awards will be subject to the merger agreement or other applicable transaction agreement. In the event that a change in control occurs with respect to us and there is no assumption or continuation of awards, the Committee in its discretion may provide that some or all outstanding awards under the 2013 Equity Plan will vest and become exercisable as of immediately before such

change in control. The term "change in control" under the 2013 Equity Plan is generally defined to include: (i) certain acquisitions of more than 50% of our outstanding shares or combined voting power; (ii) dissolution or liquidation of our company; or (iii) certain business combinations including a merger, consolidation or similar corporate transaction involving our company or its subsidiaries, or a sale, transfer or other disposition of all or substantially all of our company's assets.

The Board may terminate, amend or modify the 2013 Equity Plan at any time; however, stockholder approval will be obtained for any amendment to the extent necessary to comply with any applicable law, regulation or stock exchange rule.

Director Compensation

Our directors are not compensated for their service on our Board of Directors. In the future, we may compensate our directors for their services, but at this time no decision has been made as to the manner or type of future compensation.

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

The following table sets forth information regarding beneficial ownership of our common stock as of March 4, 2013 (the "Evaluation Date") by (a) each person known to us to beneficially own more than 5% of the outstanding shares of our common stock, (b) each director, (c) each of the named executive officers listed in the compensation tables included in this proxy statement and (d) all of our current directors and executive officers as a group. The information in this table is based on information provided by the persons named below. Percent of beneficial ownership is based on 16,298,292 shares of our common stock outstanding as of the Evaluation Date. The information in this table gives effect to the 10-for-1 reverse split of our outstanding common stock effected on December 6, 2011.

Name and Address of Beneficial Owner (1)	Shares Beneficially Owned (2)	Percent of Outstanding	
5% Stockholders:			
Wallace T. Boyack 2290 East 4500 South, Suite 130 Salt Lake City, UT 84117	840,579	5.2	%
Ramon Jadra c/o Raloid Corporation 109 Wabash Avenue Reisterstown, MD 21136	989,198	6.1	%
Directors and Named Executive Officers:			
Bassam Damaj, Ph.D. (3)	4,763,821	29.2	%
Henry Esber, Ph.D. (4)	2,252,126	13.9	%
Ziad Mirza, M.D.	403,346	2.5	%
Vivian Liu	833,669	5.1	%
All directors and executive officers as a group (4 persons)	8,252,962	50.6	%

* Less than 1%

(1) Unless otherwise indicated, the address of each of the listed persons is c/o Innovus Pharmaceuticals, Inc., 4275 Executive Square, Suite 200, La Jolla, California 92037.

(2) Beneficial ownership of shares is determined in accordance with SEC rules and generally includes any shares over which a person exercises sole or shared voting or investment power, or of which a person has the right to acquire ownership within 60 days of the Evaluation Date. Except as otherwise noted, (a) each person or entity has sole voting and investment power with respect to the shares shown and (b) none of the shares shown as beneficially owned on this table are subject to pledge. In calculating the percentage ownership of each person identified in the table, shares underlying options, warrants or other rights to acquire shares of our common stock held by that person that are either currently exercisable or exercisable within 60 days of the Evaluation Date are deemed outstanding. These shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any

other individual or entity. Percentage ownership for each person is based on the number of shares of our common stock outstanding as of the Evaluation Date, together with the applicable number of shares of common stock subject to options, warrants or other rights to acquire shares of our common stock currently exercisable or exercisable within 60 days of the Evaluation Date for that person or group of persons.

(3) Includes 1,297,836 shares held by his spouse.

(4) Includes 763,433 shares held by his spouse.

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

Other than the following transactions and the transactions described under “Item 11. Executive Compensation” above, since January 1, 2011, there has not been, nor currently are there proposed, any transactions or series of similar transactions in which we were or are to be a participant and the amount involved exceeds or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2011 and 2012, and in which any of our directors, executive officers, holders of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest.

During 2011, Wallace T. Boyack, the holder of more than 5% of our common stock, and who was the principal stockholder of North Horizon and also one of its directors and its president, advanced $26,601 to pay expenses of North Horizon.

