

PROVECTUS BIOPHARMACEUTICALS, INC.

Form 10-K

March 30, 2016

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2015**

**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 001-36457**

**PROVECTUS BIOPHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware** **90-0031917**  
**(State or other jurisdiction of** **(I.R.S. Employer**  
**incorporation or organization)** **Identification No.)**  
**7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931**

**(Address of principal executive offices) (Zip Code)**

**866-594-5999**

**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(b) of the Act:**

**Common Stock, par value \$.001 per share**

**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, par value \$.001 per share**

**(Title of class)**

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. See the definitions of large accelerated filer, accelerated filer and smaller reporting

company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2015 was \$105,469,044 (computed on the basis of \$0.54 per share).

The number of shares outstanding of the registrant's common stock, par value \$.001 per share, as of March 24, 2016 was 205,030,845.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The information required by Part III is incorporated by reference to portions of the definitive proxy statement to be filed within 120 days after December 31, 2015, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on June 16, 2016.

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**CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements regarding, among other things, our anticipated financial and operating results. Forward-looking statements reflect our management's current assumptions, beliefs, and expectations. Words such as anticipate, believe, estimate, seek, expect, intend, plan, and similar expressions are intended to identify forward-looking statements. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there. Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC), and we assume no obligation to update the forward-looking statements after the date hereof whether as a result of new information or events, changed circumstances, or otherwise, except as required by law.

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**PART I**

**ITEM 1. BUSINESS.**

**General**

Provectus Biopharmaceuticals, Inc., a Delaware corporation formed in 2002, together with its six wholly owned subsidiaries and one majority owned subsidiary managed on a consolidated basis, referred to herein as we, us, and our, is a development-stage biopharmaceutical 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.

The table below sets forth our two prescription drug candidates and our progress in developing those candidates for the indications shown:

**Product Pipeline**

**Melanoma\***

**PV-10**

Phase 3 study in progress: Opened recruitment in April 2015

Phase 1 and 2 studies completed, full reports submitted

Orphan drug status obtained in January 2007

**Melanoma**

**PV-10 +**

**Pembrolizumab**

Phase 1b/2 study initiated September 2015

**Melanoma**

**(Method of Action)**

**PV-10**

Phase 1 study to detect immune cell infiltration into melanomas treated with PV-10 has now finished recruiting

Data will be published

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**Cancers of the Liver**

**PV-10**

Orphan drug status obtained in April 2011

Phase 1 patient accrual and treatment completed

Phase 1 protocol expansion (Sep 2012 into 2016)

Data communicated in 2015

Phase 1b/2 being planned for West and East SOC

**Breast Cancer**

**PV-10**

Phase 1 study completed

Further clinical development is being planned

**Psoriasis**

**PH-10**

Phase 2c randomized study completed and full report submitted to FDA

Toxicity study R&D for advanced studies 2012 to 2016

**Psoriasis**

**(Mechanism of Action)**

**PH-10**

Phase 2 mechanism of action study initiated in January 2015 by leading research facility



Phase 2 study recruitment began in Q1 2015

Phase 2 study recruitment completed in Q3 2015

**Atopic Dermatitis**

**PH-10**

Phase 2 study completed and full report submitted to FDA

Toxicity study R&D for advanced studies 2012 to 2016

\* In addition to clinical trials, patients enrolled in the Compassionate Use Program for PV-10 are also receiving PV-10 treatments.

*Oncology (PV-10)*

Reported by Global Cancer Facts & Figures, 3<sup>rd</sup> Edition, according to estimates from the International Agency for Research on Cancer (IARC), there were 14.1 million new cancer cases in 2012 worldwide, of which 8 million occurred in economically developing countries, which contain about 82% of the world's population. These estimates do not include non-melanoma skin cancers, which are not tracked in cancer registries. The corresponding estimates for total cancer deaths in 2012 were 8.2 million (about 22,000 cancer deaths a day) 2.9 million in economically developed countries, and 5.3 million

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in economically developing countries. By 2030, the global burden is expected to grow to 21.7 million new cancer cases and 13 million cancer deaths simply due to the growth and aging of the population. However, the estimated future cancer burden will probably be considerably larger due to the adoption of lifestyles that are known to increase cancer risk, such as smoking, poor diet, physical inactivity, and fewer pregnancies, in economically developing countries. Cancers related to these factors, such as lung, breast, and colorectal cancers, are already on the rise in economically transitioning countries. In economically developed countries, the three most commonly diagnosed cancers were prostate, lung, and colorectal among males, and breast, colorectal, and lung among females. In economically developing countries, the three most commonly diagnosed cancers were lung, liver, and stomach in males, and breast, cervix uteri, and lung in females. In both economically developed and developing countries, the three most common cancer sites were also the three leading causes of cancer death. Rates of cancers common in Western countries will continue to rise in developing countries if preventive measures are not widely applied. The most common types of cancer also vary by geographic area. For example, among women breast cancer was the most common cancer in 19 out of the 21 world areas, while cervical cancer was the most common in the remaining two areas. Further variations are observed by examining individual countries. In 2012, the most common cancer site among males in most economically developed countries was prostate, with the exception of certain countries of Southern and Eastern Europe (lung cancer), Slovakia (colorectal cancer), and Japan (stomach cancer). Lung and stomach cancer were the top cancer sites in Asia. The greatest variation among males was in Africa, where the most common cancer was prostate, liver, Kaposi sarcoma, lung, non-Hodgkin lymphoma, colorectal, leukemia, esophagus, or stomach. Among females, the most common cancer sites were either breast or cervical cancer, with the exceptions of China and North Korea (lung), South Korea (thyroid), and Mongolia and Laos (liver).

We believe our prescription drug candidate PV-10, a novel investigational drug, may afford competitive advantage compared to currently available options for the treatment of certain types of cancer; particularly solid tumors. Additional geographic variations exist as well. In short, we believe PV-10 is appropriate to treat any solid tumor anywhere. We are developing PV-10, a sterile injectable form of rose bengal disodium (Rose Bengal), for direct injection into tumors. It is an ablative immunotherapy or 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 recurrent and metastatic melanoma, and phase 1 studies of PV-10 for the treatment of liver and breast cancers, each of which are described in more detail below. Furthermore, in 2015, we commenced a phase 3 study of PV-10 to treat locally advanced cutaneous melanoma as well as a phase 1b/2 study that combines PV-10 and pembrolizumab, both of which are described in more detail below.

**Recurrent or Locally Advanced Cutaneous Melanoma and Widely Metastatic [Melanoma] Disease**

According to Global Cancer Facts & Figures, 3<sup>rd</sup> Edition, estimated new cases for men in developed countries totaled 99,400 in 2012, and 91,700 for women. Estimated deaths continue to increase as well. PV-10 is potentially applicable for treating all stage III and IV patients, either as a neoadjuvant therapy, monotherapy, or in combination with a systemic agent for late stage patients in particular.

Our Phase 3 clinical trial of intralesional PV-10 as a melanoma treatment is progressing as we expected. We are actively recruiting and treating patients in centers in the U.S. Other sites are now also listed on clinicaltrials.gov and more will be added. We expect to have other sites for the U.S., Australia and elsewhere joining the study soon. We are seeking 225 patients for this study. The primary outcome measure is progression-free survival, PFS, to be assessed every 12 weeks up to 18 months. The secondary outcome measures include complete response rate, CRR, and its duration to be set every 12 weeks up to 18 months and overall survival to be assessed every 12 weeks up to 18 months. Unlike our Phase 2 study, which was a single arm study, the Phase 3 is a randomized trial. And we hope to

further demonstrate conclusively that PV-10 is both safe and effective and is statistically superior to the control systemic chemotherapy.

Our estimated primary completion date is September 2017, and an estimated study completion date of October 2017. When 50 percent of the events required for the primary endpoint have occurred, the Independent Data Monitoring Committee will report an interim assessment of efficacy and safety. So, meaningful clinical data could come as early as the middle of this year, which is halfway through the study, as documented on [clinicaltrials.gov](http://clinicaltrials.gov).

This phase 3 randomized controlled trial of PV-10 in patients with unresectable locally advanced cutaneous melanoma will assess response to PV-10 versus that of systemic chemotherapy in patients who have disease limited to cutaneous and subcutaneous sites and who have failed or are ineligible for systemic immunotherapy. Progression-free survival and complete response rate will be assessed using standard criteria (RECIST 1.1). Overall survival and exploratory assessment of patient reported outcomes related to lesion pain and other melanoma symptoms will also be assessed.

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We are not alone in advocating for an intralesional approach in the treatment of cancer. For melanoma patients with recurrent or in-transit disease confined to their skin this approach has been used to treat patients for many years, as evidenced by guidelines published by the National Comprehensive Cancer Network (NCCN Guidelines<sup>®</sup>) defining the standard of care for cancer treatment in the United States. Intralesional injection with BCG and certain immunomodulatory agents, local ablation, topical therapy for superficial lesions and regional radiotherapy are consensus interventions for these patients, while systemic therapy remains an option and participation in a clinical trial is the preferred option. We believe that, in this context, PV-10 is well positioned to show superiority in phase 3 testing as a single agent.

For those patients who do not have all disease accessible to injection, medical oncologists have stated that using an agent like PV-10 to prime the immune system could be synergistic in combination with a systemic agent. Our patent application on this strategy was published in 2012 and we have been vigorously pursuing this approach. We believe the nonclinical research we first presented at the Society for Immunotherapy of Cancer (SITC) annual meeting that year, together with ongoing translational clinical research on PV-10's mechanism of action we are sponsoring at Moffitt and our own phase 2 data, provide a rationale for combination testing of PV-10. This development track, separate from the phase 3 study, using PV-10 in combination with checkpoint protein inhibitors could present a path forward for patients with significant disease burden not amenable to intralesional injection.

While we believe the rapid ablative effect immediately evident in patients treated with PV-10 highlights our path to initial approval, the bystander effect, or secondary immunomodulatory benefit of PV-10 as a result of direct ablation, continues to be of scientific interest and studies to quantify systemic tumor-specific immune response in cancer patients are ongoing. This is why we term the overall function of PV-10 as ablative immunotherapy. This emerging understanding of the secondary effect of tumor ablation with PV-10 is an important foundation for future studies to assess the long-term impact of PV-10 on distant metastasis and possible combination strategies for use of PV-10 in the treatment of cancer patients with more advanced disease. PV-10 is therefore becoming known as an ablative immunotherapy, and we believe it is therefore a next generation ablative immunological treatment.

As mentioned before, we are also engaged in studying the use of PV-10 as part of a combination therapy for melanoma for Stage 4 patients. Scientifically, combination therapy in cancer treatment is a rapidly maturing area, where a rational combination of agents is replacing the empirical approaches of the past. In this specific instance, we have completed development of the protocol for Phase 1b-2 testing of PV-10 in combination with Merck's Keytruda in patients with Stage 4 melanoma. And we are actively recruiting and treating patients. Keytruda is an immune checkpoint inhibitor approved for treatment of patients with advanced or unresectable melanoma. The PV-10 mechanism of action study's preliminary clinical findings reported initially and then further updated by Moffitt Cancer Center showed that the immunologic effect of tumor ablation with PV-10 may be complementary to immune checkpoint inhibition. Companion preclinical testing of PV-10 in murine models of melanoma also reported that the therapeutic effects of PV-10 in immune checkpoint inhibition are increased when the two are used in combination. Put simply, they may work better together, especially for late stage patients. And this Phase 1b-2 study will help us prepare for potential marketing of PV-10 as part of a combination therapy with Keytruda. When we announced the joint patent co-owned with Pfizer in August 2015, it specifically covered the use of PV-10 to treat melanoma and liver cancers in combination with systemic inhibitors of immune system down regulation, such as anti-CTLA-4, PD-1 and PD-L1 antibodies, along with enhancers of immune system up regulation, such as IL-2 and interferon-gamma. In other words, the Keytruda work we have begun is patent protected.

PV-10 represents both a unique opportunity and an incredible responsibility because the type of agent has the potential to change the way cancer is treated around the world. PV-10 is a small molecule designed to be injected directly into tumors, thereby focusing its effect on disease tissue, while limiting exposure in healthy tissue. We believe that this focused effective tumors has the potential to educate the immune system to find other cancer cells with the same

characteristics, thereby potentially having an effect on metastases elsewhere in the body. The work previously reported by our collaborators at Moffitt Cancer Center in Tampa and at the University of Illinois in Chicago clearly indicate that this is taking place in laboratory models of multiple tumor types. Additional information on how this translates to patients was reported November 2015 by the Moffitt team at the Society of Immunotherapy of Cancer Annual Meeting in Washington. We expect information as well to be communicated throughout 2016.

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We also report ongoing progress with our Compassionate Use Program for PV-10 for non-visceral cancers. With well over 140 patients enrolled in eight centers across the U.S. and Australia, the protocol enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the phase 2 trials. Its dosage has been very helpful with planning for the phase 3 melanoma study as well as treating other types of cutaneous and subcutaneous cancers, and we are gratified we can provide PV-10 now for patients that request it who have no other available option.

We are continuing to assess how much additional work we should do by ourselves, and when to partner with a larger company to further co-develop PV-10, as well as potential paths to accelerated and expedited approval in the U.S. and abroad, including in China and India.

We strengthened our position in the Chinese market with our letter of intent with Boehringer Ingelheim (China) Investment Company Limited, signed July 2, 2015. We are benefiting from their 20 plus years of experience in China, and we are building a relationship with them that may help us in commercializing and marketing PV-10 in mainland China, Hong Kong and Taiwan, as we work with the appropriate regulatory bodies. We are committed to being successful in China, in particular, and Asia in general.

Discussions have continued on the basis of a memorandum of understanding signed last year with Sinopharm-China State Institute of Pharmaceutical Industry, CSIPI, the leader among all pharmaceutical research institutes in China and Sinopharm A-Think Pharmaceutical Company Limited, Sinopharm A-Think, the only injectable anti-tumor drug research and development manufacturer and distribution integrated platform within Sinopharm Group. While our working arrangement is more developed with Boehringer, management of Provectus and senior personnel and Sinopharm, CSIPI, and Sinopharm A-Think has held numerous conference calls, have met face-to-face in both China and the U.S., and Chinese scientists on staff at Sinopharm have discussed in person PV-10 and its clinical results with various lead investigators we work with globally. Some more formal relationship with them remains an option for us in China, and will endeavor to include Boehringer as well in any future developments and potential partnerships.

Efforts have been more active in Brazil as we work with potential partners there, and Latin America in general, as well as in India, as we continue our focus to enter into geographic license and our collaborations that allow us to generate meaningful clinical data more rapidly than otherwise.

We have signed agreements with two manufacturers to supply us with clinical-quality PV-10, and we now have sufficient quantities of PV-10 available to continue the phase 3 trial and our other PV-10 development activities. To assure smooth execution of the study we have lined up specialty contract research organizations (CROs) and other service providers with expertise in clinical operations and integrated data management. As is standard in our industry, this includes full-service, international CROs who will coordinate the global efforts of this team of specialists.

We have worked to establish an independent Clinical Trial Data Monitoring Committee (DMC). The FDA states A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial. The DMC will ensure that our study provides patients with maximum possible safety while protecting the scientific validity and integrity of the data we gather.

## Liver Cancer

According to Global Cancer Facts & Figures, 3<sup>rd</sup> Edition, liver cancer is the fifth most common cancer in men and the ninth in women. An estimated 782,500 new liver cancer cases occurred in the world during 2012, with China alone

accounting for about 50% of the total. Rates are more than twice as high in men as in women. Liver cancer rates are the highest in Central America, West and Central Africa, and East and Southeast Asia (Figure 9). Most primary liver cancers occurring worldwide are hepatocellular carcinoma (HCC), which likely accounts for 70% to 90% of cases. One type of liver cancer (cholangiocarcinoma) that is rare in most parts of the world has high incidence rates in Thailand and other parts of Asia due to the high prevalence of liver fluke infection. Worldwide, liver cancer is the second leading cause of cancer death in men and the sixth leading cause among women, with about 745,500 deaths in 2012.

Early detection is difficult and as a result, most cases reach an advanced metastatic stage and are unresectable. If the cancer cannot be completely removed, the disease is usually deadly within three to six months. Malignant lesions in the liver arising from HCC or metastases from a wide range of cancers represent an ongoing treatment challenge for oncologists. HCC is one

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of the most common malignancies worldwide, and its incidence is rapidly increasing in the United States. The liver is a common site of metastases from solid tumors, particularly those arising in the gastrointestinal tract. Other tumors, such as lung and breast cancer and melanoma, also readily spread to the liver.

We collaborated with XenoTech, a preclinical CRO and pioneer in collaborative research surrounding in vitro drug metabolism and pharmacokinetics (DMPK) services, in writing an article describing a study to determine the potential of rose bengal disodium to cause drug-drug interactions which has been published by Xenobiotica, a peer-reviewed scientific journal that publishes comprehensive research papers on pharmacokinetics (the study of distribution, metabolism, disposition and excretion of drugs). The published research indicated that the risk of PV-10 causing clinically relevant drug-drug interactions is likely minimal.

The study was undertaken prior to initiation of the now ongoing testing of PV-10 plus sorafenib (cohort 2) in a clinical trial of PV-10 intralesional injection in hepatocellular carcinoma patients taking a stable dose of sorafenib. Sorafenib is a competitive inhibitor of cytochrome P450 (CYP) drug metabolism enzymes and is reliant on the UDP-glucuronosyltransferase (UGT) pathway for efficient clearance. CYP and UGT enzymes help to biotransform small lipophilic drugs like sorafenib into water-soluble excretable metabolites.

Provectus researchers collaborated with XenoTech's experts to design the appropriate in vitro experiments necessary to assess the risk for potential liability when rose bengal is co-administered with other drugs in humans. Rose Bengal, known for inducing singlet oxygen on exposure to light, can cause erroneous results in conventional in vitro test systems. These assay artifacts were shown to be test system dependent in DMPK studies. XenoTech scientists successfully tailored experiments to ascertain CYP and UGT inhibition potential in more appropriate model systems.

We have recently expanded our exploratory phase 1 study of cancers of the liver to three centers (St. Luke's University Health Network, Bethlehem, Pennsylvania, and The Southeastern Center for Digestive Disorders & Pancreatic Cancer, Tampa, Florida, in addition to Sharp Memorial Hospital, San Diego, California), and we are evaluating the addition of several more centers to further advance this initial effort. We are working with our investigators to report results from long-term follow-up of our initial patients in the coming months. We are assessing strategies to accelerate transition to phase 2 testing in a randomized controlled trial, either alone or in combination with systemic therapy. Any combination studies in the liver are likely to follow similar development strategies to those outlined above for melanoma and rely on much of the same foundational science.

The current phase 1 study, initially designed solely to establish safety of percutaneous injection of PV-10 into liver tumors (that is, injection through the skin), is providing valuable data crucial for planning such phase 2 development. This trial is open to patients with hepatocellular carcinoma or other cancers metastatic to the liver who have at least one tumor that has either originated in or spread to the liver and are not candidates for surgery or transplant. All patients enrolled in this open-label study receive the same treatment: an interventional radiologist injects PV-10 percutaneously into a single liver tumor. Patients with multiple injectable tumors may later receive further PV-10 to their other tumors. We have received numerous inquiries about this study from researchers as well as patients and their doctors, and refer these to our investigators through the contact information available on the [clinicaltrials.gov](http://clinicaltrials.gov) website. We plan to commence the phase 1b/2 liver study in early 2016. This study has potential for generating sufficient data to support expedited approval under one or more FDA programs.

