PROVECTUS PHARMACEUTICALS INC
Form 424B3
April 16, 2013
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Filed pursuant to Rule 424(b)(3)
Registration No. 333-187803

PROSPECTUS

PROVECTUS PHARMACEUTICALS, INC.

8,453,941 Shares of Common Stock

This prospectus relates to the sale or other disposition from time to time of shares of our common stock, par value $.001 per share, by certain of our security holders (the selling security holders). The shares offered for resale by this prospectus include the following:

- 3,400,001 shares of common stock issuable upon conversion of the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering;
- 4,250,000 shares of common stock issuable upon exercise of the warrants sold in our February 22, 2013 offering which may be exercised at a price of $1.00 per share; and
- an estimated 803,940 shares of common stock issuable in lieu of the cash payment of dividends on the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering payable through February 22, 2016.

We will not receive any of the proceeds from the sale of shares of common stock by the selling security holders. However, we will receive the proceeds from the exercise of warrants by the selling security holders, if any, to the extent that the warrants are exercised on a cash basis; to the extent we receive such proceeds, they will be used for general corporate and working capital purposes, research and development activities and/or the expansion of our business through internal growth or acquisitions. See USE OF PROCEEDS beginning on page 13 of this prospectus.

The selling security holders may sell these securities from time to time at the prevailing market price or in negotiated transactions or in any other manner specified under PLAN OF DISTRIBUTION in this prospectus. The selling security holders will bear all discounts, concessions commissions and similar expenses, if any, attributable to the sale of shares of common stock. We will bear all other costs, expenses and fees in connection with the registration of shares of common stock. For more information, see PLAN OF DISTRIBUTION beginning on page 14 of this prospectus.

Our common stock is quoted on the OTCQB under the symbol PVCT. Our principal offices are located at 7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931, and our phone number is (866) 594-5999.

This prospectus may only be used where it is legal to offer and sell the shares covered by this prospectus. We have not taken any action to register or obtain permission for this offering or the distribution of this prospectus in any country other than the United States.

Investing in our common stock is highly speculative and involves a high degree of risk. You should purchase these securities only if you can afford a complete loss of your investment. You should carefully consider the risks and uncertainties described under the heading Risk Factors beginning on page 4 of this prospectus before making a decision to purchase our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 16, 2013.

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PROSPECTUS SUMMARY

This summary highlights information set forth in greater detail elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections entitled Risk Factors beginning on page 4, the financial statements and the notes to the financial statements. Unless otherwise indicated or unless the context otherwise requires, all references in this prospectus to Provectus, Provectus Pharmaceuticals, we, us, or similar references mean Provectus Pharmaceuticals, Inc. and our subsidiaries.

Our Business

Provectus Pharmaceuticals, Inc., together with its six wholly owned subsidiaries and one majority owned subsidiary managed on a consolidated basis, is a development-stage pharmaceutical company that is primarily engaged in developing ethical pharmaceuticals for oncology and dermatology indications. Our goal is to develop alternative treatments that are safer, more effective, less invasive and more economical than conventional therapies. We develop and intend to license or market and sell our two prescription drug candidates, PV-10 and PH-10. We also hold patents and other intellectual property which we believe may be used in over-the-counter products, which we refer to as OTC products, and various other non-core technologies. We have transferred all our intellectual property related to OTC products and non-core technologies to our subsidiaries and have designated such subsidiaries as non-core to our primary business of developing our oncology and dermatology prescription drug candidates.

Prescription Drugs

We focus on developing our prescription drug candidates PV-10 and PH-10. We are developing PV-10 for treatment of several life threatening cancers including metastatic melanoma, liver cancer, and breast cancer. We are developing PH-10 to provide minimally invasive treatment of chronic severe skin afflictions such as psoriasis and atopic dermatitis, a type of eczema. We believe that our prescription drug candidates will be safer and more specific than currently existing products. All of our prescription drug candidates are in either the pre-clinical or clinical trial stage.