In April 2011, Dr. Esber advanced $1,000 to cover certain expenses of FasTrack. Such amount was repaid in full in cash.

Related Party Financings

January 2012 Convertible Debentures

In January 2012, we sold a total of $174,668 in 8% convertible debentures to six individuals. One convertible debenture in the principal amount of $74,668 was issued to Wallace T. Boyack, who holds more than 5% of our outstanding common stock, to settle liabilities assumed from North Horizon and therefore this did not result in any cash inflow for us. Convertible debentures in an aggregate principal amount of $100,000 were issued to five accredited investors, three of whom are members of our board of directors—Dr. Henry Esber, Vivian Liu and Dr. Ziad Mirza.

In January 2013, the holders of the convertible debentures agreed to extend the January 13, 2013 maturity date to January 13, 2014 at the same interest rate of 8% per annum. See “Part II, Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchase of Equity Securities—Recent Sales of Unregistered Securities,” above, for more information regarding these convertible debentures.

At December 31, 2011, we had recorded expenses in the aggregate amount of $87,168 paid on our behalf by Mr. Boyack. During the year ended December 31, 2012, we repaid $12,500 of such amount, and the remaining $74,668 was converted into the convertible debenture described above.

January 2013 Convertible Debentures

In January 2013, we issued an 8% convertible debenture to Dr. Esber, a member of our Board of Directors, in the principal amount of $70,000, and we entered into a $250,000 convertible debenture with Dr. Damaj, a member of our Board of Directors and our President and Chief Executive Officer, which provides for requests of funding from time to time by our company, which Dr. Damaj may or may not accept. Through the date of this report, Dr. Damaj has loaned us $35,000 in principal amount under the convertible debenture.

On March 18, 2013, Dr. Damaj's convertible debenture was amended and restated to increase the maximum principal amount to $500,000. Dr. Damaj is required to provide additional funds under such debenture if we have insufficient liquidity to meet any material payment obligations arising in the ordinary course of business as they come due, up to the maximum of $500,000 in funding. The funding commitment increases by the gross amount of any cash salary, bonus or severance payments provided to Dr. Damaj under his employment agreement with our company. Dr. Damaj's salary has been accrued and not paid under the provision of such agreement stating that salary payments will be accrued and not paid for so long as payment of such salary would jeopardize our ability to continue as a going concern. We have the right to pre-pay interest and principal under Dr. Damaj's convertible debenture. We anticipate that Dr. Damaj's salary will continue to be so accrued at least until we have received at least $500,000 in external funding. See "Part III, Item 11. Executive Compensation—Employment Agreements," above. Dr. Damaj's funding commitment terminates on the earlier to occur of (i) the consummation of one or more transactions pursuant to which we raise net proceeds of at least $500,000 or (ii) January 1, 2014.

The convertible debentures we issued to Dr. Damaj and Dr. Esber bear an annual interest rate of 8% and are payable in cash at the earlier of January 13, 2014, or when we complete a financing with minimum proceeds of $4 million. The holders of the convertible debentures have the option to convert their principal and interest accrued into securities that we issue in any future financing with minimum proceeds of $4 million. In the event of a default on repayment, the annual interest rate would increase to 13% and the holders of the convertible debentures would have the option to convert the principal and accrued interest outstanding under their convertible debenture into shares of our common stock at a value of $0.05 per share. We do not have the right to pre-pay the convertible debenture issued to Dr. Esber, but we do have the right to pre-pay the convertible debenture issued to Dr. Damaj.

Transactions with Bio-Quant and Sorrento Pharmaceuticals

FasTrack was organized by stockholders 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., which focused on the development of Rx and OTC products, respectively. In March 2011, FasTrack acquired Sorrento’s assets and liabilities.

In 2009, FasTrack purchased SSAO inhibitors compound technology from La Jolla Pharmaceutical Company (a non-related entity) for approximately $20,000. The purchase was paid for by Bio-Quant and FasTrack issued a demand note to Bio-Quant for the same face amount.