In July 2015, data were presented at two conferences that show our progress to date on the treatment of hepatocellular carcinoma and cancers metastatic to the liver. We made a poster presentation at the ESMO 17th World Congress on Gastrointestinal Cancer (ESMO GI) in Barcelona at the beginning of July, and detailed data from our relevant Phase 1 study of PV-10. The main conclusion was that preliminary evidence of efficacy in treatment of cancers of the liver with PV-10 was observed. That same week, Dr. Sanjiv Agarwala presented the data in poster form at the 6th



Asia-Pacific Primary Liver Cancer Expert Meeting, APPLE 2015, in Osaka, Japan. Both of these posters can be found on our website pvct.com. What these data show is that PV-10 affects cancers of the liver in much the same way it does melanoma. More work has to be done, but we believe that these results support rapidly development of PV-10 in a randomized Phase 2 study after dosing with standard of care is optimized. This is the Phase 1b/2 study we also refer to above.

### Breast Cancer

According to Global Cancer Facts & Figures, 3<sup>rd</sup> Edition, breast cancer is the most frequently diagnosed cancer in women worldwide with nearly 1.7 million new cases diagnosed in 2012, accounting for 25% of all new cancer cases in women. A little more than half (53%) of these cases occurred in economically developing countries, which represents about 82% of the

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world population. An estimated 521,900 breast cancer deaths occurred in women in 2012. Breast cancer is the leading cause of cancer death among women in developing countries and the second leading cause of cancer death (following lung cancer) among women in developed countries. Asian countries, which represent 59% of the global population, have the largest burden of breast cancer, with 39% of new cases, 44% of deaths, and 37% of the world's five-year survivors. Although Northern America (US and Canada) represents only 5% of the world population, it accounts for 15% of new cases, 9% of deaths, and 17% of survivors, reflecting the high incidence and survival rates in the region. In contrast, African countries (15% of world population) represent 8% of the total new cases, but 12% of breast cancer deaths because of poor survival due to late stage at diagnosis and limited treatment.

In 2005, we began a phase 1 study of PV-10 to assess the safety and tolerability of injections of PV-10 into recurrent breast carcinoma. We completed the phase 1 study in 2008. The primary outcome measure was systemic and locoregional adverse experience. The secondary outcome measures were (i) histopathologic response of PV-10 injected lesions and (ii) wound healing of PV-10 injected lesions.

The goals of the phase 1 clinical trial were to determine the safety of the treatment and the appropriate dosage. We have also wanted to show that PV-10 has multi-indication potential. We continued to demonstrate this objective in 2011 through 2015, and expect to do so in 2016. We are now in a position for a phase 2 study in recurrent breast carcinoma with our lead oncology drug product candidate PV-10. We are evaluating potential for further development of PV-10 to treat recurrent breast cancer based on the published data provided by Moffitt as well as interest to address this important indication.

## Colon and Rectum Cancer

According to Global Cancer Facts & Figures, 3<sup>rd</sup> Edition Colon and Rectum, colorectal cancer is the third most common cancer in men and the second in women. Worldwide, an estimated 1.4 million cases of colorectal cancer occurred in 2012. The highest incidence rates were in Northern America, Australia, New Zealand, Europe, and South Korea. Rates were low in Africa and South Central Asia. About 693,900 deaths from colorectal cancer occurred in 2012 worldwide, accounting for 8% of all cancer deaths. The incidence of colorectal cancer is increasing in certain countries where risk was historically low (e.g., Japan).

The greatest increases are in Asia (Japan, Kuwait, and Israel) and Eastern Europe (Czech Republic, Slovakia, and Slovenia). In fact, incidence rates among males in the Czech Republic, Slovakia, and Japan have exceeded the peak rates observed in longstanding developed countries, such as the United States, Canada, and Australia, and continue to increase. In high-risk/high-income countries, trends over the past 20 years have either gradually increased (Finland and Norway), stabilized (France and Australia), or declined (United States) with time. The decrease in colorectal cancer incidence in the United States among those 50 years of age and older partially reflects the increase in detection and removal of precancerous lesions through screening. In contrast to the stabilizing rates observed in most Western and Northern European countries, relatively large increases have been observed in Spain, which may be related to the increasing prevalence of obesity in recent years in that country. The increase in several Asian and Eastern European countries may also reflect increased prevalence of risk factors for colorectal cancer associated with westernization such as unhealthy diet, obesity, and smoking. In contrast to incidence trends, decreasing colorectal cancer mortality rates have been observed in a large number of countries worldwide and are most likely due to colorectal cancer screening and/or improved treatments. However, increases in mortality rates are still occurring in countries that have more limited resources, including Brazil and Chile in South America and Romania and Russia in Eastern Europe.

On February 2, 2015, data discussing the immunologic effects of PV-10 on colon cancer cells were presented at the 11th Annual Academic Surgical Congress in Jacksonville, Florida. The abstract, titled "PV-10 Induces Potent Immunogenic Apoptosis in Colon Cancer Cells," was presented by N. M. Kunda of the University of Illinois at

Chicago, Division of Surgical Oncology, Department of Surgery, College of Medicine, Chicago, IL, USA. The research team is led by Dr. A.V. Maker, and co-authors in addition to Drs. Kunda and Maker are: J. Qin, G. Qiao also of UIC, Division of Surgical Oncology, Department of Surgery. The team of authors also includes B. Prabhakar of the University of Illinois at Chicago, Department of Microbiology & Immunology, College of Medicine, Chicago, IL, USA. Dr. Maker belongs to both Departments.

In the presentation, Dr. Kunda noted that in vitro testing of PV-10 on colon cancer (murine CT-26 cells) showed cytotoxicity consistent with immunogenic apoptosis. Further, he stated that the researchers observed cell arrest, apoptosis, autophagy and endoplasmic reticulum (ER) stress. He concluded that these results are consistent with immunologic cell death caused by PV-10.

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The work reported in Dr. Kunda's presentation further expands our understanding of the mechanism of action of PV-10 as an ablative immunotherapy for solid tumors, and parallels immunologic signaling noted upon ablation of melanoma with PV-10.

## Other Indications

The compassionate use program for PV-10 is only available for cancer indications that do not involve treatment of visceral organs and are not subject to enrollment in ongoing clinical trials. These indications include certain breast cancers, basal cell carcinoma, squamous cell carcinoma, certain head and neck cancers and melanoma. Compassionate use programs provide patients with access to experimental therapeutics prior to FDA approval.

The protocol for the compassionate use program enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the phase 2 trial of PV-10. Based on the success of the compassionate use program, its dose regimen served as the blueprint for the phase 3 study for melanoma. The majority of patients enrolled in the program have been treated for melanoma, with other patients for other indications such as recurrent squamous cell carcinoma and refractory scalp sarcoma.

Additionally, we are considering a clinical study of PV-10 for each of multiple other solid tumor indications.

## *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 believe PH-10 is appropriate to treat all indications that are described as inflammatory dermatoses. 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.

We have been actively discussing licensing transactions with a number of potential out licensing partners for PH-10. We believe that our phase 2c trial of PH-10 for psoriasis will further solidify the commercial viability of PH-10 in these discussions. In August 2011, we completed follow-up of all phase 2c patients and communicated data of the study to both prospective partners as well as the public market in early 2012. In January 2015, we commenced a mechanism of action study of PH-10 to better characterize the unique immunologic signaling aspects along with PH-10 safety and efficacy. This study was completed in January 2016 and data will be reported when available this year.

## Psoriasis

Psoriasis is a common chronic disorder of the skin characterized by dry scaling patches, called plaques, for which current treatments are few and those that are available have potentially serious side effects. There is no known cure for the disease at this time. According to the National Institutes of Health, as many as 7.5 million Americans, or approximately 2.2 percent of the U.S. population, have psoriasis. The National Psoriasis Foundation reports that approximately 125 million people worldwide, 2 to 3 percent of the total population, have psoriasis. It also reports that total direct and indirect health care costs of psoriasis for patients exceed \$11 billion annually.

According to the National Psoriasis Foundation, the majority of psoriasis sufferers, those with mild to moderate cases, are treated with topical steroids that can have unpleasant side effects. None of the other treatments for moderate cases

of psoriasis have proven completely effective. The 25-30% of psoriasis patients who suffer from more severe cases generally are treated with more intensive drug therapies or PUVA, a light-based therapy that combines the drug Psoralen with exposure to ultraviolet A light. While PUVA is one of the more effective treatments, it increases a patient's risk of skin cancer.

Our phase 1 study for PH-10 was initiated in April 2001 to evaluate the safety of three different doses of PH-10 in separate patient segment groups. Subjects in the study each received a single dose of PH-10 followed by administration of green light on psoriatic plaques. Subjects were examined post-treatment, with a final follow-up examination at 90 days.

Our phase 2 study of PH-10 for treatment of psoriasis was initiated in 2009 and completed in April 2010. There were 30 subjects treated in the completed phase 2 study, and an additional six subjects were treated in an earlier study that was terminated in favor of an increased dosing frequency. Consistent with the preliminary data that we announced in December 2009, 70% of the 30 subjects enrolled in the phase 2 clinical trial of PH-10 for psoriasis demonstrated improvement in their Psoriasis Severity Index (PSI) scores at the end of four weeks of daily treatment with PH-10. In addition, 86% of subjects reported no or only mild pruritus (itching) by week four of the trial, and no significant safety issues were noted. At the four-week interval substantial improvement was observed across all standard disease assessment scores.

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During 2010, we initiated a phase 2c clinical trial of PH-10 for psoriasis. This multicenter, randomized controlled phase 2c study enrolled 99 subjects at four different sites, which began in December 2010. The subjects were randomized sequentially by center to one of four treatment cohorts, and assessed efficacy and safety of topical PH-10 applied once daily to areas of mild to moderate plaque psoriasis. The primary efficacy endpoint was treatment success, a static endpoint assessed at day 29 after initial PH-10 treatment and defined as 0 or 1 on all Psoriasis Severity Index (PSI) components and 0 or 1 on the Plaque Response scale. The primary safety endpoint was incidence of adverse experiences, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality). The secondary outcome measures were (i) Psoriasis Severity Index (PSI) score changes at each visit from day 1 pre-treatment, (ii) Plaque Response score changes at each visit from day 1 pre-treatment, and (iii) Pruritus Self-Assessment score changes at each visit from day 1 pre-treatment.

The phase 2c trial was conducted at four sites in the U.S. including the Mount Sinai School of Medicine in New York City, Wake Research Associates in Raleigh, North Carolina, Dermatology Specialists in Oceanside, California, and International Dermatology Research in Miami, Florida. With over 90 subjects, this trial is the largest dermatological trial that we have conducted to date.

The results of this study helped define the parameters necessary for the design of a pivotal phase 3 trial, and it was an important milestone on the regulatory pathway leading towards commercialization. In addition, we have held discussions with a number of potential out licensing partners, and we believe this phase 2c trial has further solidified the commercial viability of PH-10 in these discussions. We have also continued important toxicity study research and development in 2012 through 2014 and into 2015 to prepare for a phase 3 study and to support a New Drug Approval filing.

On December 23, 2014, we announced that the protocol for our phase 2 study of the mechanism of action of PH-10 in psoriasis is now available on ClinicalTrials.gov, Identifier NCT02322086: [<https://www.clinicaltrials.gov/ct2/show/NCT02322086>]. The purpose of the trial is to study the safety and efficacy of PH-10, a 0.005% preparation of Rose Bengal, in the treatment of psoriasis.

Officially titled, A Phase 2 Study of Cellular and Immunologic Changes in the Skin of Subjects Receiving PH-10 Aqueous Hydrogel to Plaque Psoriasis, total enrollment is expected to consist of 30 patients. Subjects will apply PH-10 vehicle daily for 28 consecutive days followed by active PH-10 daily for 28 consecutive days to their plaque psoriasis areas on the trunk or extremities (excluding palms, soles, scalp, facial and intertriginous sites). Biopsies of one target plaque will be collected at baseline (at least 7 days prior to first study treatment on Day 1) and at Days 29 and 64, with a 7-day interval between biopsy at Day 29 at the end of vehicle application and commencement of application of active PH-10 on Day 36. Study data from each subject will serve as an internal control (i.e., with assessment at baseline and at the end of application of PH-10 vehicle) for evaluation of clinical and cellular response to active investigational agent.

The protocol states that the multicenter study is designed to assess treated psoriatic plaque for changes in immunologic, structural and hyperproliferative state and for any evidence of cellular atypia when treated with PH-10 and to correlate observed changes in the skin with clinical response to treatment. These assessments are expected to advance the understanding of the mechanism of action of PH-10 in psoriasis and other inflammatory dermatoses, such as atopic dermatitis, and further substantiate the safety profile of the agent. Biopsy specimens will be assessed for changes in epidermal hyperplasia (i.e., disordered condition of the skin creating thickening and scaling); infiltration with immune cells; and molecular markers of inflammation. Correlation of clinical response to these cellular and molecular changes will be performed at the plaque level using Psoriasis Severity Index (PSI) assessment data. Safety will be assessed by monitoring the frequency, duration, severity and attribution of clinical adverse events; evaluating changes in laboratory values and vital signs; and by correlation of clinical adverse events with observed

histopathologic and immunohistopathologic changes in the skin.

By capturing data at the clinical and cellular level, we expect this study to allow us to establish how PH-10 affects psoriatic plaque and other similar inflammatory diseases of the skin, and to relate the safety profile from earlier studies to such effects. We believe that understanding these effects with this level of detail will allow us to properly position PH-10 within the competitive landscape and should provide crucial safety data to support extended dosing. We expect this effort to provide a comparable level of understanding of the effects of PH-10 in diseased skin to the keen insight we have gained through our clinical and nonclinical mechanism studies of PV-10, our novel investigational cancer drug, in melanoma and other cancers. Because there are no good model systems for psoriasis, we believe this study affords a critical opportunity to link the clinical effects we have observed to changes in well-established immunologic drivers of the disease. The study will be performed at three centers in the United States.

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On January 29, 2015, we announced that we have opened recruitment for our PH-10 mechanism study. PH-10 has already been testing phase 1 and 2 studies and a total of 226 patients. In this study, we are looking at possible changes in the immunologic, structural and hyperproliferative state of the skin in the target plaque and evidence of cellular atypia following PH-10 application. We will use this data to aid in further development of PH-10 with our objective to co-develop or license PH-10 with dermatological partner as we continue to prepare to advance PH-10 for approval as topical anti-inflammatory non-steroidal agent for treating psoriasis and other inflammatory dermatoses. According to clinicaltrials.gov, the estimated completion date of the study was January 2016 and data is now being compiled for communication to the FDA and the public.

## Atopic Dermatitis

Atopic Dermatitis, the most severe and common type of eczema, is a long-term skin disease that causes dry and itchy skin, rashes on the face, inside the elbows, behind the knees, and on the hands and feet. Scratching of the afflicted skin can cause redness, swelling, cracking, weeping clear fluid, crusting, thick skin, and scaling. According to the National Eczema Association, physicians estimate that 65% of eczema patients are diagnosed in the first year of life and 90% of patients experience it before age five. Often the symptoms fade during childhood, though most will have atopic dermatitis for life. The National Eczema Association estimates that atopic dermatitis affects over 30 million Americans.

In 2008, we initiated a phase 2 study of PH-10 for the treatment of atopic dermatitis. This phase 2 study assessed whether topical PH-10 applied once daily to mild, moderate or severe atopic dermatitis may ameliorate inflammation of the skin when activated by ambient light. The subjects applied PH-10 daily for 28 days to skin areas affected by atopic dermatitis. The subjects were assessed weekly during the treatment period and for four weeks following the treatment period. The primary outcome measures were (i) treatment success, defined as a score of 0 to 1 at day 28, the end of the study treatment period, by the Investigator's Global Assessment (IGA) scoring system for atopic dermatitis status, and (ii) adverse experience, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality) during the eight weeks following treatment.

Data from the subjects indicated that a substantial majority of subjects had improvement in the Eczema Area Severity Index (EASI) during four weeks of treatment. The treatments were generally well tolerated with no significant safety issues identified. At the four-week interval substantial improvement was observed across all standard disease assessment scores. We have also continued important toxicity study research and development in 2012 through 2015 and thus far in 2016 to prepare for continued development in this indication and to support a New Drug Approval filing.

## Other Indications

We have investigated the use of PH-10 for treatment of actinic keratosis (also called solar keratosis or senile keratosis), which is the most common pre-cancerous skin lesion among fair-skinned people and is estimated to occur in over 50% of elderly fair-skinned persons living in sunny climates. We have previously conducted a phase I clinical trial of PH-10 for actinic keratosis to examine the safety profile of a single treatment using topical PH-10 with green light photoactivation. No significant safety concerns were identified in the study. We have decided to prioritize further clinical development of PH-10 for treatment of psoriasis and atopic dermatitis rather than actinic keratosis at this time since the market is much larger for psoriasis and atopic dermatitis.

We have also conducted pre-clinical studies of PH-10 for use in treating severe acne vulgaris. Moderate to severe forms of the disease have proven responsive to several photodynamic regimens, and we anticipate that PH-10 can be used as an advanced treatment for this disease. Our pre-clinical studies show that the active ingredient in PH-10



readily kills bacteria associated with acne. This finding, coupled with our clinical experience in psoriasis, atopic dermatitis, and actinic keratosis, suggests that therapy with PH-10 will exhibit no significant side effects and will afford improved performance relative to other therapeutic alternatives. If correct, this would be a major advance over currently available products for severe acne.

The active ingredient in PH-10 is photoactive in that it reacts to light of certain wavelengths thereby potentially increasing its therapeutic effects. We believe that photodynamic treatment regimens can deliver a higher therapeutic effect at lower dosages of active ingredient, thus minimizing potential side effects including damage to nearby healthy tissues. PH-10 is especially responsive to green light, which is strongly absorbed by the skin and thus only penetrates the body to a depth of about three to five millimeters. For this reason, in the past we have investigated PH-10 combined with green-light activation, for topical use in surface applications where serious damage could result if medicinal effects were to occur in deeper tissues.

### **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. The potential further development and licensure of our OTC products would likely be facilitated by selling a majority

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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 stockholders of the Company, although there can be no assurance that this process will occur.

### *GloveAid*

Personnel in many occupations and industries now use disposable gloves daily in the performance of their jobs, including airport security personnel, food handling and preparation personnel, health care workers such as hospital and blood bank personnel, laboratory researchers, police, fire and emergency response personnel, postal and package delivery handlers and sorters, and sanitation workers.

Accompanying the increased use of disposable gloves is a mounting incidence of chronic skin irritation. To address this market, we have developed *GloveAid*, a hand cream with both antiperspirant and antibacterial properties, to increase the comfort of users' hands during and after the wearing of disposable gloves. During 2003, we ran a pilot scale run at the manufacturer of *GloveAid*.

### *Pure-ific*

Our *Pure-ific* line of products includes two quick-drying sprays, *Pure-ific* and *Pure-ific Kids*, that immediately kill up to 99.9% of germs on skin and prevent regrowth for six hours. We have determined the effectiveness of *Pure-ific* based on our internal testing and testing performed by Paratus Laboratories H.B., an independent research lab. *Pure-ific* products help prevent the spread of germs and thus complement our other OTC products designed to treat irritated skin or skin conditions such as acne, eczema, dandruff and fungal infections. Our *Pure-ific* sprays have been designed with convenience in mind and are targeted towards mothers, travelers, and anyone concerned about the spread of sickness-causing germs. During 2003 and 2004, we identified and engaged sales and brokerage forces for *Pure-ific*. We emphasized getting sales in independent pharmacies and mass (chain stores) markets. The supply chain for *Pure-ific* was established with the ability to support large-scale sales and a starting inventory was manufactured and stored in a contract warehouse/fulfillment center. In addition, a website for *Pure-ific* was developed with the ability for supporting online sales of the antibacterial hand spray. During 2005 and 2006, most of our sales were generated from customers accessing our website for *Pure-ific* and making purchases online. We discontinued our proof-of-concept program in November 2006 and have, therefore, ceased selling our OTC products. We now intend to license the *Pure-ific* product, a strategy we have been discussing with interested groups. Additionally, we also intend to sell a majority stake in the underlying assets via a non-core spin-out transaction, as discussed below.