Oncology (PV-10)

We believe our prescription drug candidate PV-10 may afford competitive advantage compared to currently available options for the treatment of certain types of cancer. We are developing PV-10, a sterile injectible form of rose bengal disodium (Rose Bengal), for direct injection into tumors. It is an immuno-chemoablative agent that when injected intralesionally is tantamount to an in situ vaccination following acute and durable necrosis of diseased tissue. Because PV-10 is retained in diseased or damaged tissue but quickly dissipates from healthy tissue, we believe we can develop therapies that confine treatment to cancerous tissue and reduce collateral impact on healthy tissue. We have conducted Phase 1 and Phase 2 studies of PV-10 for the treatment of metastatic melanoma, and Phase 1 studies of PV-10 for the treatment of liver and breast cancers.

Dermatology (PH-10)

Our prescription drug candidate PH-10 is an aqueous hydrogel formulation of Rose Bengal for topical administration to the skin. It is a novel nonsteroidal anti-inflammatory agent that interacts with ambient and other light sources. We are developing PH-10 for the treatment of cutaneous skin disorders, specifically psoriasis and atopic dermatitis, and we believe that PH-10 may be successful in treating other skin diseases. We believe that PH-10 offers a superior treatment for psoriasis and atopic dermatitis because it selectively treats diseased tissue with negligible potential for side effects in healthy tissue.

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Over-the-Counter Pharmaceuticals

We have designated our subsidiary that holds our OTC products, GloveAid and Pure-ific, Pure-Stick, Pure N Clear as non-core to our business. The potential further development and licensure of our OTC products would likely be facilitated by selling a majority stake of the underlying assets of the non-core subsidiary holding the OTC products. This transaction would likely be accomplished through a non-core spin-out process, which would enable the non-core subsidiary to become a separate publicly held company. The new public entity could then raise funds without diluting the ownership of the then current shareholders of the Company.

Risks Related to Our Business

We are subject to a number of risks of which you should be aware before you decide to buy our common stock. These risks are discussed more fully in the Risk Factors section of this prospectus beginning on page 4 and should be read in their entirety. In general, we face risks associated with the following:

- the fact that we are a development stage company with no prescription drug products approved for commercial sale and have incurred substantial losses;
- the sufficiency of our capital resources to fund our current and planned operations;
- our ability to obtain U.S. or international regulatory approvals required to commercialize our products;
- delays in the commencement and completion of clinical trials due to unforeseen safety issues, determination of dosing issues, lack of effectiveness during clinical trials, slower than expected rates of patient recruitment, inability to monitor patients adequately during or after treatment, and inability or unwillingness of medical investigators to follow our clinical protocols;
- physician and patient acceptance of our prescription drug candidates;
- our ability to establish or maintain relationships with third party collaborators or to develop in-house sales and distribution capabilities; and
- securing and maintaining proprietary patent protection for our products and technologies we develop or license.

Corporate Information

We were incorporated in Nevada in 2002. Our principal offices are located at 7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931, and our phone number is (866) 594-5999. Our website is located at www.pvct.com. We do not incorporate the information on our website into this prospectus, and you should not consider such information part of this prospectus.

Summary of the Offering

The shares offered for resale by this prospectus include the following:

- 3,400,001 shares of common stock issuable upon conversion of the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering;

4,250,000 shares of common stock issuable upon exercise of the warrants sold in our February 22, 2013 offering which may be exercised at a price of $1.00 per share; and

an estimated 803,940 shares of common stock issuable in lieu of the cash payment of dividends on the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering payable through February 22, 2016.

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Use of Proceeds

The selling security holders will receive all of the proceeds from the sale of any of our common stock offered in this prospectus and issued upon a cashless exercise of outstanding warrants. We will not receive any of the proceeds from any sale of the shares of common stock by selling security holders. However, we will receive the proceeds from the exercise of warrants by the selling security holders, if any, to the extent that the warrants are exercised on a cash basis; to the extent we receive such proceeds, they will be used for general corporate and working capital purposes, research and development activities and/or the expansion of our business through internal growth or acquisitions.

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RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below and all information contained in this prospectus, before you decide whether to purchase our common stock. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations and prospects would likely suffer, possibly materially. In addition, the trading price of our common stock could decline due to any of these risks or uncertainties, and you may lose part or all of your investment.

Risks Related to Our Business

We are a development stage company, have no prescription drug products approved for commercial sale, have incurred substantial losses, and expect to incur substantial losses and negative operating cash flow for the foreseeable future.