In October 2009, FasTrack entered into an Asset Purchase Agreement with Bio-Quant, pursuant to which FasTrack acquired the rights to PrevOnco™ and another early stage cancer product candidate. The total purchase price was $276,020, which was paid with the issuance of 13,372,284 shares of FasTrack’s common stock valued at $26,020 and the issuance of a $250,000 promissory note.

In October 2009, Sorrento entered into an Asset Purchase Agreement with Bio-Quant, pursuant to which Sorrento acquired the rights of Apeaz™ and Regia™. The purchase price was $120,858, which was paid with the issuance of 4,379 shares of Sorrento’s common stock valued at $11,000 and the issuance of a promissory note in the amount of $109,858.

In January 2010, FasTrack’s Board of Directors approved the payment of $7,000 to Dr. Damaj for overhead expenses. The parties agreed that if FasTrack was unable to pay the $7,000 in cash, Dr. Damaj would receive 1% of FasTrack’s outstanding equity based on its outstanding shares as of January 15, 2011. In February 2011, FasTrack issued 134,364 shares of common stock to Dr. Damaj to satisfy the obligation.

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.

In March 2011, FasTrack and Sorrento entered into an Asset Purchase Agreement, pursuant to which FasTrack acquired the development and commercialization rights to Apeaz and Regia. In consideration for these rights, FasTrack agreed to assume the liabilities of Sorrento, comprised of accounts payable of $22,600 and $120,208 for the interest and principal, respectively, due on Sorrento promissory notes.

Transactions with Bio-Quant, Sorrento Pharmaceuticals and Apricus Bio

Dr. Damaj was President, Chief Executive Officer and a member of the board of directors of Apricus BioSciences (formerly known as NexMed) until November 2012.

In March 2010, FasTrack entered into an Asset Purchase Agreement with Apricus Bio, pursuant to which FasTrack sold the development rights of PrevOnco to Apricus Bio in exchange for cancellation of $204,896 of a promissory note and if Apricus Bio 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 Apricus Bio from the license).

In April 2011, FasTrack entered into an Asset Purchase Agreement with Apricus Bio, pursuant to which FasTrack sold the patent rights for the backup compound for PrevOnco to Apricus Bio in exchange for Apricus Bio providing FasTrack with (1) a fully funded loan of $250,000 evidenced by a secured convertible promissory note, (2) 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 and related accrued interest in the amount of $23,568 and (3) the right to develop two products using the NexACT technology.

In October 2012, we entered into a Settlement Agreement with Apricus Bio pursuant to which we sold to Apricus Bio our remaining 50% share of the future commercial right of PrevOnco™, in exchange for the return to us of 135,888 shares of our common stock which Apricus Bio had acquired through the conversion of promissory notes issued by FasTrack and a one-time cash payment to us of $25,000. In addition, we agreed to terminate our licensing right to the NexACT® technology and any claim to any PrevOnco™ backup compounds.

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. Interest expense recorded to Apricus Bio amounted to $18,797 and $16,322, for the years ended December 31, 2012 and 2011, respectively, and $38,245 from inception on October 31, 2008 through December 31, 2012.

In December 2011 the total balance due Apricus Bio of $489,197, comprised of $450,952 of principal and related accrued interest of $38,245, was subject to automatic conversion into shares of our common stock upon the business combination with FasTrack at a 10% discount to market value pursuant to the convertible note agreements. Accordingly, the amount of principal, related accrued interest and interest due to conversion discount (total of $538,117) was deemed contributed to paid-in capital at December 31, 2011. The conversion discount resulted in a $48,920 charge to interest expense in 2011. In March 2012, we issued 135,888 shares to Apricus Bio in respect of the automatic conversion, which shares were valued for conversion at a 10% discount to the prevailing market price of $3.60 at the date of issuance.

During the year ended December 31, 2011, we paid approximately $59,000 to Apricus Bio for feasibility studies in relation to two compounds we identified.

Item 14. Principal Accounting Fees and Services.

The following table presents the aggregate fees for the periods presented for professional services rendered to us by EisnerAmper LLP.