On December 15, 2011, we sold Units to accredited investors which included shares of common stock in *Pure-ific* and a warrant to purchase 3/4 of a share of the Company's common stock. A total of 666,666 Units were sold for gross proceeds of \$500,000 resulting in the sale of a 33% non-controlling interest in *Pure-ific*. At the time of the sale and as of December 31, 2011, the carrying value of the net assets in *Pure-ific* was \$0. The sale also resulted in the issuance of warrants to purchase 500,000 shares of the Company's common stock at an exercise price of \$1.25 per share with a five-year term. We intend to use the proceeds, after deducting offering expenses of approximately \$56,500, to spin-off *Pure-ific* as a new publicly-traded company, a process we have initiated but have not yet completed. Network 1 Financial Securities, Inc., served as placement agent for the offering.

### *Acne*

Our acne products *Pure-Stick* and *Pure N Clear* work by decreasing the production of fats, oils and sweat that create an environment conducive to unchecked growth of bacteria. Secondly, the products also act to reduce the number of

bacteria already present. Pure-Stick and Pure N Clear represent new formulations of proven, safe ingredients that achieve both steps required to successfully treat acne. Since Pure-Stick and Pure N Clear are applied topically to affected areas there are no safety concerns with healthy skin. The unique combinations have allowed the Company to secure patent protection for these products.

### **Medical Devices**

We have non-core medical device technologies that we believe may address two major markets:

cosmetic treatments, such as reduction of wrinkles and elimination of spider veins and other cosmetic blemishes; and

therapeutic uses, including photoactivation of PH-10, other prescription drugs and non-surgical destruction of certain skin cancers.

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We expect to further develop our non-core medical devices through partnerships with, or selling our assets to, third-party device manufacturers or, if appropriate opportunities arise, through acquisition of one or more device manufacturers. Additionally, the Company also intends to sell a majority stake in the underlying assets via a non-core spin-out transaction.

### Photoactivation

Our clinical tests of PH-10 for dermatology have in the past utilized a number of commercially available lasers for activation of the drug. This approach has several advantages, including the leveraging of an extensive base of installed devices present throughout the pool of potential physician-adopters for PH-10. Access to such a base could play an integral role in early market capture. However, since the use of such lasers, which were designed for occasional use in other types of dermatological treatment, is potentially too cumbersome and costly for routine treatment of the large population of patients with psoriasis, we have begun investigating potential use of other types of photoactivation hardware, such as light booths. The use of such booths is consistent with current care standards in the dermatology field, and may provide a cost-effective means for addressing the needs of patients and physicians alike. We anticipate that such photoactivation hardware would be developed, manufactured, and supported in conjunction with one or more third-party device manufacturers.

### Laser-Based Treatment of Melanoma

We have conducted extensive research on ocular melanoma at the Massachusetts Eye and Ear Infirmary (a teaching affiliate of Harvard Medical School) using a new laser treatment that may offer significant advantage over current treatment options. A single quick non-invasive treatment of ocular melanoma tumors in a rabbit model resulted in elimination of over 90% of tumors, and may afford significant advantage over invasive alternatives, such as surgical excision, enucleation, or radiotherapy implantation. Ocular melanoma is rare, with approximately 2,000 new cases annually in the U.S. However, we believe that our extremely successful results could be extrapolated to treatment of primary melanomas of the skin, which have an incidence of over 60,000 new cases annually in the U.S. and a 6% five-year survival rate after metastasis of the tumor. We have performed similar laser treatments on large (averaging approximately 3 millimeters thick) cutaneous melanoma tumors implanted in mice, and have been able to eradicate over 90% of these pigmented skin tumors with a single treatment. Moreover, we have shown that this treatment stimulates an anti-tumor immune response that may lead to improved outcome at both the treatment site and at sites of distant metastasis. From these results, we believe that a device for laser treatment of primary melanomas of the skin and eye is nearly ready for human studies. We anticipate partnering with, or selling our assets to, a medical device manufacturer to bring it to market in reliance on a 510(k) notification. For more information about the 510(k) notification process, see [Federal Regulation of Therapeutic Products](#) below.

## **Research and Development**

We continue to actively develop projects that are product-directed and are attempting to conserve available capital and achieve full capitalization of our company through equity and convertible debt offerings, generation of product revenues, and other means. All ongoing research and development activities are directed toward maximizing shareholder value and advancing our corporate objectives in conjunction with our OTC product licensure, our current product development and maintaining our intellectual property portfolio.

Research and development costs totaling \$10,708,569 for 2015 included payroll of \$2,292,710, consulting and contract labor of \$6,652,406, lab supplies and pharmaceutical preparations of \$1,115,140, legal of \$358,582, insurance of \$189,358, rent and utilities of \$87,208, and depreciation expense of \$13,165. Research and development costs totaling \$5,137,927 for 2014 included payroll of \$1,395,321, consulting and contract labor of \$2,355,780, lab

supplies and pharmaceutical preparations of \$790,653, legal of \$384,061, insurance of \$115,957, rent and utilities of \$87,623, and depreciation expense of \$8,532. Research and development costs totaling \$3,595,555 for 2013 included payroll of \$1,459,057, consulting and contract labor of \$1,317,472, lab supplies and pharmaceutical preparations of \$310,160, legal of \$262,720, insurance of \$161,268, rent and utilities of \$78,512, and depreciation expense of \$6,366.

### **Production**

We have determined that the most efficient use of our capital in further developing our OTC products is to license the products. The Company has been discussing this strategy with interested groups. Additionally, the Company also intends to sell a majority stake in the underlying assets via a non-core spin-out transaction.

### **Sales**

We have not had any significant sales of any of our OTC products, though we commenced limited sales of Pure-ific, our antibacterial hand spray in 2004 through 2006, in a proof-of-concept program. We discontinued our proof-of-concept

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program in 2006 and have, therefore, ceased selling our OTC products. We will continue to seek additional markets for our products through existing distributorships that market and distribute medical products, ethical pharmaceuticals, and OTC products for the professional and consumer marketplaces through licensure, partnership and asset sale arrangements, and through potential merger and acquisition candidates.

In addition to developing products ourselves, we are negotiating actively with a number of potential licensees for several of our intellectual properties, including patents and related technologies. To date, we have not yet entered into any licensing agreements; however, we anticipate consummating one or more such licenses in the future.

**Table of Contents****Intellectual Property***Patents*

We hold a number of U.S. patents covering the technologies we have developed and are continuing to develop for the production of prescription drugs, non-core technologies and OTC pharmaceuticals. All patents material to an understanding of the Company are included and a cross reference to a discussion that explains the patent technologies and products is identified for each patent in the following table:

| <b>U.S. Patent No</b> | <b>Title and Cross Reference</b>   | <b>Issue Date</b>  | <b>Expiration Date</b> |
|-----------------------|--|--------------------|------------------------|
| 5,829,448             | Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business   | November 3, 1998   | October 30, 2016       |
| 5,832,931             | Method for improved selectivity in photo-activation and detection of diagnostic agents; see discussion under Medical Devices in Description of Business  | November 10, 1998  | October 30, 2016       |
| 5,998,597             | Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business   | December 7, 1999   | October 30, 2016       |
| 6,042,603             | Method for improved selectivity in photo-activation of molecular agents; see discussion under Medical Devices in Description of Business   | March 28, 2000     | October 30, 2016       |
| 6,331,286             | Methods for high energy phototherapeutics; see discussion under Oncology in Description of Business  | December 18, 2001  | February 27, 2019      |
| 6,451,597             | Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property | September 17, 2002 | April 6, 2020          |
| 6,468,777             | Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property | October 22, 2002   | April 6, 2020          |
| 6,493,570             | Method for improved imaging and photodynamic therapy; see discussion under Oncology in Description of Business   | December 10, 2002  | November 2, 2018       |
| 6,495,360             | Method for enhanced protein stabilization for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property     | December 17, 2002  | April 6, 2020          |
| 6,519,076             | Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business   | February 11, 2003  | October 30, 2016       |
| 6,525,862             |  | February 25, 2003  |                        |

|           |  |                  |                  |
|-----------|--|------------------|------------------|
|           | Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business   |                  | October 30, 2016 |
| 6,541,223 | Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property | April 1, 2003    | April 6, 2020    |
| 6,986,740 | Ultrasound contrast using halogenated xanthenes; see discussion under Oncology in Description of Business  | January 17, 2006 | August 3, 2019   |



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| <b>U.S. Patent No</b> | <b>Title and Cross Reference</b>  | <b>Issue Date</b>  | <b>Expiration Date</b> |
|-----------------------|---|--------------------|------------------------|
| 6,991,776             | Improved intracorporeal medicaments for high energy phototherapeutic treatment of disease; see discussion under Oncology in Description of Business                             | January 31, 2006   | August 24, 2019        |
| 7,036,516             | Treatment of pigmented tissues using optical energy; see discussion under Medical Devices in Description of Business  | May 2, 2006        | October 30, 2016       |
| 7,201,914             | Combination antiperspirant and antimicrobial compositions; see discussion under Over-the-Counter Pharmaceuticals in Description of Business                                     | April 10, 2007     | May 15, 2024           |
| 7,338,652             | Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business   | March 4, 2008      | November 2, 2018       |
| 7,346,387             | Improved Selectivity in Photo-Activation and Detection of Molecular Diagnostic Agents; see discussion under Medical Devices in Description of Business                          | March 18, 2008     | October 30, 2016       |
| 7,353,829             | Improved Methods and Apparatus For Multi-Photon Photo-Activation of Therapeutic Agents; see discussion under Medical Devices in Description of Business                         | April 8, 2008      | October 30, 2016       |
| 7,384,623             | A Radiosensitizer Agent comprising Tetrabromoerythrosin; see discussion under Oncology in Description of Business   | June 10, 2008      | October 30, 2016       |
| 7,390,668             | Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business | June 24, 2008      | October 30, 2016       |
| 7,402,299             | Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business | July 22, 2008      | September 1, 2017      |
| 7,427,389             | Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business   | September 23, 2008 | October 30, 2016       |
| 7,648,695             | Improved Medicaments for chemotherapeutic treatment of disease; see discussion under Oncology in Description of Business  | January 19, 2010   | October 30, 2016       |
| 7,863,047             | Improved intracorporeal medicaments for photodynamic treatment of disease; see discussion under Dermatology in Description of Business  | January 4, 2011    | October 30, 2016       |
| 8,470,296             | Improved intracorporeal medicaments for high energy photodynamic treatment of disease; see discussion under Dermatology in Description of Business                              | June 25, 2013      | July 28, 2022          |
| 8,530,675             | Process for the synthesis rose bengal and related xanthenes; see discussion under Oncology in Description of Business   | September 10, 2013 | April 21, 2031         |

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|           |  |                   |                  |
|-----------|--|-------------------|------------------|
| 8,557,298 | Chemotherapeutic agents for cancer; see discussion under Oncology in Description of Business | October 15, 2013  | October 30, 2016 |
| 8,974,363 | Topical medicaments for disease; see discussion under Dermatology in Description of Business | February 10, 2015 | December 2, 2019 |
| 9,107,887 | Combination therapy for cancer; see discussion under Oncology in Description of Business     | August 15, 2015   | March 9, 2032    |

We continue to pursue patent applications on numerous other developments we believe to be patentable. We consider our issued patents, our pending and patent applications, and any patentable inventions which we may develop to be extremely valuable assets of our business.

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### *Material Transfer Agreement*

We have entered into a Material Transfer Agreement dated as of July 31, 2003 with Schering-Plough Animal Health Corporation, which we refer to as SPAH, the animal-health subsidiary of Schering-Plough Corporation, a major international pharmaceutical company which is still in effect. Under the Material Transfer Agreement, we will provide SPAH with access to some of our patented technologies to permit SPAH to evaluate those technologies for use in animal-health applications. If SPAH determines that it can commercialize our technologies, then the Material Transfer Agreement obligates us and SPAH to enter into a license agreement providing for us to license those technologies to SPAH in exchange for progress payments upon the achievement of goals.

The Material Transfer Agreement covers four U.S. patents that cover biological material manufacturing technologies (i.e., biotech related). The Material Transfer Agreement continues indefinitely, unless SPAH terminates it by giving us notice or determines that it does not wish to secure from us a license for our technologies. The Material Transfer Agreement can also be terminated by either of us in the event the other party breaches the agreement and does not cure the breach within 30 days of notice from the other party. We cannot assure you that SPAH will determine that it can commercialize our technologies or that the goals required for us to obtain progress payments from SPAH will be achieved.

The Company has received no progress payments in relation to its Material Transfer Agreement with SPAH. Progress payments could potentially total \$50,000 for the first cell line for which SPAH uses our technology and \$25,000 for each use of the same technology thereafter. We do not know how many cell lines SPAH may have and we currently have no indication from SPAH that it intends to use any of our technologies in the foreseeable future.

Additionally, the Company also intends to sell a majority stake in these underlying assets via a non-core spin-out transaction.

### **Competition**

In general, the pharmaceutical and biotechnology industries are intensely competitive, characterized by rapid advances in products and technology. A number of companies have developed and continue to develop products that address the areas we have targeted. Some of these companies are major pharmaceutical companies and biotechnology companies that are international in scope and very large in size, while others are niche players that may be less familiar but have been successful in one or more areas we are targeting. Existing or future pharmaceutical, device, or other competitors may develop products that accomplish similar functions to our technologies in ways that are less expensive, receive faster regulatory approval, or receive greater market acceptance than our products. Many of our competitors have been in existence for considerably longer than we have, have greater capital resources, broader internal structure for research, development, manufacturing and marketing, and are in many ways further along in their respective product cycles.

While it is possible that eventually we may compete directly with major pharmaceutical companies, we believe it is more likely that we will enter into joint development, marketing, or other licensure arrangements with such competitors. Eventually, we believe that we will be acquired.

We also have a number of market areas in common with traditional skincare cosmetics companies, but in contrast to these companies, our products are based on unique, proprietary formulations and approaches. For example, we are unaware of any products in our targeted OTC skincare markets that are similar to our Pure-ific product. Further, proprietary protection of our products may help limit or prevent market erosion until our patents expire.

### **Federal Regulation of Therapeutic Products**

All of the prescription drugs we currently contemplate developing will require approval by the FDA prior to sales within the United States and by comparable foreign agencies prior to sales outside the United States. The FDA and comparable regulatory agencies impose substantial requirements on the manufacturing and marketing of pharmaceutical products and medical devices. These agencies and other entities extensively regulate, among other things, research and development activities and the testing, manufacturing, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our proposed products. While we attempt to minimize and avoid significant regulatory bars when formulating our products, some degree of regulation from these regulatory agencies is unavoidable. Some of the things we do to attempt to minimize and avoid significant regulatory bars include the following:

Using chemicals and combinations already allowed by the FDA;

Using drugs that have been previously approved by the FDA and that have a long history of safe use; and

Using chemical compounds with known safety profiles

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The regulatory process required by the FDA, through which our drug or device products must pass successfully before they may be marketed in the U.S., generally involves the following:

Preclinical laboratory and animal testing;

Submission of an application that must become effective before clinical trials may begin;

Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication; and

FDA approval to market a given product for a given indication after the appropriate application has been filed.

For pharmaceutical products, preclinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. Where appropriate (for example, for human disease indications for which there exist inadequate animal models), we will attempt to obtain preliminary data concerning safety and efficacy of proposed products using carefully designed human pilot studies. We will require sponsored work to be conducted in compliance with pertinent local and international regulatory requirements, including those providing for Institutional Review Board approval, national governing agency approval and patient informed consent, using protocols consistent with ethical principles stated in the Declaration of Helsinki and other internationally recognized standards. We expect any pilot studies to be conducted outside the United States; but if any are conducted in the United States, they will comply with applicable FDA regulations. Data obtained through pilot studies will allow us to make more informed decisions concerning possible expansion into traditional FDA-regulated clinical trials.

If the FDA is satisfied with the results and data from preclinical tests, it will authorize human clinical trials. Human clinical trials typically are conducted in three sequential phases which may overlap. Each of the three phases involves testing and study of specific aspects of the effects of the pharmaceutical on human subjects, including testing for safety, dosage tolerance, side effects, absorption, metabolism, distribution, excretion and clinical efficacy.

Phase 1 clinical trials include the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. While the FDA can cause us to end clinical trials at any phase due to safety concerns, phase 1 clinical trials are primarily concerned with safety issues. We also attempt to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects during phase 1 clinical trial to permit the design of well-controlled, scientifically valid, phase 2 studies.

Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

Phase 2 clinical trials include the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

Applicable medical devices can be cleared for commercial distribution through a notification to the FDA under Section 510(k) of the applicable statute. The 510(k) notification must demonstrate to the FDA that the device is as safe and effective and substantially equivalent to a legally marketed or classified device that is currently in interstate commerce. Such devices may not require detailed testing. Certain high-risk devices that sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury, are subject to a more comprehensive FDA approval process initiated by filing a premarket approval, also known as a PMA, application (for devices) or accelerated approval (for drugs).

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We have established a core clinical development team and have been working with outside FDA consultants to assist us in developing product-specific development and approval strategies, preparing the required submittals, guiding us through the regulatory process, and providing input to the design and site selection of human clinical studies. Historically, obtaining FDA approval for photodynamic therapies has been a challenge. Wherever possible, we intend to utilize lasers or other activating systems that have been previously approved by the FDA to mitigate the risk that our therapies will not be approved by the FDA. The FDA has considerable experience with lasers by virtue of having reviewed and acted upon many 510(k) and premarket approval filings submitted to it for various photodynamic and non-photodynamic therapy laser applications, including a large number of cosmetic laser treatment systems used by dermatologists.

The testing and approval process requires substantial time, effort, and financial resources, and we may not obtain FDA approval on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. The FDA or the research institution sponsoring the trials may suspend clinical trials or may not permit trials to advance from one phase to another at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Once issued, the FDA may withdraw a product approval if we do not comply with pertinent regulatory requirements and standards or if problems occur after the product reaches the market. If the FDA grants approval of a product, the approval may impose limitations, including limits on the indicated uses for which we may market a product. In addition, the FDA may require additional testing and surveillance programs to monitor the safety and/or effectiveness of approved products that have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Further, later discovery of previously unknown problems with a product may result in restrictions on the product, including its withdrawal from the market.

Marketing our products abroad will require similar regulatory approvals by equivalent national authorities and is subject to similar risks. To expedite development, we may pursue some or all of our initial clinical testing and approval activities outside the United States, and in particular in those nations where our products may have substantial medical and commercial relevance. In some such cases, any resulting products may be brought to the U.S. after substantial offshore experience is gained. Accordingly, we intend to pursue any such development in a manner consistent with U.S. standards so that the resultant development data is maximally applicable for potential FDA approval.

OTC products are subject to regulation by the FDA and similar regulatory agencies, but the regulations relating to these products are much less stringent than those relating to prescription drugs and medical devices. The types of OTC products developed and previously sold by us only require that we follow cosmetic rules relating to labeling and the claims that we make about our product. The process for obtaining approval of prescription drugs with the FDA does not apply to the OTC products, which we have sold. The FDA can, however, require us to stop selling our product if we fail to comply with the rules applicable to our OTC products.

## **Employees**

Effective on February 27, 2016, the effective date of the resignation of H. Craig Dees, Ph.D., as our Chief Executive Officer and Chairman of the Board of Directors, we employ three persons, all of whom are full-time employees. We currently engage four full-time consultants, including a lab technician, a contract research associate, an analytical chemist, and an information technology consultant. We also work with various vendors and disclose on our corporate website that we currently have human resources focused on our activities that equate to sixty (60) full-time equivalents, including our seven full-time employees and consultants.