Our company is a development stage company that has no prescription drug products approved for commercial sale. We have never generated any substantial revenues and may never achieve substantial revenues or profitability. As of December 31, 2012, we have incurred net losses of $118 million in the aggregate since inception in January 2002. We expect to incur substantial losses and negative operating cash flow for the foreseeable future. We may never achieve or maintain profitability, even if we succeed in developing and commercializing one or more of our prescription drug candidates, OTC products, or non-core technologies. We also expect to continue to incur significant operating expenditures and anticipate that our operating and capital expenses may increase substantially in the foreseeable future as we:

- continue to develop and seek regulatory approval for our prescription drug candidates PV-10 and PH-10;
- seek licensure of PV-10, PH-10, our OTC products, and our other non-core technologies;
- further develop our non-core technologies;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative operating cash flow for the foreseeable future as we fund our operating losses and any future capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

All of our existing prescription drug candidates are in early stages of development. It may be several years, if ever, until we have a prescription drug product available for commercial resale. If we do not successfully develop and license or commercialize our prescription drug candidates, or sell or license our OTC products or non-core technologies, we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

We may need additional capital to conduct our operations and commercialize and/or further develop our prescription drug candidates in 2014 and beyond, and our ability to obtain the necessary funding is uncertain.

We estimate that our existing capital resources will be sufficient to fund our current and planned operations until 2014. However, we may need additional capital in 2014 and beyond as we continue to develop and seek commercialization of our prescription drug candidates. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our expanding Phase 2 atopic dermatitis and psoriasis results, which were significantly developed in 2012. We potentially may license PV-10 depending on the timing for the optimal deal structure for our stockholders. We intend to also proceed as rapidly as possible with the sale or licensure of our OTC products and other non-core technologies. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to both the

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licensure of PH-10 and the sale or licensure of our OTC products and non-core technologies, we cannot assure you that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

We have based our estimate of capital needs on assumptions that may prove to be wrong, and we cannot assure you that estimates and assumptions will remain unchanged. For example, we are currently assuming that we will continue to operate without any significant staff or other resources expansion. We intend to acquire additional funding through public or private equity or debt financings or other financing sources that may be available. Additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our products, product candidates, and technologies that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate one or more of our programs, any of which could have a material adverse effect on our business and may impair the value of our patents and other intangible assets.

Our prescription drug candidates are at an intermediary stage of development and may never obtain U.S. or international regulatory approvals required for us to commercialize our prescription drug candidates.

We will need approval of the United States Food and Drug Administration, which we refer to as the FDA, to commercialize our prescription drug candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our prescription drug candidates in those jurisdictions.

We are continuing to pursue clinical development of our most advanced prescription drug candidates, PV-10 and PH-10, for use as treatments for specific conditions. The continued and further development of these prescription drug candidates will require significant additional research, formulation and manufacture development, and pre-clinical and extensive clinical testing prior to their regulatory approval and commercialization. Pre-clinical and clinical studies of our prescription drug candidates may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical drug and medical device products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including the following:

- a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials,
- a product may fail to receive necessary regulatory clearance,
- a product may be too difficult to manufacture on a large scale,
- a product may be too expensive to manufacture or market,
- a product may not achieve broad market acceptance,
- others may hold proprietary rights that will prevent a product from being marketed, and
- others may market equivalent or superior products.

Satisfaction of the FDA s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy

that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

delay commercialization of, and our ability to derive product revenues from, our product candidates;

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impose costly procedures on us; and

diminish any competitive advantages that we may otherwise enjoy.

We do not expect any prescription drug and other product candidates that we are developing to be commercially available without a partner. Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized products. Further, after commercial introduction of a new product, discovery of problems through adverse event reporting could result in restrictions on the product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Even if we comply with all FDA requests, we cannot be sure that we will ever obtain regulatory clearance for any of our prescription drug or other product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that current or future clinical trials of our prescription drug candidates will take additional years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment;

inability to monitor patients adequately during or after treatment; and

inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or the conduct of these trials.

The results of our clinical trials may not support our claims concerning our prescription drug candidates.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims concerning our prescription drug candidates. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

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Physicians and patients may not accept and use our prescription drug candidates.