	2011	2012
Audit Fees (1)	$27,000	$64,700
Audit-Related Fees	–	–
Tax Fees	6,000	–
All Other Fees (2)	–	–
Total	$33,000	$64,700

(1) "Audit Fees" represent fees for professional services provided in connection with the audit of our annual financial statements, review of financial statements included in our quarterly reports, review of our registration statement on Forms S-1, and related services normally provided in connection with statutory and regulatory filings and engagements.

(2) "All Other Fees" represent fees for professional services provided in connection with tax returns.

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents Filed. The following documents are filed as part of this report:

(1) Financial Statements. The following reports of EisnerAmper LLP and financial statements:

- Report of EisnerAmper LLP, Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2012 and 2011
- Consolidated Statements of Operations for the years ended December 31, 2012 and 2011 and from inception through December 31, 2012
- Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Loss from inception through December 31, 2012
- Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011 and from inception through December 31, 2012
- Notes to Consolidated Financial Statements

(2) Financial Statement Schedules. See subsection (c) below.

(3) Exhibits. See subsection (b) below.

(b) Exhibits. The exhibits filed or furnished with this report are set forth on the Exhibit Index immediately following the signature page of this report, which Exhibit Index is incorporated herein by reference.

(c) Financial Statement Schedules. All schedules are omitted because they are not applicable, the amounts involved are not significant or the required information is shown in the financial statements or notes thereto.

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:

Date: March 19, 2013 Innovus Pharmaceuticals, Inc.

By: /s/ Bassam Damaj
Bassam Damaj
President and Chief Executive Officer
(principal executive officer and principal financial and accounting officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bassam Damaj, as his/her true and lawful attorney-in-fact and agent, with full power to act alone, with full powers of substitution and resubstitution, for him/her and in his/her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he/she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or resubstitute, may lawfully do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ Henry Esber Henry Esber, Ph.D.	Chairman of the Board	March 19, 2013
/s/ Bassam Damaj Bassam Damaj, Ph.D.	Director, President and Chief Executive Officer (principal executive officer and principal financial and accounting officer)	March 19, 2013
/s/ Ziad Mirza Ziad Mirza, M.D.	Director	March 19, 2013
/s/ Vivian Liu Vivian Liu	Director	March 19, 2013

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Merger Agreement and Plan of Merger, dated as of July 13, 2011, by and among FasTrack, Inc., a Delaware corporation, North Horizon, Inc., a Nevada corporation and North First General, Inc., a Utah corporation, a wholly owned subsidiary of North Horizon, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K, filed with the SEC on July 20, 2011 (SEC File No. 000-52991- 11977637)).
3.1	Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on July 23, 2007 (incorporated by reference to Exhibit 3.1 to the Registrant's general form for small business issuer on Form 10-SB12G/A, filed on December 28, 2007 (SEC File No. 000-52991- 071330026)).
3.2	Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's general form for small business issuer on Form 10-SB12G/A, filed on December 28, 2007 (SEC File No. 000-52991- 071330026)).
3.3	Certificate of Merger as filed with the Office Secretary of State of the State of Delaware on October 13, 2011, which merges North First General, Inc., a Utah corporation, with and into and under the name of FasTrack Pharmaceuticals, Inc., a Delaware corporation (incorporated by reference to Exhibit 3.4 to the Registrant's current report on Form 8-K, filed on December 12, 2011 (SEC File No. 000-52991-111256138)).
3.4	Certificate of Amendment to Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on October 13, 2011 changing the Registrant's name from North Horizon, Inc., a Nevada corporation to Innovus Pharmaceuticals, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.3 to the Registrant's current report on Form 8-K, filed on December 12, 2011 (SEC File No. 000-52991- 111256138)).
3.5	Articles of Merger as filed with the State of Utah Department of Commerce on October 14, 2011, which evidences the merger of North First General, Inc., a Utah corporation, the non-surviving corporation, into FasTrack Pharmaceuticals, Inc., a Delaware corporation, the surviving corporation (incorporated by reference to Exhibit 3.5 to the Registrant's current report on Form 8-K, filed on December 12, 2011 (SEC File No. 000-52991- 111256138)).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.1(a)	Placement Agent Agreement, dated December 16, 2011, between Innovus Pharmaceuticals, Inc. and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-K, filed on March 30, 2012 (SEC File No. 000-52991-12726641)).
10.1(b)	Amendment, dated March 22, 2012, to Placement Agent Agreement dated December 16, 2011 between Innovus Pharmaceuticals, Inc. and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.3

to the Registrant's Form 10-K, filed on March 30, 2012 (SEC File No. 000-52991-12726641)).