Our executive officers and directors are:

Timothy C. Scott, Ph.D., 57, has served as our President and as a member of our board of directors since we acquired PPI on April 23, 2002. Prior to joining us, Dr. Scott was a senior member of the Photogen management team from 1997 to 2002, including serving as Photogen's Chief Operating Officer from 1999 to 2002, as a director of Photogen from 1997 to 2000, and as interim CEO for a period in 2000. Before joining Photogen, he served as senior management of Genase LLC, a developer of enzymes for fabric treatment and held senior research and management positions at Oak Ridge National Laboratory. Dr. Scott earned a Ph.D. in Chemical Engineering from the University of Wisconsin - Madison in 1985.

Eric A. Wachter, Ph.D., 53, currently serves as our Chief Technology Officer since May 14, 2012 and prior to that served as Executive Vice President - Pharmaceuticals and as a member of our board of directors since we acquired PPI on April 23, 2002 until May 14, 2012. Prior to joining us, from 1997 to 2002 he was a senior member of the management team of Photogen, including serving as Secretary and a director of Photogen since 1997 and as Vice President and Secretary and a director of Photogen since 1999. Prior to joining Photogen, Dr. Wachter served as a senior research staff member with Oak Ridge National Laboratory. He earned a Ph.D. in Chemistry from the University of Wisconsin - Madison in 1988.



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Peter R. Culpepper, 56, serves as our Interim Chief Executive Officer effective as of February 27, 2016, and also serves as our Chief Financial Officer and Chief Operating Officer since February 2004. Previously, Mr. Culpepper served as Chief Financial Officer for Felix Culpepper International, Inc. from 2001 to 2004; was a Registered Representative with AXA Advisors, LLC from 2002 to 2003; has served as Chief Accounting Officer and Corporate Controller for Neptec, Inc. from 2000 to 2001; has served in various Senior Director positions with Metromedia Affiliated Companies from 1998 to 2000; has served in various Senior Director and other financial positions with Paging Network, Inc. from 1993 to 1998; and has served in a variety of financial roles in public accounting and industry from 1982 to 1993. He earned a Masters in Business Administration in Finance from the University of Maryland College Park in 1992. He earned an AAS in Accounting from the Northern Virginia Community College Annandale, Virginia in 1985. He earned a B.A. in Philosophy from the College of William and Mary Williamsburg, Virginia in 1982. He is a licensed Certified Public Accountant in both Tennessee and Maryland.

### **Equity Issuances and Financing During 2015**

During the three months ended March 31, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$64,000. During the three months ended March 31, 2015, the Company issued 3,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$1,632. During the three months ended March 31, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$776,000. The Company received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended June 30, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$63,000. During the three months ended June 30, 2015, the Company issued 100,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$53,582. During the three months ended June 30, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,011,100. The Company received subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended September 30, 2015, the Company issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$38,439. During the three months ended September 30, 2015, the Company issued 79,500 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$24,262.

During the three months ended December 31, 2015, the Company issued 76,750 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$37,375. During the three months ended December 31, 2015, the Company issued 1,766,202 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$472,882.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(a)(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

On June 24, 2015, the Company completed a public offering of common stock and warrants for gross proceeds of \$13,151,250 (the Offering). The Offering consisted of 17,500,000 shares of common stock and warrants to purchase 17,500,000 shares of common stock with a public offering price of \$0.75 for a fixed combination of one share of common stock and a warrant to purchase one share of common stock. Investors received five year fully vested warrants to purchase up to 100% of the number of shares purchased by the investors in the Offering. The warrants have an exercise price of \$0.85 per share. At the closing, the underwriters exercised their over-allotment option with respect to warrants to purchase up to an additional 2,625,000 shares of common stock at \$0.01 per warrant. The warrants issued in the Offering began trading on the NYSE MKT on June 22, 2015, under the ticker symbol PVCTWS. As of June 30, 2015, 20,125,000 tradable warrants are outstanding. The Company plans to use the proceeds of the Offering for clinical development, working capital and general corporate purposes. Maxim Group LLC acted as sole book-running manager for the Offering. In connection with the Offering, the Company paid \$1,052,100 to Maxim Group LLC.

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**Recent Developments**

*Leadership Changes*

On February 29, 2016, the Company announced the resignation of H. Craig Dees, PhD, as Chief Executive Officer and Chairman of the Board of Directors of the Company, effective immediately. Dr. Dees resigned for personal and health reasons. On February 29, 2016, the Company also announced that the Board of Directors appointed Peter R. Culpepper, the Company's current Chief Financial Officer and Chief Operating Officer, to serve as Interim Chief Executive Officer effective immediately, and is expected to serve as the Interim Chief Executive Officer until the Board of Directors completes its search process for a successor Chief Executive Officer. The Board of Directors is also searching for an Interim Chief Financial Officer to support Mr. Culpepper with respect to the responsibilities associated with the Chief Financial Officer role until a successor Chief Executive Officer is named.

On February 27, 2016, the Board of Directors appointed Eric Wachter, the Company's Chief Technology Officer, to serve as a director on the Company's Board of Directors, to fill the vacancy on the Board of Directors caused by Dr. Dees's resignation. Dr. Wachter will stand for election by the Company's stockholders at the Company's Annual Meeting of Stockholders in June 2016. Dr. Wachter has not been appointed to serve on any committees of the Board of Directors at this time. The Board of Directors appointed Alfred E. Smith, IV, the lead independent director on the Board of Directors, to replace Dr. Dees as Chairman of the Board of Directors. For more information about these changes in management and the composition of the Company's Board of Directors, see the Company's Current Report on Form 8-K filed with the SEC on February 29, 2016.

Under the terms of the Amended and Restated Executive Employment Agreement entered into by Craig Dees and the Company on April 28, 2014 (the "Agreement"), Dr. Dees is owed no severance payments as a result of his resignation as the Company's Chief Executive Officer and Chairman of the Board of Directors. Dr. Dees's employment terminated with his resignation without "Good Reason" as that term is defined in the Agreement. Under section 6 of the Agreement, "Effect of Termination," a resignation by Dr. Dees without "Good Reason" terminates any payments due to Dr. Dees as of the last day of his employment. As reported in the Company's press release furnished with the Company's Current Report on Form 8-K filed with the Commission on February 29, 2016, in connection with the resignation of Dr. Dees as the Company's Chief Executive Officer and Chairman of the Board of Directors, which was effective February 27, 2016, the Audit Committee conducted a review of Company procedures, policies and practices, including travel expense advancements and reimbursements. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. On March 15, 2016, the Audit Committee completed this investigation and made the following findings: (1) in 2015, Dr. Dees received \$898,430 in travel expense advances but submitted receipts totaling only \$297,170, most of which did not appear to be authentic; (2) in 2014, Dr. Dees received \$819,000 for travel expense advances, for which no receipts were submitted; and (3) in 2013, Dr. Dees received \$752,034 for travel expense advances; no receipts were submitted by Dr. Dees for \$698,000 of these expenses and \$54,034 of submitted receipts did not appear to be authentic. The Company intends to pursue collection efforts on all of Dr. Dees's unsubstantiated travel expenses, including those which did not appear to be authentic. The Company treats all relevant travel expenses of Dr. Dees as a theft loss and therefore any uncollectible amounts will be treated as income to Dr. Dees and a Form 1099-MISC will be issued by the Company to him in that regard.

*Warrant Exchange Offer*

In the first quarter of 2016 the Company offered to certain of its holders of outstanding warrants the opportunity to receive new warrants expiring June 19, 2020 upon the exercise of their warrants (the "Exchange Offer" or the "Offer"). The Offer was made to certain holders of our warrants to purchase shares of common stock, \$0.001 par value per

share ( Common Stock ), issued between January 6, 2011 and November 1, 2015 (the Existing Warrants ) in transactions exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act ). The Offer temporarily modified the terms of such Existing Warrants so that each holder who tenders Existing Warrants during the Offer Period (as defined below) for early exercise were able to do so at a discounted exercise price of \$0.50 per share (Existing Warrants currently have exercise prices ranging between \$1.00 and \$3.00 per share). The Exchange Offer expired at 4:00 P.M. (Eastern time) on Monday, March 28, 2016 (see Note 10 to the financial statements). 7,798,507 Existing Warrants were tendered in the Exchange Offer.

### **Available Information**

Our website is located at [www.pvct.com](http://www.pvct.com). We make available free of charge through this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Reference to our website does not constitute incorporation by reference of the information contained on the site and should not be considered part of this document.

All filings made by us with the SEC may be copied or read at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC as we do. The website is <http://www.sec.gov>.

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**ITEM 1A. RISK FACTORS.**

Our business and its future performance may be affected by various factors, the most significant of which are discussed below.

*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, 2015, we have incurred net losses of \$181 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 2017 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 2017. However, we may need additional capital in 2017 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 continue to be developed. We potentially may license PV-10 depending on the timing for the optimal deal structure for our stockholders. We are also focusing on PV-10 geographic

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licensing and partnering opportunities in such countries as China and India. We are also focusing on potential co-development partnering opportunities with combination of PV-10 and immune checkpoint blockade or systemic immunotherapy agents. 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 licensure of PH-10 and PV-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 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;

impose costly procedures on us; and

diminish any competitive advantages that we may otherwise enjoy.



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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.

***We are subject to securities class action lawsuits and shareholder derivative lawsuits that could adversely affect our business. This litigation, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.***

Beginning on May 27, 2014, three putative securities class action lawsuits (the Federal Class Actions) were commenced in the United States District Court for the Middle District of Tennessee against us, and H. Craig Dees, Timothy C. Scott and Peter R. Culpepper, (the Defendants), alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The Federal Class Actions allege, among other things, that the defendants made false and materially misleading statements and failed to disclose material information regarding our application to the FDA for BTM of PV-10.

On July 9, 2014, the Company and the Federal Class Action plaintiffs filed joint motions to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee consolidated the Federal Class Actions and transferred them to the United States District Court for the Eastern District of Tennessee. Since the consolidation and transfer of the Federal Class Actions, several shareholders have filed motions seeking their appointment as the Lead Plaintiff to direct the class action litigation. The United States District Court for the Eastern District of Tennessee scheduled a hearing for November 11, 2014 to determine which shareholder should be appointed Lead Plaintiff.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint) in the Class Action Case, alleging that the Defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTM, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

On June 5, 2015, the Defendants filed their Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response). Pursuant to order of the Court, the Defendants replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions between the parties continued. On January 28, 2016, a settlement terms sheet (the Terms Sheet ) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Federal Class Actions.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Federal Class Actions, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier will pay the total amount of \$3.5 Million (the Settlement Funds ) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Federal Class Actions (see Note 9 to the financial statements). Notice will be provided to shareholder members of the class. Shareholder members of the

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class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Federal Class Actions will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Federal Class Actions and the Federal Class Actions will be fully concluded. If the court does not give final approval of the Settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the Settlement and procedures for preliminary and final court approval was filed in the Federal Class Action on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and provides for the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Federal Class Action. The court in the Federal Class Action has set April 7, 2016 for a hearing on preliminary settlement approval. If the Settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

In addition, on June 4, 2014, a shareholder derivative lawsuit captioned *Hurtado v. Provectus Biopharmaceuticals, Inc., et al.* was filed derivatively on behalf of the Company against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant in the United States District Court for the Middle District of Tennessee (the Hurtado Shareholder Derivative Lawsuit). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties, and (ii) abuse of control, both claims based on the Plaintiff's allegations that the Individual Defendants recklessly permitted the Company to disclose false and misleading information and failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the Hurtado Shareholder Derivative Lawsuit to the United States District Court for the Eastern District of Tennessee and, in light of the pending Federal Class Actions, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee.

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit) against the Individual Defendants. Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy's allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that PV-10 would qualify for BTB.

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Individual Defendants and against the Company as a nominal defendant (the Foley Shareholder Derivative Lawsuit). The Foley Shareholder Derivative Lawsuit asserts the exact same facts and legal claims as the Montiminy Shareholder Derivative Lawsuit.

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Individual Defendants, and against the Company as a nominal defendant (the Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. (the Hurtado

Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit, the Foley Shareholder Derivative Lawsuit and the Donato Shareholder Derivative Lawsuit are collectively referred to as the Shareholder Derivative Lawsuits ).

In each of the four Shareholder Derivative Lawsuits, the Company is a nominal defendant only. As such, the plaintiffs seek relief from the Individual Defendants, but not the Company itself. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company's purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. Discussions are underway to resolve the Shareholder Derivative Lawsuits.

We believe that the resolution of these suits will not result in a material adverse effect to our consolidated financial statements. However, due to the inherent uncertainties that accompany litigation of this nature, there can be no assurance that we will be successful, and an adverse resolution of any of the lawsuits could have a material adverse effect on our consolidated financial statements. Furthermore, these actions may divert management's time and attention from our business, and we could be forced to expend significant resources and pay significant costs and expenses, including legal fees, in connection with defending the lawsuits.

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***Our former Chief Executive Officer and Chairman of the Board of Directors received travel expense advancements, which may be deemed a violation of Section 402 of the Sarbanes-Oxley Act of 2002 and/or other federal securities laws.***

Our internal control testing identified inadequate supporting documentation and lack of adequate review for the travel advances and expense reimbursements.

The Audit Committee conducted a review of Company procedures, policies and practices, including travel expense advancements and reimbursements to Dr. Dees. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. As part of the investigation, the Committee reviewed the Company's financial policies and procedures, including management expenses. The Audit Committee concluded that Dr. Dees did not produce receipts for most of the travel expense advances he received from 2013 to 2015, and that some receipts produced by Dr. Dees during this period appear to have been altered.

Section 402 of the Sarbanes Oxley Act of 2002 prohibits personal loans to a director or executive officer of a public company. If the SEC were to commence an investigation or institute proceedings to enforce a violation of this statute or other federal securities laws as a result of the travel advances to Dr. Dees, we may become a party to litigation or proceedings over these matters, and the outcome of such litigation or proceedings (including criminal, civil or administrative sanctions or penalties by the SEC), alone or in addition to the costs of litigation, may materially and adversely affect our business. The Company is unable to predict the extent of its ultimate liability with respect to the advances to Dr. Dees.

***We have identified a material weakness in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. We cannot assure you that additional material weaknesses or significant deficiencies do not exist or that they will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Based on the results of management's assessment and evaluation of our internal controls, our principal executive officer and principal financial officer concluded that our internal control over financial reporting was not effective due to the material weakness described below.

The Company has identified the following material weakness related to its travel expense advancement and reimbursement policies and procedures to Dr. Dees: (1) the documentation provided for an expenditure was not sufficient to support the authorization of such expenditure, (2) only the check register and not the supporting documentation was obtained by an executive officer approving the expenses incurred by another executive officer, and (3) there was not adequate reconciliation of travel advances to actual expenses. As a result, our management also has concluded that our disclosure controls and procedures are not effective such that the information relating to our Company required to be disclosed in the reports we file with the SEC (a) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

If we do not successfully remediate the material weakness described above, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results on a timely basis or prevent

fraud, which could cause our reported financial results to be materially misstated and require restatement which could result in the loss of investor confidence, delisting or cause the market price of our common stock to decline.

***We did not obtain and may not obtain or maintain the benefits associated with breakthrough therapy designation.***

On March 21, 2014, we submitted a request for breakthrough therapy designation (BTD) to the FDA for PV-10 in the treatment of metastatic melanoma in the United States. The FDA denied the request in May 2014, but stated that a new request may be submitted if we obtain new clinical evidence that supports BTD. Accordingly, we are not entitled to the benefits of BTD, including expedited development and review of PV-10 in the treatment of melanoma.

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If we resubmit such request for BTM, we may not be granted BTM, or even if granted, we may not receive the benefits associated with BTM. This may result from a failure to maintain breakthrough therapy status if PV-10 is no longer considered to be a breakthrough therapy. For example, a drug's development program may be granted BTM using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where BTM is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When BTM is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a BTM program.

***We depend on the successful completion of clinical trials for our product candidates, including PV-10. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.***

Before obtaining regulatory approval for the sale of our product candidates, including PV-10, we must conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

In October 2012, we presented final top-line data from the phase 2 trial of PV-10 for metastatic melanoma, and in March 2014, applied for BTM with the FDA, which was subsequently denied pending new clinical evidence that supports BTM. We (i) are conducting an expanded phase 1 trial for PV-10 for metastatic liver cancer, which is expected to be completed in early 2015; (ii) have completed a phase 1 clinical study for PV-10 for recurrent breast cancer; (iii) are conducting a phase 1 trial for PV-10 in an investigator initial study to ascertain the feasibility of detecting immune cell infiltrates in injected melanoma tumors which is expected to be completed in early 2015; (iv) are conducting a phase 2 clinical trial for mechanism of action of PH-10 for psoriasis; (v) have completed multiple phase 2 clinical trials for PH-10 for psoriasis and atopic dermatitis; and (vi) expect to commence a phase 3 clinical trial to assess response to intralesional PV-10 versus that of systemic chemotherapy in patients with disease confined to cutaneous and subcutaneous sites. Meetings with scientific advisors, investigators and advocates in the field have led us to expect a starting date for the phase 3 clinical study sometime in the first quarter of 2015. However, we have never conducted a phase 3 clinical trial. The positive results we have seen to date in our phase 2 clinical trials of PV-10 for metastatic melanoma do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in phase 3 clinical development; even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during clinical trials for our product candidates, including PV-10, that could delay or prevent the commencement and/or completion of our clinical trials, including the following:

regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

the clinical study protocol may require one or more amendments delaying study completion;

clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;

clinical investigators or study subjects fail to comply with clinical study protocols;

trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling errors;

our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;



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we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

the cost of clinical trials of our product candidates may be greater than we anticipate;

the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we commence a phase 3 clinical trial with respect to PV-10 as planned, and undertake additional clinical trials of our other product candidates. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development; however, we believe we have sufficient cash on hand to fund the planned phase 3 clinical trial with respect to PV-10.

Negative or inconclusive results of our future clinical trials of PV-10, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for PV-10, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including PV-10. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including PV-10, may be adversely impacted.

***Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval.***

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials for PV-10, include the following:

inability to raise funding, if necessary, to initiate or continue a trial;

delays in obtaining regulatory approval to commence a trial;

delays in reaching agreement with the FDA on final trial design;

imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;

delays in obtaining required institutional review board (IRB) approval at each site;

delays in recruiting suitable patients to participate in a trial;

delays in having subjects complete participation in a trial or return for post-treatment follow-up;

delays caused by subjects dropping out of a trial due to side effects or otherwise;

delays caused by clinical sites dropping out of a trial;

time required to add new clinical sites; and

delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

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If initiation or completion of any of our clinical trials for our product candidates, including PV-10, are delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

### ***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.

***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 healthcare 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

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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 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;

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.

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***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.

***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.

***The resignation of our Chief Executive Officer and Chairman of the Board of Directors, the appointment of our Interim Chief Executive Officer and any search for, and appointment of, a long-term Chief Executive Officer and an Interim Chief Financial Officer creates uncertainties and could have a material adverse impact on our business.***

Effective February 27, 2016, Dr. Dees resigned as Chief Executive Officer and Chairman of the Board of Directors. Mr. Culpepper, our current Chief Financial Officer and Chief Operating Officer, was appointed to serve as our Interim Chief Executive Officer until our Board of Directors completes its search process for a successor Chief Executive Officer to replace Dr. Dees. Our Board of Directors is also searching for an Interim Chief Financial Officer to support Mr. Culpepper with respect to the responsibilities associated with the Chief Financial Officer role until a successor Chief Executive Officer is named. We face significant competition for executives with the qualifications and experience we are seeking. There can be no assurances concerning the timing or outcome of the Company's search for

a new permanent Chief Executive Officer and Interim Chief Financial Officer. The Company's ability to execute its business strategies may be adversely affected by the uncertainty associated with this transition.

Executive leadership transitions can be inherently difficult to manage and may cause disruption to our business. As a result of the recent changes in our management team, our existing management team has taken on substantially more responsibility, which has resulted in greater workload demands and could divert their attention away from certain key areas of our business. In addition, management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution, and our results of operations and financial condition could suffer as a result. The loss of services of one or more other members of senior management, or the inability to attract a qualified permanent Chief Executive Officer and/or Interim Chief Financial Officer, could have a material adverse effect on our business.