Even if the FDA approves our prescription drug candidates, physicians and patients may not accept and use them. Acceptance and use of our prescription drug products will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our prescription drug products;
- cost-effectiveness of our prescription drug products relative to competing products;
- availability of reimbursement for our prescription drug products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales or licensure of our prescription drug candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing or distribution capabilities for our prescription drug candidates or our OTC products and non-core technologies.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our prescription drug candidates or our OTC products and non-core technologies. Our future success depends, in part, on our ability to enter into and maintain such collaborative relationships, the collaborator s strategic interest in the products under development and such collaborator s ability to successfully market and sell any such products. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in process of being further developed. We have determined that that the most efficient use of our capital in further developing our OTC products is to license the products. There can be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

We cannot be sure that our OTC products or non-core technologies will be licensed or sold in the marketplace.

In order for our OTC products to become commercially successful and our non-core technologies to be further developed, we must license or sell those products and technologies. We have been discussing this strategy with interested groups, though we cannot be sure that we will be successful in licensing or selling such products or technologies.

Competition in the prescription pharmaceutical and biotechnology industries is intense, and we may be unable to succeed if our competitors have more funding or better marketing.

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of dermatological conditions or cancers of the skin, liver and breast, which could lead to the development of products or therapies that could compete directly with the prescription drug and other product candidates, and OTC products that we are seeking to develop and market.

Many companies are also developing alternative therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have significantly greater financial resources and expertise than we do in:

research and development;

manufacturing;

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preclinical and clinical testing;

obtaining regulatory approvals; and

marketing.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies, and other public and private research organizations may also conduct research, seek patent protection, and establish collaborative arrangements for research, clinical development, and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

In addition to the above factors, we expect to face competition in the following areas:

product efficacy and safety;

the timing and scope of regulatory consents;

availability of resources;

reimbursement coverage;

price; and

patent position, including potentially dominant patent positions of others.

Since our prescription candidates PV-10 and PH-10 have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these products might face when they are finally introduced, if at all. We cannot assure you that these products will not face significant competition for other prescription drugs and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our products and technologies we develop or license. In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our anticipated sales. While some of our products have proprietary patent protection, a challenge to these patents can subject us to expensive litigation. Litigation concerning patents, other forms of intellectual property, and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing their duties.

We also rely upon trade secrets, unpatented proprietary know-how, and continuing technological innovation to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets, or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the intellectual property of others, our business could be harmed.

We could be sued for infringing patents or other intellectual property that purportedly cover products and/or methods of using such products held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our products, any of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

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If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by rapid technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, to discover new technologies as a result of that research, to develop products based on our technologies, and to commercialize those products. While we believe that our current technology is adequate for our present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors are using substantial resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different technologies by one or more of our current or future competitors.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by four key employees:

- H. Craig Dees, Ph.D., our Chief Executive Officer;
- Timothy C. Scott, Ph.D., our President;
- Eric A. Wachter, Ph.D. our Chief Technology Officer; and
- Peter R. Culpepper, CPA, MBA, our Chief Financial Officer and Chief Operating Officer.

In addition to their responsibilities for management of our overall business strategy, Drs. Dees, Scott and Wachter are our chief researchers in the fields in which we are developing and planning to develop our prescription drug and other product candidates, and our OTC products. The loss of any of these key employees could have a material adverse effect on our operations, and our ability to execute our business plan might be negatively impacted. Any of these key employees may leave their employment with us if they choose to do so, and we cannot assure you that we would be able to hire similarly qualified employees if any of our key employees should choose to leave.

Because we have only four employees in total, our management may be unable to successfully manage our business.

In order to successfully execute our business plan, our management must succeed in all of the following critical areas:

- Researching diseases and possible therapies in the areas of dermatology and skin care, oncology, and biotechnology;
- Developing our prescription drug and other product candidates, and OTC products based on our research;
- Marketing and selling developed products;
- Obtaining additional capital to finance research, development, production, and marketing of our products; and
- Managing our business as it grows.