10.2(a)* Form of 8% Convertible Debenture dated as of January 13, 2012

10.2(b)* Form of Amendment to 8% Convertible Debenture dated as of January 12, 2013

Exhibit No.	Description
10.3(a)	Employment Agreement, dated March 7, 2012, between Innovus Pharmaceuticals, Inc. and Vivian Liu (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-K, filed on March 30, 2012 (SEC File No. 000-52991-12726641)).
10.3(b)*	Acknowledgement Agreement entered into as of March 11, 2013, by and between Vivian Liu and Innovus Pharmaceuticals, Inc.
10.4*	Employment Agreement, dated January 22, 2013, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D.
10.5*	Settlement Agreement, dated October 4, 2012, between Innovus Pharmaceuticals, Inc. and Apricus Biosciences, Inc.
10.6	2013 Equity Incentive Plan of the Registrant, effective February 15, 2013 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.7	Form of Restricted Stock Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013 (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.8	Form of Stock Unit Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013 (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.9	Form of Nonstatutory Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013 (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.10	Form of Incentive Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013 (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-8, filed on February 15, 2013 (SEC File No. 333-186725-13620840)).
10.11(a)*	8% Convertible Debenture dated January 22, 2013 between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D.
10.11(b)*	Amended and Restated 8% Convertible Debenture dated March 18, 2013 between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D.
21.1*	List of Subsidiaries
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney, included as part of signature page to this report.

31.1*	Certification of the Registrant's Principal Executive Officer and Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a).
32.1**	Certification of the Registrant's Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. SS. 1350, as adopted pursuant to SS. 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith

** This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language of such filing.

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”) as of December 31, 2012 and 2011 and the related consolidated statements of operations, changes in stockholders’ deficit and cash flows for each of the years in the two-year period ended December 31, 2012 and for the period from inception (October 31, 2008) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 the Company as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2012 and for period from inception (October 31, 2008) to December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company’s President and Chief Executive Officer, who is also a major stockholder of the Company, has provided a funding commitment to the Company subsequent to December 31, 2012.

/s/ EisnerAmper LLP

March 19, 2013

Edison, New Jersey

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INNOVUS PHARMACEUTICALS, INC.

(Formerly North Horizon, Inc.)

(A Development Stage Company)

Consolidated Balance Sheets

	December 31, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS		
Cash	$ 18,445	$ 25,014
Total Current Assets	18,445	25,014
TOTAL ASSETS	$ 18,445	$ 25,014
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable	$ 1,602	$ 1,687
Convertible debentures - related party	162,668	-
Promissory notes	50,000	50,000
Accrued interest payable	16,596	-
Related-party payables	-	87,168
Total Current Liabilities	230,866	138,855
Contigent liability related to common shares, subject to recsission rights, issuable to FasTrack shareholders arising from Merger (14,722,077 shares)	-	28,926
STOCKHOLDERS' DEFICIT		
Common stock; 150,000,000 shares authorized, at $0.001 par value, 16,197,782 and 1,325,125 shares issued and outstanding, respectively	16,198	1,325
Additional paid-in capital	2,220,202	2,606,331
Deficit accumulated during the development stage	(2,448,821)	(2,750,423)
Total Stockholders' Deficit	(212,421)	(142,767)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 18,445	$ 25,014

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

INNOVUS PHARMACEUTICALS, INC.

(Formerly North Horizon, Inc.)