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

Our business is presently managed by three key employees:

Peter R. Culpepper, CPA, MBA, our Interim Chief Executive Officer, Chief Financial Officer and Chief Operating Officer;

Timothy C. Scott, Ph.D., our President; and

Eric A. Wachter, Ph.D. our Chief Technology Officer.

In addition to their responsibilities for management of our overall business strategy, Drs. 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 three 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 three employees, all of whom are full-time employees. The greatest burden of succeeding in the above areas, therefore, falls on Drs. Scott and 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 have added, including our

employees, a total of sixty (60) human resources on a full-time equivalent basis. 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.

***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 \$0.30 per share and as high as \$6.03 per share during the period beginning on January 1, 2014 and ending on December 31, 2015. 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 NYSE MKT, 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.

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***Our 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.

***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 recent 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We currently lease approximately 6,000 square feet of space outside of Knoxville, Tennessee for our corporate office and operations. Our monthly rental charge for these offices is approximately \$5,000 per month, and the lease is on an annual basis, renewable for one year at our option. We have a lease commitment of \$0 as of December 31, 2015. We believe that these offices generally are adequate for our needs currently and in the immediate future.

**ITEM 3. LEGAL PROCEEDINGS.**

Except as described below, we are not involved in any legal proceedings nor are we party to any pending claims that we believe could reasonably be expected to have a material adverse effect on our business, financial condition, or results of operations.

*Kleba Shareholder Derivative Lawsuit*

On January 2, 2013, Glenn Kleba, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against H. Craig Dees, Timothy C. Scott, Eric A. Wachter, and Peter R. Culpepper (collectively, the Executives), Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, together with the Executives, the Individual Defendants), and against the Company as a nominal defendant (the Shareholder Derivative Lawsuit). The Shareholder Derivative Lawsuit alleged (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on Mr. Kleba's allegations that the

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defendants authorized and/or accepted stock option awards in violation of the terms of the Company's 2002 Stock Plan (the Plan) by issuing stock options in excess of the amounts authorized under the Plan and delegated to defendant H. Craig Dees the sole authority to grant himself and the other Executives cash bonuses that Mr. Kleba alleges to be excessive.

In April 2013, the Company's Board of Directors appointed a special litigation committee to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee conducted its investigation, and proceedings in the case were stayed pending the conclusion of the committee's investigation. The Company has established a reserve of \$100,000 for potential liabilities because such is the amount of the self-insured retention of its insurance policy. On February 21, 2014, an Amended Shareholder Derivative Complaint was filed which added Don B. Dale (Mr. Dale) as a plaintiff.

On March 6, 2014, the Company filed a Joint Notice of Settlement (the Notice of Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Notice of Settlement are Mr. Kleba, Mr. Dale and the Individual Defendants.

On June 6, 2014, the Company, in its capacity as a nominal defendant, entered into a Stipulated Settlement Agreement and Mutual Release (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company and the Individual Defendants, Plaintiffs Glenn Kleba and Don B. Dale are parties to the Settlement.

By entering into the Settlement, the settling parties have resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the settling plaintiffs have not admitted that any claims or allegations lack merit or foundation. Under the terms of the Settlement, (i) the Executives each agreed (A) to re-pay to the Company \$2.24 Million of the cash bonuses they each received in 2010 and 2011, which amount equals 70% of such bonuses or an estimate of the after-tax net proceeds to each Executive; provided, however, that subject to certain terms and conditions set forth in the Settlement, the Executives are entitled to a 2:1 credit such that total actual repayment may be \$1.12 Million each; (B) to reimburse the Company for 25% of the actual costs, net of recovery from any other source, incurred by the Company as a result of the Shareholder Derivative Lawsuit; and (C) to grant to the Company a first priority security interest in 1,000,000 shares of the Company's common stock owned by each such Executive to serve as collateral for the amounts due to the Company under the Settlement; (ii) Drs. Dees and Scott and Mr. Culpepper agreed to retain incentive stock options for 100,000 shares but shall forfeit 50% of the nonqualified stock options granted to each such Executive in both 2010 and 2011. The Settlement also requires that each of the Executives enter into new employment agreements with the Company, which were entered into on April 28, 2014, and that the Company adhere to certain corporate governance principles and processes in the future. Under the Settlement, Messrs. Fuchs and Smith and Dr. McMasters have each agreed to pay the Company \$25,000 in cash, subject to reduction by such amount that the Company's insurance carrier pays to the Company on behalf of such defendant pursuant to such defendant's directors and officers liability insurance policy. The Settlement also provides for an award to plaintiffs' counsel of attorneys' fees and reimbursement of expenses in connection with their role in this litigation, subject to Court approval.

On July 24, 2014, the Court approved the terms of the proposed Settlement and awarded \$911,000 to plaintiffs' counsel for attorneys' fees and reimbursement of expenses in connection with their role in the Shareholder Derivative Lawsuit. The payment to plaintiff's counsel was made by the Company during October 2014 and was recorded as other current assets at December 31, 2014. The Company is seeking reimbursement of the full amount from insurance and if the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants. The amount was reclassified to long-term receivable at December 31, 2015. A reserve for uncollectibility of \$227,750 was established at December 31, 2015 in connection with the resignation of Dr. Dees.

On October 3, 2014, the Settlement was effective and stock options for Drs. Dees and Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$900,000 was repaid by the Executives as of December 31, 2015. The first year payment due has been paid. The remaining cash settlement amounts will continue to be repaid to the Company over a period of four years with the second payment due in total by October 2016 and the final payment is expected to be received by October 3, 2019. \$103,969 of the settlement discount was amortized as of December 31, 2015. The remaining balance due the Company as of December 31, 2015 is \$2,511,735, including a reserve for uncollectibility of \$870,578 in connection with the resignation of Dr. Dees, with a present value discount remaining of \$197,686. As a result of his resignation, Dr. Dees is no longer entitled to the 2:1 credit, such that his total repayment obligation of \$2,040,000 (the total \$2.24 million owed by Dr. Dees pursuant to the Settlement less the \$200,000 that he repaid as of December 31, 2015) plus Dr. Dees' proportionate share of the litigation costs is immediately due and payable. The Company sent Dr. Dees a notice of default in March 2016 for the total amount he owes the Company.

*Class Action Lawsuits*

On May 27, 2014, Cary Farrah and James H. Harrison, Jr., individually and on behalf of all others similarly situated (the Farrah Case ), and on May 29, 2014, each of Paul Jason Chaney, individually and on behalf of all others similarly situated (the Chaney Case ), and Jayson Dauphinee, individually and on behalf of all others similarly situated (the Dauphinee

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Case ) (the plaintiffs in the Farrah Case, the Chaney Case and the Dauphinee Case collectively referred to as the Plaintiffs ), each filed a class action lawsuit in the United States District Court for the Middle District of Tennessee against the Company, H. Craig Dees, Timothy C. Scott and Peter R. Culpepper (the Defendants ) alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and seeking monetary damages. Specifically, the Plaintiffs in each of the Farrah Case, the Chaney Case and the Dauphinee Case allege that the Defendants are liable for making false statements and failing to disclose adverse facts known to them about the Company, in connection with the Company s application to the FDA for Breakthrough Therapy Designation ( BTD ) of the Company s melanoma drug, PV-10, in the Spring of 2014, and the FDA s subsequent denial of the Company s application for BTD.

On July 9, 2014, the Plaintiffs and the Defendants filed joint motions in the Farrah Case, the Chaney Case and the Dauphinee Case to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered an order consolidating the Farrah Case, the Chaney Case and the Dauphinee Case (collectively and, as consolidated, the Securities Litigation ) and transferred the Securities Litigation to the United States District Court for the Eastern District of Tennessee.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint ) in the Class Action Case, alleging that Provectus and the other individual defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTD, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

On June 5, 2015, Provectus filed its Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss ). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response ). Pursuant to order of the Court, Provectus replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions are continuing. On January 28, 2016, a settlement terms sheet (the Terms Sheet ) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Federal Class Actions.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Federal Class Actions, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier will pay the total amount of \$3.5 Million (the Settlement Funds ) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Federal Class Actions (see Note 9 to the financial statements). Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Federal Class Actions will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Federal Class Actions and the Federal Class Actions will be fully concluded. If the court does not give final approval of the Settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the Settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and provides for the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Federal Class Action. The court in the Federal Class Action has set April 7, 2016 for a hearing on preliminary settlement approval. If the Settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.



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### *Hurtado Shareholder Derivative Lawsuit*

On June 4, 2014, Karla Hurtado, derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ), and against the Company as a nominal defendant (the Hurtado Shareholder Derivative Lawsuit ). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) abuse of control, both claims based on Ms. Hurtado s allegations that the Individual Defendants (a) recklessly permitted the Company to make false and misleading disclosures and (b) failed to implement adequate controls and procedures to ensure the accuracy of the Company s disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the case to the United States District Court for the Eastern District of Tennessee and, in light of the pending Securities Litigation, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado Shareholder Derivative Lawsuit pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado Shareholder Derivative Lawsuit.

### *Montiminy Shareholder Derivative Lawsuit*

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit ) against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ). Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy s allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that the Company s melanoma drug, PV-10, would qualify for BTM. As a practical matter, the factual allegations and requested relief in the Montiminy Shareholder Derivative Lawsuit are substantively the same as those in the Hurtado Shareholder Derivative Lawsuit.

On December 29, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order consolidating the Hurtado Shareholder Derivative Lawsuit and the Montiminy Derivative Lawsuit. On February 25, 2015, the parties submitted a proposed agreed order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits until the Court issues a ruling on the anticipated motion to dismiss the amended consolidated complaint to be filed in the Securities Litigation. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado Shareholder Derivative Lawsuit, no relief is sought against the Company itself; the action is against the Individual Defendants only.

### *Foley Shareholder Derivative Complaint*

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M.

McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ), and against the Company as a nominal defendant (the Foley Shareholder Derivative Lawsuit ). The Foley Shareholder Derivative Lawsuit was brought by the same attorney as the Montiminy Shareholder Derivative Lawsuit, Paul Kent Bramlett of Bramlett Law Offices. Other than the difference in the named plaintiff, the complaints in the Foley Shareholder Derivative Lawsuit and the Montiminy Shareholder Derivative Lawsuit are identical. On March 6, 2015, the Chancery Court of Knox County, Tennessee entered an Order staying the Foley Derivative Lawsuit until the United States District Court for the Eastern District of Tennessee issues a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

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As in the Hurtado and Montiminy Shareholder Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

*Donato Shareholder Derivative Lawsuit*

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against H. Craig Dees, Timothy C. Scott, Jan. E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company's purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. We are not in a position at this time to give you an evaluation of the likelihood of an unfavorable outcome, or an estimate of the amount or range of potential loss to the Company.

As in the Hurtado, Montiminy and Foley Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.****Market Information and Holders**

On May 16, 2014, our common stock ceased to be traded on the OTCQB Marketplace operated by OTC Markets Group and is now trading on the NYSE MKT. Our trading symbol remains PVCT. The following table sets forth the range of high and low sale prices of our common stock for the periods indicated since January 1, 2014:

|   | <b>High</b> | <b>Low</b> |
|---|-------------|------------|
| <b>2015</b>                               |             |            |
| First Quarter (January 1 to March 31)     | \$ 0.93     | \$ 0.76    |
| Second Quarter (April 1 to June 30)       | \$ 0.99     | \$ 0.49    |
| Third Quarter (July 1 to September 30)    | \$ 0.70     | \$ 0.32    |
| Fourth Quarter (October 1 to December 31) | \$ 0.60     | \$ 0.36    |
| <b>2014</b>                               |             |            |
| First Quarter (January 1 to March 31)     | \$ 6.03     | \$ 1.16    |
| Second Quarter (April 1 to June 30)       | \$ 3.75     | \$ 0.30    |
| Third Quarter (July 1 to September 30)    | \$ 1.20     | \$ 0.81    |
| Fourth Quarter (October 1 to December 31) | \$ 1.10     | \$ 0.75    |

The closing price for our common stock on March 24, 2016 was \$0.38. High and low sale price information was obtained from data provided by Yahoo! Inc.

As of March 24, 2016, we had 982 stockholders of record of our common stock.

**Dividend Policy**

We have never declared or paid any cash dividends on our capital stock. We currently plan to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. We may incur indebtedness in the future which may prohibit or effectively restrict the payment of dividends, although we have no current plans to do so. Any future determination to pay cash dividends will be at the discretion of our board of directors.

**Table of Contents****Stock Performance Graph**

The following graph shows the changes, over the past five-year period, in the value of \$100 invested in Provectus common stock, the NASDAQ Composite Total Return Index and a Peer group of companies composed of development stage, biopharmaceutical companies that have a focus on developing oncology compounds. The graph assumes that all dividends are reinvested.

|                                    | 2010      | 2011     | 2012      | 2013      | 2014      | 2015      |
|------------------------------------|-----------|----------|-----------|-----------|-----------|-----------|
| Provectus Biopharmaceuticals, Inc. | \$ 100.00 | \$ 86.17 | \$ 59.57  | \$ 256.38 | \$ 85.11  | \$ 41.49  |
| NASDAQ Composite-Total Returns     | \$ 100.00 | \$ 99.17 | \$ 116.48 | \$ 163.21 | \$ 187.27 | \$ 200.31 |
| New Peer Group                     | \$ 100.00 | \$ 82.42 | \$ 88.26  | \$ 92.99  | \$ 81.83  | \$ 51.56  |
| Old Peer Group                     | \$ 100.00 | \$ 92.57 | \$ 106.18 | \$ 91.63  | \$ 85.11  | \$ 134.22 |

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### **Recent Issuances of Unregistered Securities**

During the three months ended March 31, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$64,000. During the three months ended March 31, 2015, the Company issued 3,000 fully vested warrants to consultants in exchange for services with an exercise price of \$1.00 for each of the warrants. Consulting costs charged to operations were \$1,632. During the three months ended March 31, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$776,000. The Company received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended June 30, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$63,000. During the three months ended June 30, 2015, the Company issued 100,000 fully vested warrants to consultants in exchange for services with an exercise price of \$1.00 for each of the warrants. Consulting costs charged to operations were \$53,582. During the three months ended June 30, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,011,100. The Company received subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended September 30, 2015, the Company issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$38,439. During the three months ended September 30, 2015, the Company issued 79,500 fully vested warrants to consultants in exchange for services with an exercise price of \$1.00 for each of the warrants. Consulting costs charged to operations were \$24,262.

During the three months ended December 31, 2015, the Company issued 76,750 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$37,375. During the three months ended December 31, 2015, the Company issued 1,513,702 fully vested warrants to consultants in exchange for services with an exercise price of \$1.00 for each of the warrants and 252,500 fully vested warrants to consultants in exchange for services with an exercise price of \$1.12 for each of the warrants. Consulting costs charged to operations were \$472,882.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(a)(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

For the issuance of securities to executives, see table labeled **Equity Compensation Plan Information** to be contained in the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act, incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

**ITEM 6. SELECTED FINANCIAL DATA.**

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2015 and 2014, as well as consolidated statements of

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operations for the years ended December 31, 2015, 2014, and 2013, and the report thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with our audited consolidated financial statements (and notes thereon) and Management's Discussion and Analysis of Financial Condition and Results of Operations, included below in Item 7.

|  | Years ended December 31,                         |             |             |             |             |
|--|--|-------------|-------------|-------------|-------------|
|  | 2015   | 2014        | 2013        | 2012        | 2011        |
|  | (all amounts in thousands except per share data) |             |             |             |             |
| <b>Consolidated Statement of Operations Data:</b>                      |  |             |             |             |             |
| Gain on settlement net of discount                                     | \$   | \$          | 4,178       | \$          | \$          |
| Operating expenses   |  |             |             |             |             |
| Research and development   | 10,709   | 5,138       | 3,596       | 5,006       | 8,808       |
| General and administrative   | 13,274   | 11,002      | 8,761       | 8,661       | 11,962      |
| Amortization   | 671  | 671         | 671         | 671         | 671         |
| Total operating loss   | (24,654)   | (12,633)    | (13,028)    | (14,338)    | (21,441)    |
| Other income, net  | 152  | 2,390       | (14,670)    | 1,769       | 2,006       |
| Net loss   | (24,502)   | (10,243)    | (27,698)    | (12,569)    | (19,435)    |
| Dividends on preferred stock   |  |             | (1,188)     | (183)       | (247)       |
| Net loss applicable to common stockholders                             | \$ (24,502)                                      | \$ (10,243) | \$ (28,886) | \$ (12,752) | \$ (19,682) |
| Basic and diluted loss per common share                                | \$ (0.13)  | \$ (0.06)   | \$ (0.22)   | \$ (0.11)   | \$ (0.19)   |
| Weighted average number of common shares outstanding basic and diluted | 195,662  | 175,828     | 132,001     | 112,987     | 105,725     |

|   | As of December 31, |        |        |       |       |
|---|--------------------|--------|--------|-------|-------|
|   | 2015               | 2014   | 2013   | 2012  | 2011  |
| <b>Consolidated Balance Sheet Data:</b> |                    |        |        |       |       |
|   | \$                 | \$     | \$     | \$    | \$    |
|   | 14,179             | 17,392 | 15,696 | 1,222 | 7,705 |



|  |           |           |           |           |           |
|--|-----------|-----------|-----------|-----------|-----------|
| Cash, cash equivalents and marketable securities |           |           |           |           |           |
| Patents, net                                     | 2,913     | 3,584     | 4,255     | 4,926     | 5,598     |
| Other assets                                     | 3,348     | 5,208     | 57        | 56        | 47        |
| Total assets                                     | 20,440    | 26,184    | 20,008    | 6,204     | 13,350    |
| Current liabilities                              | 4,123     | 848       | 513       | 511       | 263       |
| Warrant liability                                |           | 147       | 12,866    | 1,300     | 3,067     |
| Preferred stock                                  |           |           |           | 2         | 4         |
| Common stock                                     | 205       | 185       | 160       | 118       | 110       |
| Additional paid-in capital                       | 196,908   | 181,299   | 152,520   | 122,626   | 115,690   |
| Accumulated deficit                              | (180,796) | (156,294) | (146,051) | (118,353) | (105,784) |
| Total stockholders equity                        | 16,317    | 25,190    | 6,629     | 4,393     | 10,020    |

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report on Form 10-K. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

### Critical Accounting Policies

#### *Long-Lived Assets*

We review the carrying values of our long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment.

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### *Patent Costs*

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over their remaining lives, which range from 1-6 years. Annual amortization of the patents is expected to approximate \$671,000 for 2016, \$659,000 in 2017 and 2018, \$547,000 in 2019, and \$330,000 in 2020, and \$47,000 thereafter.

### *Stock-Based Compensation*

The compensation cost relating to share-based payment transactions is measured based on the fair value of the equity or liability instruments issued and is expensed on a straight-line basis. For purposes of estimating the fair value of each stock option, on the date of grant, we utilize the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the company's common stock (as determined by reviewing its historical public market closing prices).

Warrants to non-employees are generally vested and nonforfeitable upon the date of the grant. Accordingly, fair value is determined on the grant date.

### *Research and Development*

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, legal, insurance, rent and utilities, and depreciation.

### *Derivative Instruments*

The warrants issued in conjunction with convertible preferred stock in March and April 2010 private placements include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of \$1.00. Effective January 1, 2009, the reset provision of these warrants preclude equity accounting treatment under ASC 815. Accordingly, the Company is required to record the warrants as liabilities at their fair value upon issuance and remeasure the fair value at each period end with the change in fair value recorded in the statement of operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. At December 31, 2015 there are no remaining 2010 warrants and, therefore, no associated liability. Significant assumptions used at December 31, 2014 include a weighted average term of 0.2 years, a 5% probability that the warrant exercise price would be reset, a volatility of 63.7% and a risk free interest rate that ranges between 0.03% and 0.04%.