As discussed above, we currently have only four employees, all of whom are full-time employees. The greatest burden of succeeding in the above areas, therefore, falls on Drs. Dees, Scott, Wachter, and Mr. Culpepper. Focusing on any one of these areas may divert their attention from

our other areas of concern and could affect our ability to manage other aspects of our business. We cannot assure you that our management will be able to succeed in all of these areas or, even if we do so succeed, that our business will be successful as a result. We anticipate adding an additional regulatory affairs officer on a consulting basis within several months. While we have not historically had difficulty in attracting employees, our small size and limited operating history may make it difficult for us to attract and retain employees in the future, which could further divert management s attention from the operation of our business.

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Risks Related to Our Shares of Common Stock

The market price of our common stock has been highly volatile due to several factors that will continue to affect the price of our common stock.

Our common stock has traded as low as $0.52 per share and as high as $1.23 per share during the period beginning on January 1, 2011 and ending on March 31, 2013. We believe that our common stock is subject to wide price fluctuations because of several factors, including:

- absence of meaningful earnings and ongoing need for external financing;
- a relatively thin trading market for our common stock, which causes trades of small blocks of stock to have a significant impact on our stock price;
- general volatility of the stock market and the market prices of other publicly-traded companies; and
- investor sentiment regarding equity markets generally, including public perception of corporate ethics and governance and the accuracy and transparency of financial reporting.

Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our common stock trades on the OTC Bulletin Board, as well as the issuance of warrants or convertible equity or debt that require exercise or conversion prices that are calculated in the future at a discount to the then market price of our common stock. The current economic downturn has made the financings available to development-stage companies like us more dilutive in nature than they would otherwise be.

Any agreement to sell, or convert debt or equity securities into, our common stock at a future date and at a price based on the then current market price will provide an incentive to the investor or third parties to sell our common stock short to decrease the price and increase the number of shares they may receive in a future purchase, whether directly from us or in the market.

Our common stock price is below $5.00 per share and is treated as a penny stock , which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as penny stock under the Exchange Act and its rules. The SEC has adopted regulations that define penny stock to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

- broker-dealers must deliver, prior to the transaction, a disclosure schedule prepared by the SEC relating to the penny stock market;
- broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
- broker-dealers must disclose current quotations for the securities; and
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer s account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser s written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder s ability to sell their shares.

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Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following any prospective offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable. The current economic downturn has made the financings available to development-stage companies like us more dilutive in nature than they would otherwise be.

We currently intend to retain all of our future earnings rather than pay a cash dividend.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common stock in the foreseeable future.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words may, will, could, should, expect, anticipate, intend, estimate, belie plan, assume or other similar expressions, or negatives of those expressions, although not all forward-looking statements contain these identifying words. All statements contained in this prospectus regarding our business strategy, future operations, projected financial position, potential strategic transactions, proposed distribution channels, projected sales growth, proposed new products, estimated future revenues, cash flows and profitability, projected costs, potential sources of additional capital, future prospects, future economic conditions, the future of our industry and results that might be obtained by pursuing management s current plans and objectives are forward-looking statements.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to certain risks, uncertainties and assumptions that are difficult to predict. Our forward-looking statements are based on the information currently available to us and speak only as of the date of this prospectus. Over time, our actual results, performance or achievements may differ from those expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our security holders. Except as required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

The following are some of the factors that could cause actual results to differ from those expressed or implied by our forward-looking statements:

- our need for, and the availability of, substantial capital in the future to fund our operations and planned clinical trials;
- the conditions in the capital markets and the biopharmaceutical industry that may make raising capital or entering into strategic arrangements difficult and expensive;
- the timing of our product development and evaluation;
- the timing and magnitude of expenditures we may incur in connection with our ongoing research and development activities;
- the results of our preclinical and clinical trials, including regulatory approvals;
- the success, timing and financial consequences of our formation of new business relationships and alliances; and
- the timing and volume of sales of products for which we obtain marketing approval.

In addition, we have identified other important factors that could cause future events to differ from our current expectations and described such factors in this prospectus under the caption Risk Factors, which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus.

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USE OF PROCEEDS

The selling security holders will receive all of the proceeds from the sale of any of our common stock offered in this prospectus and issued upon a cashless exercise of outstanding warrants. We will not receive any of the proceeds from any sale of the shares by selling security holders. If the warrants that were issued to the selling security holders to purchase an aggregate of 4,250,000 shares of common stock at an exercise price of $1.00 per share are exercised by payment of cash, we will receive proceeds of $4,250,000 from the selling security holders. In such event, we intend to use the cash proceeds received for:

general corporate purposes, additions to working capital and capital expenditures;

research and development activities; and/or

the expansion of our business through internal growth or acquisitions.