(A Development Stage Company)

Consolidated Statements of Operations

	For the Years Ended December 31, 2012	2011	From October 31, 2008 (Inception) Through December 31, 2012
REVENUES	$-	$-	$ -
OPERATING EXPENSES			
Research and development	2,000	58,960	80,960
Professional fees	163,955	131,276	295,231
Investment banking fees	-	1,954,865	1,954,865
General and administrative	53,529	43,434	150,688
Total Operating Expenses	219,484	2,188,535	2,481,744
LOSS FROM OPERATIONS	(219,484)	(2,188,535)	(2,481,744)
OTHER INCOME (EXPENSES)			
Interest expense	(17,031)	(67,717)	(108,316)
Total Other Income (Expenses)	(17,031)	(67,717)	(108,316)
LOSS BEFORE INCOME TAXES	(236,515)	(2,256,252)	(2,590,060)
PROVISION FOR INCOME TAXES	-	-	-
NET LOSS	$(236,515)	$(2,256,252)	$ (2,590,060)
BASIC LOSS AND DILUTED LOSS PER SHARE	$(0.02)	$(0.16)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	11,999,597	13,785,487	

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

INNOVUS PHARMACEUTICALS, INC.

(Formerly North Horizon, Inc.)

(A Development Stage Company)

Statements of Stockholders' Deficit

	Common Stock (Shares)	(Amount)	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
Balance at Inception on October 31, 2008	-	$ -	$ -	$ -	$ -
Balance on December 31, 2008	-	-	-	-	-
Common stock issued in FasTrack asset purchase	13,372,284	13,372	12,648	-	26,020
Common stock issued in 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)
Common stock issued for compensation of board members	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)
Common stock issued for services rendered	134,364	134	6,866	-	7,000
Common stock issued for compensation of officer	833,668	834	804	-	1,638

Forgiveness of interest by Apricus Bio	-	-	4,021	-	4,021
Contibution to capital arising from conversion of convertible promissory notes held by Apricus Bio at Merger date pursuant to terms of convertible note, resulting in the future issuance of 135,888 shares of common stock in March 2012 to Apricus Bio	-	-	538,117	-	538,117
Common stock issued for net assets acquired in reverse-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)
Common stock issued on conversion of Apricus Bio promissory note (see contribution recognition in 2011)	135,888	136	(136)	-	-
Common stock issued for cash at $0.75 per share	134,000	134	100,366	-	100,500
Common stock issued in conversion of debt	16,580	17	12,418	-	12,435
Expiration of FasTrack rescission offer and resultant reclassification to stockholders deficit	14,722,077	14,722	14,204	-	28,926
Common stock and related contribution eliminated upon settlement agreement with Apricus Bio	(135,888)	(136)	(537,981)	538,117	-
Cash payment received pursuant to related-party settlement agrement	-	-	25,000	-	25,000
Net loss for the year ended December 31, 2012	-	-	-	(236,515)	(236,515)
Balance at December 31, 2012	16,197,782	$16,198	$2,220,202	$(2,448,821)	$(212,421)

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

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INNOVUS PHARMACEUTICALS, INC.

(Formerly North Horizon, Inc.)

(A Development Stage Company)

Consolidated Statements of Cash Flows

	For the Years Ended December 31, 2012	2011	From October 31, 2008 (Inception) Through December 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(236,515)	$(2,256,252)	$ (2,590,060)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued for services	-	8,638	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	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
Changes in operating assets and liabilities			
Related-party payable	(12,500)	25,168	12,668
Interest payable	17,031	-	17,031
Accounts payable	(85)	(8,172)	1,602
Net Cash Used in Operating Activities	(232,069)	(208,036)	(457,055)
CASH FLOWS FROM INVESTING ACTIVITIES	-	-	-
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of loans from officers	-	5,003	23,603
Repayment of loans from officers	-	(23,603)	(23,603)
Proceeds from related-party settlement agreement	25,000	-	25,000
Proceeds from stock issued for cash	100,500	-	100,500
Proceeds from convertible debentures	100,000	250,000	350,000
Net Cash Provided by Financing Activities	225,500	231,400	475,500

NET CHANGE IN CASH	(6,569	) 23,364	18,445
CASH AT BEGINNING OF PERIOD	25,014	1,650	-
CASH AT END OF PERIOD	$18,445	$	