Additionally, the Series A and Series C Warrants issued in conjunction with the January 2011 registered direct public offering include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of \$1.12. During 2012, the warrant exercise price was reset to \$0.675. Significant assumptions used at December 31, 2015 include a weighted average term of 0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 40.4% and a risk free interest rate of 0.13%. Significant assumptions used at December 31, 2014 include a weighted average term of 1.0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 159.2% and a risk free interest rate of 0.25%.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of \$2,550,000 of Units at a purchase price of \$0.75 per Unit. Each Unit consists of one share of Series A 8% Convertible Preferred Stock, par value \$.001 per share, and a warrant to purchase one and one-quarter shares of the Company's common stock, par value \$.001 per share (subject to adjustment) at an exercise price of \$1.00 per whole share (subject to adjustment). The total Series A 8% Convertible Preferred Stock issued was 3,400,001 shares, and the total warrants were 4,250,000. The Company used the net proceeds of the private placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

The Company determined that warrants issued in February 2013 with the Series A 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that

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require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability. At June 30, 2014 there were no remaining 2013 warrants and therefore no associated warrant liability.

### *Fair Value of Financial Instruments*

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, short-term receivable, and accounts payable approximate their fair value because of the short-term nature of these items. Cash equivalents are measured on a recurring basis within the fair value hierarchy using Level 1 inputs.

The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. Certain derivatives with limited market activity are valued using Level 3 inputs with externally developed models that consider unobservable market parameters.

### **Contractual Obligations Leases**

We lease office and laboratory space in Knoxville, Tennessee, on an annual basis, renewable for one year at our option.

### **Capital Structure**

Our ability to continue as a going concern is reasonably assured due to our financing completed during 2015 and thus far in 2016 from our Warrant Exchange Transaction (see Note 10 to the financial statements). Given our current rate of expenditures and our ability to curtail or defer certain controllable expenditures, we do not anticipate the need to raise additional capital to further develop PV-10 on our own to treat melanoma, HCC and cancers of the liver, recurrent breast carcinoma, and other indications. Moreover, we plan to license PH-10 for psoriasis and other related indications described as inflammatory dermatoses, strategically monetize PV-10, and also complete the spin-out of Pure-ific Corporation and the other non-core subsidiaries, although there can be no assurance that any such transactions will occur. Additionally, our existing funds are sufficient to meet minimal necessary expenses until into 2017.

We believe our continued development of PV-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of solid tumor recurrences due to its unique ablative immunotherapy or immuno-chemoablation mechanism of action. The primary ablative mechanism of PV-10 is followed by a secondary immunomodulatory mechanism. Likewise, we believe our development of PH-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of inflammatory dermatoses due to its unique non-steroidal anti-inflammatory mechanism of action.

Our cash and cash equivalents were \$14,178,902 at December 31, 2015, compared with \$17,391,601 at December 31, 2014. The decrease of approximately \$3.2 million was due primarily to a decrease of the total of sales of common stock and warrants and exercises of warrants and stock options, and an increase of approximately \$3.5 million more cash that was used in operating activities. Additionally, thus far in 2016, the Company received approximately \$100,000 from the repayment of bonuses and costs associated with the settlement of the Shareholder Derivative Lawsuit.

By managing variable cash expenses due to minimal fixed costs, we believe our cash and cash equivalents on hand at December 31, 2015 will be sufficient to meet our current and planned operating needs until into 2017 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities. In addition, on April 30, 2014, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent ( Cantor ), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$50,000,000 from time to time through Cantor, acting as sales agent.

We are seeking to improve our cash flow through both the global licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, and the geographic licensure of PV-10 on the basis of our Phase 2 metastatic melanoma and Phase 1 liver results in certain areas of the world, as well as pursuing a strategic investment strategy, including equity sales to potential pharmaceutical and or biotech partners. In addition, the data now available and forthcoming from Moffitt in Tampa, Florida has been and is expected to be particularly helpful in supporting our development plans with both the FDA and prospective partners. The geographic areas of interest for PV-10 principally include China, India, Russia, Brazil, Japan and Middle East and North Africa (MENA). We are encouraged by the interest in both PV-10 and PH-10 on a geographic basis and are continuing discussions with potential partners.

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We are also considering the global licensure of PV-10 as well since it has come to our attention that this is of interest to potential partners. We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 and PH-10 via a secure electronic data room that is monitored 24 hours a day, seven days a week and houses formal data submissions to the FDA as well as various corporate governance related documents.

We also expect to continue with the majority stake asset sale and licensure of our non-core assets. However, the primary objective of the Company is to strategically monetize the core value of PV-10 and PH-10 through various transactions, leveraging value creation up to and including an appropriate merger and acquisition transaction that includes upfront cash and acquirer stock in exchange for Company ownership as well as a contingency value right (CVR) to facilitate potential upside post-acquisition. We believe regulatory clarity, including one or more breakthrough therapy designations, is determined by specifying the expected approval pathways of both PV-10 and PH-10. This may include the potential for expedited approval for PV-10 to treat locally advanced recurrent melanoma as we continue the phase 3 in 2016 with PV-10 to treat this indication. Such clarity may help facilitate transactions with potential partners. Additionally, the existing and forthcoming mechanism of action related clinical and nonclinical data for both PV-10 and PH-10 will further aid in both regulatory clarity and transactions with potential partners.

However, we cannot assure you that we will be successful in either licensing of PH-10 or PV-10, any equity transaction, any merger or acquisition transaction or selling a majority stake of the OTC and other non-core assets via a spin-out transaction and licensing our existing non-core products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our long-term requirements in 2017 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placements, the exercise of existing warrants outstanding, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

We believe that our financial position and corporate governance are such that we will continue to meet the relevant listing requirements of NYSE MKT, although there can be no assurance that we will continue to be listed on NYSE MKT. We expect that the existing and forthcoming clinical and nonclinical mechanism of action data for both PV-10 and PH-10 will aid in both regulatory clarity and transactions with potential partners. The Company's current cash position is sufficient to meet our obligations. In total, we believe we have adequate funds to operate into 2017 without a further injection of capital. We believe the existing cash position of the Company is sufficient to fund our operations through obtaining interim data from the planned phase 3 melanoma study as well as other planned programs including generating key liver data, and clinical mechanism of action data for both PV-10 and PH-10.

We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 for oncology, and PH-10 for dermatology, via a secure electronic data room. We are encouraged by the number of companies doing due diligence on our technologies. For instance, we are discussing transactions with potential partners in China, India, Brazil and in other geographies.

We also recently announced discussions continuing with Sinopharm-China State Institute of Pharmaceutical Industry ( Sinopharm-CSIPI ), the leader among all pharmaceutical research institutes in China, and Sinopharm A-THINK Pharmaceutical Co., Ltd. ( Sinopharm A-THINK ), the only injectable anti-tumor drug research and development, manufacture and distribution integrated platform within Sinopharm Group. The discussions are based on the frame of reference established in the original Memorandum of Understanding ( MOU ) signed last year and extended since the passing of the original deadline. The original MOU was signed in August 2014, and, since then, the parties have sought to enter into a definitive licensing agreement, subject to additional negotiation, due diligence, and any required

regulatory and corporate approvals.

Also recently we announced signing a Letter of Intent (the LOI ) with Boehringer Ingelheim (China) Investment Co. Ltd. ( Boehringer ). The purpose of the LOI is to lay a foundation for the two parties to collaborate in bringing PV-10 to market in mainland China, Hong Kong and Taiwan. Maxim Group LLC acted as strategic advisor to Provectus in structuring and negotiating the LOI. Under the terms of the LOI, Boehringer will provide certain commercially reasonable support in the aspects of product registration with the China Food and Drug Administration ( CFDA ), communication preparation, market intelligence and other assistance to the Company in China to the extent that is within Boehringer s approved business scope and permissible by Chinese laws.

In return, we will grant Boehringer the first priority to be the exclusive collaborator of the Company in China for PV-10 in the event that PV-10 is successfully registered and approved by the CFDA. The exclusive collaboration may take the form of

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exclusive distribution and promotion, exclusive licensing or other agreement, subject to both parties' mutual agreement. At the appropriate time, the Company and Boehringer will enter into a definitive agreement, including a non-compete provision, for PV-10 to be exclusively developed, distributed and promoted through the collaboration within China, although there can be no assurance that the parties will enter into a definitive agreement.

In the LOI signed July 2, 2015, at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2015 in Barcelona, the two parties have agreed to meet regularly and maintain effective communication in order to move forward with the registration and commercialization of the product and assess the potential cooperation between them in China, which may be adopted in a form of exclusive commercial supply, distribution and promotion, partnership or any other forms suitable to both parties' interests.

We also have begun to consider co-development transactions with one or more pharmaceutical or biotech companies to combine PV-10 with immunology agents such as those referred to as systemic immunomodulatory agents, immune checkpoint inhibitors or systemic immunotherapies. Our recently announced joint patent issuance co-owned with Pfizer supports these efforts from an intellectual property protection perspective.

If and when we obtain an MOU, definitive agreement or similar indication of interest from a potential partner, we will issue a press release and file a Current Report on Form 8-K with the SEC to notify the market. Furthermore, the strategy of the Company for the benefit of stockholders is a series of partnerships followed by an acquisition of the Company along the lines of Celgene-Abraxis, although there can be no assurance that such partnerships or acquisition will occur. An interim transaction could be a co-development deal like Roche-NewLink, Bristol-Celldex or AstraZeneca-Incyte. The Company is not in discussions regarding the sale of its business, and there can be no assurance that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

We have signed multiple advisory agreements with accomplished individuals and organizations to help identify partners, including collaborators, distribution and joint venture partners, and licensees for PV-10 in China, Brazil and Latin America in general, India, Russia, European Union ( EU ), Japan and North America. These agreements are intended to enhance our reach into key markets and will bolster our efforts in developing partnering opportunities in various countries in Asia including China, India, Russia and Japan, where we have held numerous detailed discussions with pharmaceutical companies over the last year, and now also in Brazil, Europe and elsewhere. We are already seeing the results of efforts to enter into partnerships from the activity in our electronic data room. The Company is not in discussions regarding the sale of its business, and there can be no assurance that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

The primary financial objective of the Company is to strategically monetize the core value of PV-10 and PH-10 through the various transactions discussed elsewhere in this report. Ultimately, the Company wants to leverage value creation through the sale of the business or a merger that may include upfront cash, acquirer stock, and/or a contingency value right ( CVR ) as part of the total consideration. A CVR represents the right for its holder to receive certain defined payments upon the achievement of a specified milestone and would be designed to facilitate potential upside for the Company's stockholders on a post-transaction basis. A CVR could trade on an exchange. The Company is not in discussions regarding the sale of its business and there can be no assurance, however, that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

However, we cannot assure you that we will be successful in licensing either PV-10 or PH-10, entering into any equity transaction, or selling a majority stake of the OTC and other non-core assets via a spin-out transaction and licensing our existing non-core products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our long-term requirements in 2017 and beyond, even though we do not anticipate needing additional capital to develop PV-10 on our own to treat locally advanced cutaneous melanoma.



We anticipate that these funds will otherwise come from the proceeds of private placements, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

### **Plan of Operation**

We have implemented our integrated business plan, including execution of the current and next phases in clinical development of our pharmaceutical products and continued execution of research programs for new research initiatives.

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Our current plans include continuing to operate with our three employees during the immediate future, and Mr. Culpepper is expected to serve as our Interim Chief Executive Officer until our Board of Directors completes its search process for a successor Chief Executive Officer to replace H. Craig Dees, Ph.D., who resigned effective February 27, 2016 as our Chief Executive Officer and Chairman of the Board of Directors. Our Board of Directors is also searching for an Interim Chief Financial Officer to support Mr. Culpepper with respect to the responsibilities associated with the Chief Financial Officer role until a successor Chief Executive Officer is named. We also plan to continue operating with our four primary consultants and various vendor relationships totaling sixty (60) full-time equivalents, and anticipate adding additional personnel or contract research organizations if necessary in the next 12 months. Our current plans also include minimal purchases of new property, plant and equipment, and increased research and development for additional clinical trials.

We believe that our investigational drugs PV-10 and PH-10 provide us with two products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin, and important immunologic data has been corroborated and characterized by institutions such as Moffitt in Tampa, Florida, and another leading research facility, the University of Illinois at Chicago. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will continue to be shown based on data in previous studies, and which result in one or more license transactions with pharmaceutical and or biotech companies. Together with our non-core technologies, which we intend to sell or license in the future, we believe this combination represents the foundation for maximizing shareholder value this year and beyond.

## **Comparison of the Years Ended December 31, 2015 and 2014**

### *Gain on Settlement*

The gain on settlement, net of discount, of \$4,178,345 occurred in 2014 as a result from accounting for the settlement of the Shareholder Derivative Lawsuit described in Note 9 to the financial statements.

### *Research and development*

Research and development costs totaling \$10,708,569 for 2015 included payroll of \$2,292,710, consulting and contract labor of \$6,652,406, lab supplies and pharmaceutical preparations of \$1,115,140, legal of \$358,582, insurance of \$189,358, rent and utilities of \$87,208, and depreciation expense of \$13,165. Research and development costs totaling \$5,137,927 for 2014 included payroll of \$1,395,321, consulting and contract labor of \$2,355,780, lab supplies and pharmaceutical preparations of \$790,653, legal of \$384,061, insurance of \$115,957, rent and utilities of \$87,623, and depreciation expense of \$8,532.

The increase in consulting and contract labor of approximately \$4.3 million in 2015 over 2014 is primarily the result of the preparation, and commencement of phase 3 PV-10 for locally advanced cutaneous melanoma, phase 1b/2 for PV-10 in combination with pembrolizumab, and further development in other PV-10 and PH-10 programs. The increase in lab supplies and pharmaceutical preparations of approximately \$300,000 in 2015 over 2014 is primarily the result of the preparation of additional phase 3 PV-10 drug supply, as well as for other PV-10 programs, along with phase 2 PH-10 mechanism of action drug supply. The increase in payroll of approximately \$900,000 in 2015 over 2014 is the result of increased payroll expense and stock option expense. The increase in consulting and contract labor, lab supplies and pharmaceutical preparations, and payroll expense represents virtually all of the increase in research and development expenses in 2015 versus 2014.

### *General and administrative*

General and administrative expenses increased by \$2,271,746 for 2015 to \$13,274,072 from \$11,002,326 in 2014. General and administrative expenses were very similar for both periods; however, the increase is due to approximately \$1.85 million of accrued settlement expense to settle the existing class action lawsuit and \$1.1 million of reserve for uncollectible receivable from Dr. Dees related to the settlement receivable (see Note 9 to the financial statements) and partially offset by the lower stock price of our common stock during 2015 versus 2014, which resulted in lower noncash expenses charged to operations for the value of both common stock and warrants issued for services.

*Investment income*

Investment income is immaterial for all periods presented.

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*Change in fair value of warrant liability*

Change in fair value of warrant liability decreased by \$2,237,833 to a gain of \$146,560 in 2015 from a gain of \$2,384,393 in 2014. This activity results from accounting for the warrant liability described in Notes 3(c), 3(d), 3(e) and 8 to the financial statements.

*Cash Flow*

Our cash and cash equivalents were \$14,178,902 at December 31, 2015, compared with \$17,391,601 at December 31, 2014. The decrease of approximately \$3.2 million was due primarily to a decrease of the total sales of common stock and warrants and exercises of warrants and stock options, and an increase of approximately \$3.5 million more cash that was used in operating activities. Additionally, thus far in 2016, the Company received approximately \$100,000 from the repayment of bonuses and costs associated with the settlement of the Shareholder Derivative Lawsuit. At our current cash expenditure rate, our cash and cash equivalents will be sufficient to meet our current and planned needs until into 2017 without additional cash inflows from the exercise of existing warrants, stock options, or sales of equity securities.

**Comparison of the Years Ended December 31, 2014 and 2013**

*Gain on Settlement*

The gain on settlement, net of discount, of \$4,178,345 occurred in 2014 as a result from accounting for the settlement of the Shareholder Derivative Lawsuit described in Note 9 to the financial statements.

*Research and development*

Research and development costs totaling \$5,137,927 for 2014 included payroll of \$1,395,321, consulting and contract labor of \$2,355,780, lab supplies and pharmaceutical preparations of \$790,653, legal of \$384,061, insurance of \$115,957, rent and utilities of \$87,623, and depreciation expense of \$8,532. Research and development costs totaling \$3,595,555 for 2013 included payroll of \$1,459,057, consulting and contract labor of \$1,317,472, lab supplies and pharmaceutical preparations of \$310,160, legal of \$262,720, insurance of \$161,268, rent and utilities of \$78,512, and depreciation expense of \$6,366.

The increase in consulting and contract labor of approximately \$1.0 million in 2014 over 2013 is primarily the result of the preparation of phase 3 PV-10 for locally advanced cutaneous melanoma and further development in other PV-10 and PH-10 programs. The increase in lab supplies and pharmaceutical preparations of approximately \$0.5 million in 2014 over 2013 is primarily the result of the preparation of additional phase 3 PV-10 drug supply, as well as for other PV-10 programs, along with phase 2 PH-10 mechanism of action drug supply. The increase in both consulting and contract labor, and lab supplies and pharmaceutical preparations represents virtually all of the increase in research and development expenses in 2014 versus 2013.

*General and administrative*

General and administrative expenses increased by \$2,241,062 for 2014 to \$11,002,326 from \$8,761,264 in 2013. General and administrative expenses were very similar for both periods; however, almost \$600,000 in increased expense is due to the higher stock price of our common stock during the three months ended March 31, 2014 versus the three months ended March 31, 2013, which resulted in higher noncash expenses charged to operations for the value of both common stock and warrants issued for services. Additionally, legal expense increased by about

\$500,000 primarily due to our NYSE MKT listing and the Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor and investor relations and related travel expenses increased approximately \$1,100,000 in 2014 over 2013.

*Investment income*

Investment income is immaterial for all periods presented.

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### *Change in fair value of warrant liability*

Change in fair value of warrant liability increased by \$17,055,523 to a gain of \$2,384,393 in 2014 from a loss of \$14,671,130 in 2013. This activity results from accounting for the warrant liability described in Notes 3(c), 3(d), 3(e) and 8 to the financial statements.

### *Cash Flow*

Our cash and cash equivalents were \$17,391,601 at December 31, 2014, compared with \$15,696,243 at December 31, 2013. The increase of approximately \$1.7 million was due primarily to sales of common stock and warrants as well as exercises of warrants and stock options offset partially by approximately \$4 million more cash that was used in operating activities in 2014 versus 2013.

## **Liquidity and Capital Resources**

As noted above, our present cash and cash equivalents are currently sufficient to meet our short-term operating needs. Excess cash will be used to finance any additional phases in clinical development of our pharmaceutical products that we may decide to undertake ourselves versus with a partner. We anticipate that any required funds for our operating and development needs in 2017 and beyond may come from a partnership agreement or from the proceeds of public or private sales of equity or debt securities or the exercise of existing warrants and stock options outstanding. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds if necessary, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

## **Recent Accounting Pronouncements**

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018. The Company currently does not have revenues but will consider any related impact going forward.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15), which addresses when and how to disclose going-concern uncertainties in the financial statements. ASU 2014-15 requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year after the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The amended guidance is not

expected to have a material impact on the Company's consolidated financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

We had no holdings of financial or commodity instruments as of December 31, 2015, other than cash and cash equivalents, short-term deposits, money market funds and interest bearing investments in U.S. governmental debt securities. We have accounted for certain warrants issued in March and April 2010, January 2011 and February 2013 as liabilities at their fair value upon issuance, which are remeasured at each period end with the change in fair value recorded in the statement of operations. See Note 3 of the consolidated financial statements contained in this Annual Report on Form 10-K.