SELLING SECURITY HOLDERS

When we refer to selling security holders in this prospectus, we mean those persons listed in the table below, and the pledgees, donees, permitted transferees, assignees, successors, and others who later come to hold any of the selling security holders interests in shares of our common stock other than through a public sale.

The following table sets forth as of the date of this prospectus the name of each selling stockholder for whom we have registered shares of common stock for resale to the public and the number of shares of common stock that each selling stockholder may offer pursuant to this prospectus. The information set forth below is based on information known to us. The common stock being offered by the selling security holders consists of (i) 3,400,001 shares of common stock issuable upon conversion of the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering, (ii) 4,250,000 shares of common stock issuable upon exercise of the warrants sold in our February 22, 2013 offering, which may be exercised at a price of $1.00 per share, and (iii) an estimated 803,940 shares of common stock issuable in lieu of the cash payment of dividends on the Series A 8% Convertible Preferred Stock sold in our February 22, 2013 offering payable through February 22, 2016.

Based on information known to us or provided to us by each selling stockholder and as of the date the information was known to us or was provided to us, assuming that the selling security holders sell all of their shares of our common stock beneficially owned by them that have been registered by us and do not acquire any additional shares during the offering, each selling stockholder will not own any shares other than those appearing in the column entitled Beneficial Ownership Post Offering. We cannot advise you as to whether the selling security holders will in fact sell any or all of such shares of common stock. In addition, the selling security holders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act after the date on which they provided the information set forth in the table below.

Beneficial ownership is determined in accordance with SEC rules and includes voting or investment power with respect to the securities. However, certain warrants are subject to limitations upon exercise, if any. The most significant of these limitations is that the selling stockholder may not exercise its warrants if the exercise would cause such holder s beneficial ownership of our common stock (excluding shares underlying any of their unconverted to debentures or unexercised warrants) to exceed 4.99% of the outstanding shares of common stock. Therefore, although they are included in the table below, the number of shares of common stock for some listed persons may include shares that may not be purchased during a given 60-day period used for purpose of determining beneficial ownership.

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Except for relationships noted in the selling stockholder table, none of the selling security holders has, or within the past three years has had, any position, office or material relationship with us or any of our predecessors or affiliates.

Name of Investor	Beneficial Ownership (#)[1]	Number of Shares being Registered (#)[2]	Beneficial Ownership Post Offering (#)[3]	Beneficially Owned Post Offering (%)[4]
Alpha Capital Anstalt	333,333	6,630,553	333,333	*
Brio Capital Master Fund Ltd.	100,000	1,657,633	100,000	*
Assameka Capital Inc.	85,255	165,756	82,255	*

(*) Less than 1%.

(1) Includes all shares of common stock beneficially owned by the selling security holders as of April 1, 2013, including shares of common stock the selling security holder has the right to acquire within 60 days upon conversion of 8% convertible preferred stock and exercise of warrants.

(2) The numbers in the table reflect (A) the actual number of shares of common stock issued or issuable to the selling stockholder (i) upon the conversion of the Series A 8% Convertible Preferred Stock issued on February 22, 2013 and (ii) upon exercise of warrants to purchase common stock issued on February 22, 2013 in exchange for cash, and (B) an estimate of the number of shares of common stock issuable to the selling stockholder in lieu of the cash payment of dividends on the Series A 8% Convertible Preferred Stock through February 22, 2016, calculated using the volume weighted average price of our common stock for the 15 trading days prior to April 1, 2013.

(3) Assumes that all shares of Series A 8% Convertible Preferred Stock are converted into common stock, a cash exercise of all warrants issued in the February 22, 2013 offering, and that all such shares of common stock, together with shares of common stock issuable as dividends on the Series A 8% Convertible Preferred Stock registered for resale pursuant to this offering, have been sold.

(4) Based on 124,550,960 shares of common stock issued and outstanding as of April 1, 2013.

PLAN OF DISTRIBUTION

Each selling security holder (the selling security holders) of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling security holder may use any one or more of the following methods when selling securities:

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