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