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A material amount of our business is transacted in U.S. dollars and, accordingly, foreign exchange rate fluctuations have not had a significant impact on us, and they are not expected to have a significant impact on us in the foreseeable future.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The financial statements required by this Item are included as a separate section of this report commencing on page F-1.

### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

### **ITEM 9A. CONTROLS AND PROCEDURES.**

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

The information contained in this section covers management's evaluation of our disclosure controls and procedures and our assessment of our internal control over financial reporting for the year ended December 31, 2015.

#### **Evaluation of Disclosure Controls and Procedures**

Management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures along with the related internal controls over financial reporting were not effective to provide reasonable assurance that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

#### **Inherent Limitations on Effectiveness of Controls**

Even assuming the effectiveness of our controls and procedures, our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error or all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. In general, our controls and procedures are designed to provide reasonable assurance that our control system's objective will be met, and our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures are not effective at the reasonable assurance level. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the



Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls in future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles (GAAP). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable

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detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures by us are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of the period covered by this report based on the criteria for effective internal control described in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). Based on the results of management’s assessment and evaluation, our principal executive officer and principal financial officer concluded that our internal control over financial reporting was not effective due to the material weakness described below.

Our independent registered public accounting firm, BDO USA, LLP, assessed the effectiveness of the Company’s internal control over financial reporting. BDO USA, LLP has issued an attestation report on our internal control over financial reporting as of December 31, 2015, which is set forth below.

### ***Material Weakness***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. Management’s assessment of internal controls identified the below-described material weakness.

Our internal control testing identified inadequate supporting documentation and lack of adequate review for travel advances and expense reimbursements.

The Audit Committee conducted a review of Company procedures, policies and practices, including travel expense advancements and reimbursements to Dr. Dees. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. As part of the investigation, the Committee reviewed the Company’s financial policies and procedures, including management expenses. The Audit Committee concluded that Dr. Dees did not produce receipts for most of the travel expense advances he received from 2013 to 2015, and some receipts produced by Dr. Dees during this period appear to have been altered.

The Company has identified the following material weakness related to its travel expense advancement and reimbursement policies and procedures to Dr. Dees: (1) the documentation provided for an expenditure was not sufficient to support the authorization of such expenditure, (2) only the check register and not the supporting documentation was obtained by an executive officer approving the expenses incurred by another executive officer, and (3) there was no reconciliation of travel advances to actual expenses.

### ***Remediation***

The Company intends to aggressively remediate the material weakness in its internal controls over financial reporting. To do so, the Company has put in place more clearly defined, tighter controls, including a clear process for limiting, approving and documenting advances and expenses and appropriately managing them. Specifically, the Company has:

Adopted a control enhancement to require the provision of all invoice copies along with the check register for appropriate approval, including all travel reimbursements separately approved;

Established a policy so travel advances are no longer permitted; and

Initiated implementation of a more enhanced travel and expense policy.

In addition, the Company is replacing the independent consulting group previously utilized by management to aid in its documentation and testing of internal controls over financial reporting. The Company is also in the process of implementing the recommendations made by counsel to the Audit Committee to remediate these issues, including but not limited to (1) the appointment of an interim Chief Financial Officer to assist in the organization and strategic operation of the Company as to its procedures and daily operations of the Company, (2) the identification and recruitment of a permanent Chief Executive Officer and any other positions necessary, and (3) the appointment of an outside compliance consultant.

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We believe the foregoing actions will continue to improve our internal control over financial reporting as well as our disclosure controls and procedures. The Company will continue to monitor the effectiveness of its internal control over financial reporting in the area affected by the material weakness discussed above, and will perform any additional procedures, as well as implement any new resources and policies, deemed necessary by the Company's management to remediate the material weakness.

**Changes in Internal Control Over Financial Reporting**

There were no significant changes to our internal controls during the fourth quarter of 2015 even though a material weakness in internal controls with respect to travel expense advances and expense reimbursement was identified therein. Our efforts to improve our internal controls are ongoing and focused on expanding our organizational capabilities, to improve our control environment and on implementing process changes to strengthen our internal control and monitoring activities. In addition, although we are implementing remedial measures to address the identified material weakness, these measures have not been completed as of the filing date of this report.

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

Provectus Biopharmaceuticals, Inc.

Knoxville, Tennessee

We have audited Provectus Biopharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Provectus Biopharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding management's failure to design and maintain effective controls over travel expense advances and reimbursement have been identified and described in management's assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2015 financial statements, and this report does not affect our report dated March 30, 2016, on those financial statements.

In our opinion, Provectus Biopharmaceuticals, Inc. did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Provectus Biopharmaceuticals, Inc., as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 30, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 30, 2016

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**ITEM 9B. OTHER INFORMATION.**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 16, 2016, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

**Financial Statements**

See Index to Consolidated Financial Statements in Financial and Supplementary Data.

**Financial Statement Schedules**

None

**Exhibits**

Exhibits required by Item 601 of Regulation S-K are incorporated herein by reference and are listed on the attached Exhibit Index, which begins on page X-1 of our Annual Report on Form 10-K.



Table of Contents**SIGNATURES**

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

March 30, 2016

PROVECTUS BIOPHARMACEUTICALS,  
INC.

By: /s/ Peter R. Culpepper  
Peter R. Culpepper  
Interim Chief Executive Officer, Chief  
Operating Officer and Chief Accounting  
Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <b>Signature</b>  | <b>Title</b>  | <b>Date</b>    |
|---|---|----------------|
| /s/ Peter R. Culpepper<br>Peter R. Culpepper              | Interim Chief Executive Officer (principal executive officer), Chief Financial Officer (principal financial officer and principal accounting officer), Chief Operating Officer and Chief Accounting Officer | March 30, 2016 |
| /s/ Timothy C. Scott<br>Timothy C. Scott                  | President and Director  | March 30, 2016 |
| /s/ Jan Koe<br>Jan Koe                                    | Director  | March 30, 2016 |
| /s/ Kelly M. McMasters<br>Kelly M. McMasters, M.D., Ph.D. | Director  | March 30, 2016 |
| /s/ Alfred E. Smith, IV<br>Alfred E. Smith, IV            | Director and Chairman of the Board  | March 30, 2016 |
| /s/ Eric A. Wachter<br>Eric A. Wachter, Ph.D.             | Director  | March 30, 2016 |

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**INDEX TO FINANCIAL STATEMENTS**

The following financial statements are included in Part II, Item 8:

|   | Page |
|---|------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | F-1  |
| <u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>   | F-2  |
| <u>Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013</u>           | F-3  |
| <u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013</u> | F-4  |
| <u>Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013</u>           | F-5  |
| <u>Notes to Consolidated Financial Statements</u>   | F-6  |

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

Provectus Biopharmaceuticals, Inc.

Knoxville, Tennessee

We have audited the accompanying consolidated balance sheets of Provectus Biopharmaceuticals, Inc., as of December 31, 2015 and 2014 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Provectus Biopharmaceuticals, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Provectus Biopharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 30, 2016 expressed an adverse opinion thereon.

/s/ BDO USA, LLP

Chicago, Illinois

March 30, 2016

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## PROTECTUS BIOPHARMACEUTICALS, INC.

## CONSOLIDATED BALANCE SHEETS

|  | December 31,<br>2015 | December 31,<br>2014 |
|--|----------------------|----------------------|
| <b>Assets</b>  |                      |                      |
| <b>Current Assets</b>  |                      |                      |
| Cash and cash equivalents  | \$ 14,178,902        | \$ 17,391,601        |
| Short-term receivable settlement, net of reserve for uncollectibility  | 500,000              | 733,333              |
| Other current assets   | 41,192               | 978,000              |
| <b>Total Current Assets</b>  | <b>14,720,094</b>    | <b>19,102,934</b>    |
| <b>Equipment and furnishings, less accumulated depreciation of \$451,028 and \$437,863, respectively</b>   |                      |                      |
|  | 85,145               | 92,171               |
| Patents, net of amortization of \$8,802,857 and \$8,131,737, respectively  | 2,912,588            | 3,583,708            |
| Long-term receivable reimbursable legal fees, net of reserve for uncollectibility  | 683,250              |                      |
| Long-term receivable settlement, net of discount and reserve for uncollectibility  | 2,011,735            | 3,378,345            |
| Other assets   | 27,000               | 27,000               |
|  | <b>\$ 20,439,812</b> | <b>\$ 26,184,158</b> |
| <b>Liabilities and Stockholders Equity</b>   |                      |                      |
| <b>Current Liabilities</b>   |                      |                      |
| Accounts payable trade   | \$ 1,887,171         | \$ 440,702           |
| Accrued consulting expense   | 133,282              | 91,282               |
| Accrued settlement expense   | 1,850,000            |                      |
| Other accrued expenses   | 252,418              | 315,738              |
| <b>Total Current Liabilities</b>   | <b>4,122,871</b>     | <b>847,722</b>       |
| <b>Long-Term Liability</b>   |                      |                      |
| Warrant liability  |                      | 146,560              |
| <b>Total Liabilities</b>   | <b>4,122,871</b>     | <b>994,282</b>       |
| <b>Stockholders Equity</b>   |                      |                      |
| Preferred stock; par value \$.001 per share; 25,000,000 shares authorized; no shares outstanding as of December 31, 2015 and 2014                |                      |                      |
| Common stock; par value \$.001 per share; 400,000,000 shares authorized; 204,979,100 and 184,796,275 shares issued and outstanding, respectively | 204,979              | 184,796              |
| Paid-in capital  | 196,908,112          | 181,298,890          |
| Accumulated deficit  | (180,796,150)        | (156,293,810)        |

|                    |        |               |               |
|--------------------|--------|---------------|---------------|
| Total Stockholders | Equity | 16,316,941    | 25,189,876    |
|                    |        | \$ 20,439,812 | \$ 26,184,158 |

See accompanying notes to consolidated financial statements.

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## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

|   | <b>Year Ended<br/>December 31,<br/>2015</b> | <b>Year Ended<br/>December 31,<br/>2014</b> | <b>Year Ended<br/>December 31,<br/>2013</b> |
|---|---|---|---|
| Gain on settlement net of discount  | \$  | \$ 4,178,345                                | \$  |
| Operating expenses  |   |   |   |
| Research and development  | 10,708,569                                  | 5,137,927                                   | 3,595,555                                   |
| General and administrative  | 13,274,072                                  | 11,002,326                                  | 8,761,264                                   |
| Amortization  | 671,120                                     | 671,120                                     | 671,120                                     |
| Total operating loss  | (24,653,761)                                | (12,663,028)                                | (13,027,939)                                |
| Investment income   | 4,861                                       | 5,645                                       | 1,325                                       |
| Gain (loss) on change in fair value of warrant liability                  | 146,560                                     | 2,384,393                                   | (14,671,130)                                |
| Net loss  | \$ (24,502,340)                             | \$ (10,242,990)                             | \$ (27,697,744)                             |
| Dividends on preferred stock  |   |   | (1,188,648)                                 |
| Net loss applicable to common shareholders                                | \$ (24,502,340)                             | \$ (10,242,990)                             | \$ (28,886,392)                             |
| Basic and diluted loss per common share                                   | \$ (0.13)                                   | \$ (0.06)                                   | \$ (0.22)                                   |
| Weighted average number of common shares outstanding<br>basic and diluted | 195,661,859                                 | 175,828,004                                 | 132,000,796                                 |

See accompanying notes to consolidated financial statements.

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## PROTECTUS BIOPHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

|   | Preferred Stock  |           | Common Stock     |            | Paid in capital | Accumulated Deficit | Total        |
|---|------------------|-----------|------------------|------------|-----------------|---------------------|--------------|
|   | Number of Shares | Par Value | Number of Shares | Par Value  |                 |                     |              |
| <b>Balance, at January 1, 2013</b>                                | 2,478,185        | \$ 2,478  | 118,427,925      | \$ 118,428 | \$ 122,625,654  | \$ (118,353,076)    | \$ 4,393,484 |
| Issuance of stock for services                                    |                  |           | 750,000          | 750        | 525,250         |                     | 526,000      |
| Issuance of warrants for services                                 |                  |           |                  |            | 1,786,824       |                     | 1,786,824    |
| Exercise of warrants and stock options                            |                  |           | 6,319,594        | 6,320      | 7,829,150       |                     | 7,835,470    |
| Issuance of common stock and warrants pursuant to Regulation D    |                  |           | 28,409,353       | 28,409     | 18,390,926      |                     | 18,419,335   |
| Issuance of preferred stock and warrants pursuant to Regulation D | 3,400,001        | 3,400     |                  |            | 1,248,650       |                     | 1,252,050    |
| Preferred stock conversions into common stock                     | (5,844,852)      | (5,845)   | 5,844,852        | 5,845      |                 |                     |              |
| Dividends on preferred stock                                      |                  |           |                  |            | (29,063)        |                     | (29,063)     |
| Employee compensation from stock options                          |                  |           |                  |            | 142,310         |                     | 142,310      |
| Net loss for the year ended 2013                                  |                  |           |                  |            |                 | (27,697,744)        | (27,697,744) |
| <b>Balance, at December 31, 2013</b>                              | 33,334           | 33        | 159,751,724      | 159,752    | 152,519,701     | (146,050,820)       | 6,628,666    |

|  |             |         |             |               |              |
|--|-------------|---------|-------------|---------------|--------------|
| Issuance of stock for services                                 | 300,000     | 300     | 417,950     |               | 418,250      |
| Issuance of warrants for services                              |             |         | 2,321,327   |               | 2,321,327    |
| Reclassification of warrant liability                          |             |         | 10,335,619  |               | 10,335,619   |
| Cash proceeds from exercise of warrants and stock options      | 14,926,617  | 14,926  | 4,475,831   |               | 4,490,757    |
| Issuance of common stock and warrants pursuant to Regulation D | 9,784,600   | 9,785   | 11,112,817  |               | 11,122,602   |
| Preferred stock conversions into common stock                  | (33,334)    | (33)    | 33,334      |               | 33           |
| Employee compensation from stock options                       |             |         | 115,645     |               | 115,645      |
| Net loss for the year ended 2014                               |             |         |             | (10,242,990)  | (10,242,990) |
| <b>Balance, at December 31, 2014</b>                           | 184,796,275 | 184,796 | 181,298,890 | (156,293,810) | 25,189,876   |
| Issuance of stock for services                                 | 305,627     | 306     | 202,508     |               | 202,814      |
| Issuance of warrants for services                              |             |         | 552,358     |               | 552,358      |
| Cash proceeds from exercise of warrants and stock options      | 590,098     | 590     | 549,140     |               | 549,730      |
| Issuance of common stock and warrants pursuant to Regulation D | 1,787,100   | 1,787   | 1,552,990   |               | 1,554,777    |
| Issuance of common stock and warrants                          | 17,500,000  | 17,500  | 12,081,650  |               | 12,099,150   |



|   |  |  |  |  |  |         |              |              |
|---|--|--|--|--|--|---------|--------------|--------------|
| pursuant to<br>Section 5<br>Employee<br>compensation<br>from stock<br>options |  |  |  |  |  | 670,576 |              | 670,576      |
| Net loss for the<br>year ended<br>2015  |  |  |  |  |  |         | (24,502,340) | (24,502,340) |

|  |    |             |            |                |                  |               |
|--|----|-------------|------------|----------------|------------------|---------------|
| <b>Balance, at<br/>December 31,<br/>2015</b> | \$ | 204,979,100 | \$ 204,979 | \$ 196,908,112 | \$ (180,796,150) | \$ 16,316,941 |
|--|----|-------------|------------|----------------|------------------|---------------|

See accompanying notes to consolidated financial statements.

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## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

|  | Year Ended<br>December 31,<br>2015 | Year Ended<br>December 31,<br>2014 | Year Ended<br>December 31,<br>2013 |
|--|------------------------------------|------------------------------------|------------------------------------|
| <b>Cash Flows From Operating Activities</b>                                |                                    |                                    |                                    |
| Net loss   | \$ (24,502,340)                    | \$ (10,242,990)                    | \$ (27,697,744)                    |
| Adjustments to reconcile net loss to net cash used in operating activities |                                    |                                    |                                    |
| Depreciation   | 13,165                             | 8,532                              | 6,366                              |
| Amortization of patents  | 671,120                            | 671,120                            | 671,120                            |
| Compensation through issuance of stock options                             | 670,576                            | 115,645                            | 142,310                            |
| Issuance of stock for services   | 202,814                            | 418,250                            | 526,000                            |
| Issuance of warrants for services  | 552,358                            | 2,321,327                          | 1,786,824                          |
| (Gain) loss on change in fair value of warrant liability                   | (146,560)                          | (2,384,393)                        | 14,671,130                         |
| Gain on settlement   |                                    | (4,178,345)                        |                                    |
| (Increase) decrease in assets  |                                    |                                    |                                    |
| Settlement receivable and related interest                                 | 1,599,943                          | 66,667                             |                                    |
| Other assets   | 253,558                            | (978,000)                          |                                    |
| Increase (decrease) in liabilities   |                                    |                                    |                                    |
| Accounts payable   | 1,446,469                          | 91,833                             | 105,434                            |
| Accrued settlement expense   | 1,850,000                          |                                    |                                    |
| Accrued expenses   | (21,320)                           | 242,943                            | (103,912)                          |
| Net cash used in operating activities                                      | (17,410,217)                       | (13,847,411)                       | (9,892,472)                        |
| <b>Cash Flows From Investing Activities</b>                                |                                    |                                    |                                    |
| Capital expenditures   | (6,139)                            | (70,590)                           | (6,650)                            |
| Net cash used in investing activities                                      | (6,139)                            | (70,590)                           | (6,650)                            |
| <b>Cash Flows From Financing Activities</b>                                |                                    |                                    |                                    |
| Net proceeds from sales of preferred stock and warrants                    |                                    |                                    | 2,550,000                          |
| Net proceeds from sales of common stock and warrants                       | 13,653,927                         | 11,122,602                         | 18,419,335                         |
| Proceeds from exercises of warrants and stock options                      | 549,730                            | 4,490,757                          | 3,433,392                          |
| Cash paid for preferred dividends  |                                    |                                    | (29,063)                           |
| Net cash provided by financing activities                                  | 14,203,657                         | 15,613,359                         | 24,373,664                         |
| Net change in cash and cash equivalents                                    | \$ (3,212,699)                     | \$ 1,695,358                       | \$ 14,474,542                      |
| Cash and cash equivalents, at beginning of period                          | \$ 17,391,601                      | \$ 15,696,243                      | \$ 1,221,701                       |

|   |               |               |               |
|---|---------------|---------------|---------------|
| Cash and cash equivalents, at end of period | \$ 14,178,902 | \$ 17,391,601 | \$ 15,696,243 |
|---|---------------|---------------|---------------|

## Supplemental Disclosure of Noncash Investing and Financing Activities

|   | <b>Year<br/>Ended<br/>December 31,<br/>2015</b> | <b>Year Ended<br/>December 31,<br/>2014</b> | <b>Year Ended<br/>December 31,<br/>2013</b> |
|---|---|---|---|
| Reclassification of warrant liability to equity due to exercise of warrants | \$  | \$ 10,335,619                               | \$ 4,402,078                                |

See accompanying notes to consolidated financial statements.

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**PROVECTUS BIOPHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Significant Accounting Policies**

**Nature of Operations**

Provectus Biopharmaceuticals, Inc. (together with its subsidiaries, the Company) is a biopharmaceutical company that is focusing on developing minimally invasive products for the treatment of psoriasis and other topical diseases, and certain forms of cancer including melanoma, breast cancer, and cancers of the liver. To date, the Company has no revenues from planned principal operations. The Company's activities are subject to significant risks and uncertainties, including failing to successfully develop and license or commercialize the Company's prescription drug candidates, or sell or license the Company's OTC products or non-core technologies.

**Principles of Consolidation**

Intercompany balances and transactions have been eliminated in consolidation.

**Estimates**

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

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

**Cash Concentrations**

Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits of \$250,000 although the Company seeks to minimize this through treasury management. We have never experienced any losses related to these balances.

**Equipment and Furnishings**

Equipment and furnishings are stated at cost. Depreciation of equipment is provided for using the straight-line method over the estimated useful lives of the assets. Computers and laboratory equipment are being depreciated over five years; furniture and fixtures are being depreciated over seven years.

**Long-Lived Assets**

The Company reviews the carrying values of its long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management

has determined there to be no impairment.

#### Patent Costs

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over the remaining life of the patent.

Patents at December 31, 2015 were acquired as a result of the merger with Valley Pharmaceuticals, Inc. ( Valley ) on November 19, 2002. The majority stockholders of Provectus also owned all of the shares of Valley and therefore the assets acquired from Valley were recorded at their carry-over basis. The patents are being amortized over the remaining lives of the patents, which range from 1-6 years. Annual amortization of the patents is expected to approximate \$671,000 for 2016, \$659,000 in 2017 and 2018, \$547,000 in 2019, and \$330,000 in 2020, and \$47,000 thereafter.

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### Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, legal, insurance, rent and utilities, and depreciation.

### Income Taxes

The Company accounts for income taxes under the liability method in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) 740 Income Taxes . Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established if it is more likely than not that all, or some portion, of deferred income tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. Any recognized income tax positions would be measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement would be reflected in the period in which the change in judgment occurs. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There were no income taxes, interest or penalties incurred in 2015, 2014 or 2013. Tax years going back to 2012 remain open for examination by the IRS.

### Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share is computed based on the weighted average number of common shares outstanding. Loss per share excludes the impact of outstanding options and warrants and convertible preferred stock as they are antidilutive. Potential common shares excluded from the calculation for the years ended December 31, 2015, 2014 and 2013, respectively, are 80,121,595, 63,235,956 and 73,037,416 from warrants, 10,630,000, 10,845,098 and 15,322,206 from options, and 0, 0 and 33,334 from convertible preferred shares.

### Derivative Instruments

The warrants issued in conjunction with convertible preferred stock in March and April 2010 private placements include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of \$1.00. Effective January 1, 2009, the reset provision of these warrants preclude equity accounting treatment under ASC 815. Accordingly, the Company is required to record the warrants as liabilities at their fair value upon issuance and remeasure the fair value at each period end with the change in fair value recorded in the statement of operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. At December 31, 2015, there are no remaining 2010 warrants and, therefore, no associated liability. Significant assumptions used at December 31, 2014 include a weighted average term of 0.2 years, a 5% probability that the warrant exercise price would be reset, a volatility of 63.7% and a risk free interest rate that ranges between 0.03% and 0.04%.

Additionally, the Series A and Series C Warrants issued in conjunction with the January 2011 registered direct public offering include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of \$1.12. During 2012, the warrant exercise price was reset to \$0.675. Significant assumptions used at December 31, 2015 include a weighted average term of 0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 40.4% and a risk free interest rate of 0.13%. Significant assumptions used at December 31, 2014 include a weighted average term of 1.0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 159.2% and a risk free interest rate range of 0.25%.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of \$2,550,000 of Units at a purchase price of \$0.75 per Unit. Each Unit consists of one share of Series A 8% Convertible Preferred Stock, par value \$.001 per share, and a warrant to purchase one and one-quarter shares of the Company's common stock, par value \$.001 per share (subject to adjustment) at an exercise price of \$1.00 per whole share (subject to adjustment). The total Series A 8% Convertible Preferred Stock issued was 3,400,001 shares, and the total warrants were 4,250,000. The Company used the net proceeds of the private placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

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The Company determined that warrants issued in February 2013 with the Series A 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability. At June 30, 2014, there were no remaining 2013 warrants and therefore no associated warrant liability.

## Fair Value of Financial Instruments

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, short-term settlement receivable, other current assets and accounts payable approximate their fair value because of the short-term nature of these items. Cash equivalents are measured on a recurring basis within the fair value hierarchy using Level 1 inputs.

The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. Certain derivatives with limited market activity are valued using Level 3 inputs with externally developed models that consider unobservable market parameters.

## Stock-Based Compensation

The compensation cost relating to share-based payment transactions is measured based on the fair value of the equity or liability instruments at date of issuance and is expensed on a straight-line basis. The Company utilizes the Black-Scholes option-pricing model for purposes of estimating the fair value of each stock option on the date of grant. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company's common stock (as determined by reviewing its historical public market closing prices).

Warrants to non-employees are generally vested and nonforfeitable upon the date of the grant. Accordingly, fair value is determined on the grant date.

## Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018. The Company currently does not have revenues but will consider any related impact going forward.



In August 2014, the FASB issued Accounting Standards Update 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15), which addresses when and how to disclose going-concern uncertainties in the financial statements. ASU 2014-15 requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year after the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going

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concern. ASU 2014-15 applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The amended guidance is not expected to have a material impact on the Company's consolidated financial statements.

## **2. Commitments**

### Leases

The Company leases office and laboratory space in Knoxville, Tennessee on an annual basis, renewable for one year at our option. Rent expense was \$60,000, \$60,000 and \$55,379 for the years ended December 31, 2015, 2014 and 2013, respectively.

### Employee Agreements

On April 28, 2014, the Company entered into amended and restated executive employment agreements (the "Employment Agreements") with each of the following executive officers of the Company: H. Craig Dees, Ph.D. to serve as its Chief Executive Officer, Timothy C. Scott, Ph.D. to serve as its President, Eric A. Wachter, Ph.D. to serve as its Chief Technology Officer, and Peter R. Culpepper to serve as its Chief Financial Officer and Chief Operating Officer (collectively, the "executives"). Effective February 27, 2016, Dr. Dees resigned as Chief Executive Officer and Chairman of the Board of Directors. Under the terms of the Amended and Restated Executive Employment Agreement entered into by Craig Dees and the Company on April 28, 2014 (the "Agreement"), Dr. Dees is owed no severance payments as a result of his resignation. Dr. Dees's employment terminated with his resignation without "Good Reason" as that term is defined in the Agreement. Under section 6 of the Agreement, "Effect of Termination," a resignation by Dr. Dees without "Good Reason" terminates any payments due to Dr. Dees as of the last day of his employment.

Each Employment Agreement provides that such executive will be employed for an initial term of five years, subject to automatic renewal for successive one-year periods, unless the executive or the Company (i) terminates the Employment Agreement and the executive's employment thereunder as provided in the Employment Agreement or (ii) provides notice of his or its intent not to renew. Each executive's initial base salary is \$500,000 per year, and any increases to such executive's base salary shall be determined by the Compensation Committee of the Company's Board of Directors in its sole discretion (the "Compensation Committee"). The executives are also eligible for annual bonuses and annual equity incentive awards as determined by the Compensation Committee in its sole discretion.

Each of the Employment Agreements generally provides that in the event that the executive's employment is terminated (i) voluntarily by the executive without Good Reason (as defined in the Employment Agreement), or (ii) by the Company for Cause (as defined in the Employment Agreement), the Company shall pay the executive's compensation only through the last day of the employment period and, except as may otherwise be expressly provided, the Company shall have no further obligation to the executive. In the event that the executive's employment is terminated by the Company other than for Cause (including death or disability), or if the executive voluntarily resigns for Good Reason, for so long as the executive is not in breach of his continuing obligations under the non-competition, non-solicitation and confidentiality restrictions contained in the Employment Agreement, the Company shall continue to pay the executive (or his estate) an amount equal to his base salary in effect immediately prior to the termination of his employment for a period of 24 months, to be paid in accordance with the Company's regular payroll practices through the end of the fiscal year in which termination occurs and then in one lump sum payable to the executive in the first month of the calendar year following termination, as well as any prorated bonuses determined by the Compensation Committee, plus benefits on a substantially equivalent basis to those which would have been provided to the executive.

During the term of each executive's employment by the Company, and for a period of twenty-four (24) months following termination of employment, in the event that such executive voluntarily terminates his employment with the Company other than for Good Reason or such executive is terminated for Cause, then neither the executive nor any other person or entity with executive's assistance shall (i) participate in any business that is directly competitive with the Company's business or (ii) directly or indirectly, solicit any employee of the Company to quit or terminate their employment with the Company or employ as an employee, independent contractor, consultant, or in any other position, any person who was an employee of the Company or the Company's affiliates within the preceding six months, subject to certain exceptions. In addition, without the express written consent of the Company, each executive shall not at any time (either during or after the termination of executive's employment) use (other than for the benefit of the Company) or disclose to any other business entity proprietary or confidential information concerning the Company, any of their affiliates, or any of its officers. Neither shall such executive disclose any of the Company's or the Company's affiliates' trade secrets or inventions of which he gained knowledge during his employment with the Company (subject to certain exceptions).

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(a) During the three months ended March 31, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$48,750. During the three months ended June 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$49,500. During the three months ended September 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$51,250. During the three months ended December 31, 2013, the Company issued 275,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$214,000. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of stock at grant date.

During the three months ended March 31, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$137,500. During the three months ended June 30, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$140,250. During the three months ended September 30, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$68,500. During the three months ended December 31, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$72,000. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of stock at grant date.

During the three months ended March 31, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$64,000. During the three months ended June 30, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$63,000. During the three months ended September 30, 2015, the Company issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$38,439. During the three months ended December 31, 2015, the Company issued 76,750 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$37,375. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of stock at grant date.

*Warrants Issued for Services*

(b) During the three months ended March 31, 2013, the Company issued 1,924,973 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$409,640. During the three months ended March 31, 2013, 859,833 expired warrants were forfeited. During the three months ended June 30, 2013, the Company issued 2,605,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$931,655. During the three months ended June 30, 2013, 1,051,500 expired warrants were forfeited. During the three months ended September 30, 2013, the Company issued 442,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$186,223. During the three months ended September 30, 2013, 136,500 expired warrants were forfeited. During the three months ended December 31, 2013, the Company issued 209,473 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$259,306. During the three months ended December 31, 2013, 247,973 expired warrants were forfeited. During the three months ended December 31, 2013, 4,480,005 warrants were exercised on a cashless basis resulting in 2,386,004 shares being issued. During the three months ended December 31, 2013, 3,899,840 warrants

were exercised for \$3,412,392 resulting in 3,899,840 common shares issued. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of the warrants, determined using the Black-Scholes option-pricing model. The fair market value for the warrants issued in 2013 ranged from \$0.10 to \$1.97.

During the three months ended March 31, 2014, the Company issued 733,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$900,317. During the three months ended March 31, 2014, 121,500 expired warrants were forfeited. During the three months ended March 31, 2014, 12,522,198 warrants were exercised on a cashless basis resulting in 9,100,824 common shares being issued. During the three months ended March 31, 2014, 3,036,218 warrants were exercised for \$2,672,364 resulting in 3,036,218 common shares issued. During the three months ended June 30, 2014, the Company issued 202,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$450,002. During the three months ended June 30, 2014, 315,000 expired warrants were forfeited. During the three months ended June 30, 2014, 1,594,082 warrants were exercised on a cashless basis resulting in 915,467 common shares being issued. During the three months ended June 30, 2014, 372,000 warrants were exercised for \$372,000 resulting in 372,000 common shares issued. During the three months ended September 30, 2014, the Company issued 6,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$4,189. During the three months ended September 30, 2014, 228,500 expired warrants were forfeited. During the three months ended December 31, 2014, the Company issued 1,503,913 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$966,819. During the three months ended December 31, 2014,

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1,027,635 expired warrants were forfeited. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of the warrants, determined using the Black-Scholes option-pricing model. The fair market value for the warrants issued in 2014 ranged from \$0.55 to \$2.56.

During the three months ended March 31, 2015, the Company issued 3,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$1,632. During the three months ended March 31, 2015, 3,693,898 warrants were forfeited. During the three months ended June 30, 2015, the Company issued 100,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$53,582. During the three months ended June 30, 2015, 1,161,790 warrants were forfeited. During the three months ended September 30, 2015, the Company issued 79,500 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$24,262. During the three months ended September 30, 2015, 1,152,135 warrants were forfeited. During the three months ended December 31, 2015, the Company issued 1,766,202 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$472,882. During the three months ended December 31, 2015, 252,500 warrants were forfeited. As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of the warrants, determined using the Black-Scholes option-pricing model. The fair market value for the warrants issued in 2015 ranged from \$0.14 to \$0.54.

There are no provisions or obligations that would require the Company to cash settle any of its outstanding warrants. The equity classification of certain of the Company's warrants is appropriate considering that these warrants provide the counterparties the right to purchase a fixed number of shares at a fixed price and the terms are not subject to any potential adjustments.

*Private Offerings of Common Stock and Warrants*

(c) The Company determined that warrants issued January 13, 2011 and referred to as Series A Warrants and Series C Warrants should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The value of the warrant liability was determined based on the Monte-Carlo Simulation model at the date the warrants were issued. The warrant liability is then revalued at each subsequent quarter. At December 31, 2012, the Series A Warrants and the Series C Warrants exercise price of \$1.12 per share was reduced to \$0.675 per share due to a new issuance price, net of commissions, from a private offering of common stock and warrants to accredited investors during the three months ended December 31, 2012 and pursuant to their exercise price reset provision. During the three months ended December 31, 2013, 1,269,520 of the Series A Warrants were exercised. During the three months ended December 31, 2013, 748,663 of the Series C Warrants were exercised. The Company determined the fair value of the Series A and Series C Warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the Series A and Series C Warrants exercised of \$1,620,081 was reclassified into additional paid-in capital. For the year ended December 31, 2013 there was a loss recognized from the revaluation of the warrant liability of \$3,873,187. During the three months ended March 31, 2014, 858,825 of the Series A Warrants were exercised. During the three months ended March 31, 2014, 697,092 of the Series C Warrants were exercised. The Company determined the fair value of the Series A and Series C Warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the Series A and Series C Warrants exercised in 2014 of \$3,911,370 was reclassified into additional paid-in capital. For the year ended December 31, 2014 there was a loss recognized from the revaluation of the warrant liability of \$959,320. For the year ended December 31, 2015 there was a gain recognized from the revaluation of the warrant liability of \$66,809.

During the three months ended March 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$4,045,510. The Company accepted subscriptions, in the aggregate, for 5,394,013 shares of common stock, and five year warrants to purchase 7,277,264 shares of common stock. Investors received five year fully vested warrants to purchase up to 100% to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$522,640 and issued five year fully vested warrants to purchase 539,401 shares of common stock with an exercise price of \$1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended June 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$2,641,501. The Company accepted subscriptions, in the aggregate, for 3,522,001 shares of common stock, and five year warrants to purchase 5,283,003 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number

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of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$314,173, accrued \$32,500 at June 30, 2013 which was paid in July 2013 and issued five year fully vested warrants to purchase 352,200 shares of common stock with an exercise price of \$1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$4,613,037. The Company accepted subscriptions, in the aggregate, for 6,150,718 shares of common stock and five year warrants to purchase 9,226,077 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$564,686 and issued five year fully vested warrants to purchase 615,072 shares of common stock with an exercise price of \$1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended September 30, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$2,687,500. The Company accepted subscriptions, in the aggregate, for 3,583,333 shares of common stock and five year warrants to purchase 5,375,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid \$349,375 and issued five year fully vested warrants to purchase 358,333 shares of common stock with an exercise price of \$1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to investors solicited by Maxim Group LLC. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$5,820,588. The Company accepted subscriptions, in the aggregate, for 7,760,784 shares of common stock and five year warrants to purchase 11,641,176 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$747,302 and issued five year fully vested warrants to purchase 776,078 shares of common stock with an exercise price of \$1.00 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended December 31, 2013 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,312,500. The Company accepted subscriptions, in the aggregate, for 1,750,000 shares of common stock and five year warrants to purchase 2,625,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 150% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.00 per share. The purchase price for each share of common stock together with the warrants was \$0.75. The Company used the proceeds for working capital and other general corporate purposes. Maxim Group LLC served as placement agent for the offering. In connection with the offering, the Company paid \$170,625 and issued five year fully vested warrants to purchase 175,000 shares of common stock with an exercise price of \$1.00 to Maxim Group LLC, which represents 10% of the total number of shares of common stock sold to investors solicited by Maxim Group LLC.



During the three months ended June 30, 2014, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$5,000,000. The Company accepted subscriptions, in the aggregate, for 2,000,000 shares of common stock and five year warrants to purchase 2,000,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 100% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$3.00 per share. The purchase price for each share of common stock together with the warrants was \$2.50. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$650,000 and issued five year fully vested warrants to purchase 300,000 shares of common stock with an exercise price of \$2.50 to Network 1 Financial Securities, Inc., which represents 15% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc. During the three months ended September 30, 2014, the Company commenced a private offering of up to \$15 million of common stock and five-year warrants to accredited investors. The

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warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. is serving as placement agent for the offering. During the three months ended September 30, 2014, the Company received subscriptions, in the aggregate, for 3,586,300 shares of common stock and five year warrants to purchase 1,793,150 shares of common stock for an aggregate of \$3,586,300. Investors will receive five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. is serving as placement agent for the offering. In connection with the offering, the Company paid \$466,219 and issued five year fully vested warrants to purchase 358,630 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc. During the three months ended December 31, 2014 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$4,198,300. The Company accepted subscriptions, in the aggregate, for 4,198,300 shares of common stock and five year warrants to purchase 2,099,150 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants was \$1.00. The Company used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$545,779 and issued five year fully vested warrants to purchase 419,830 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

During the three months ended March 31, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$776,000. The Company received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc. During the three months ended June 30, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,011,100. The Company received subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

*Private Offering of Convertible Preferred Stock with Warrants*

(d) In March and April 2010, the Company issued 8% Convertible Preferred Stock with warrants. The Company determined that warrants issued with the 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The value of the warrant liability was determined based on the Monte-Carlo Simulation model at the date the warrants were issued. The warrant liability is then revalued at each subsequent quarter. During the three months ended December 31, 2013, 1,146,662 of the warrants included in the warrant liability were exercised. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the warrants exercised of \$765,997 was reclassified into additional paid-in capital. For the year ended December 31, 2013 there was a loss recognized from the revaluation of the warrant liability of \$6,911,583. During the three months ended March 31, 2014, 1,756,665 of the warrants included in the warrant liability were exercised. During the three months ended June 30, 2014, 133,232 of the warrants included in the warrant liability were exercised. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the

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warrants exercised in 2014 of \$2,377,133 was reclassified into additional paid-in capital. For the year ended December 31, 2014 there was a gain recognized from the revaluation of the warrant liability of \$4,222,519. During the three months ended March 31, 2015, the remaining warrants included in the warrant liability were forfeited so no more 2010 warrants remain. For the year ended December 31, 2015 there was a gain recognized from the revaluation of the warrant liability of \$79,751.

Dividends on the 8% Convertible Preferred Stock accrued at an annual rate of 8% of the original issue price and are payable in either cash or common stock. If the dividend is paid in common stock, the number of shares of common stock will equal the quotient of the amount of cash dividends divided by the market price of the stock on the dividend payment date. The dividends are payable quarterly on the 15<sup>th</sup> day after the quarter-end. The Company has a deficit and, as a result, the dividends are recorded against additional paid-in capital in January 2013, the Company issued 61,022 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of January 15, 2013. At March 31, 2013, the Company recognized dividends of \$21,921 which are included in dividends on preferred stock on the consolidated statement of operations. In April 2013, the Company issued 29,384 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of April 15, 2013. At June 30, 2013, the Company recognized dividends of \$22,164 which are included in dividends on preferred stock on the consolidated statement of operations. In July 2013, the Company issued 34,598 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of July 15, 2013. At September 30, 2013, the Company recognized dividends of \$10,586 which are included in dividends on preferred stock on the consolidated statement of operations. In October 2013, the Company issued 12,066 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of October 15, 2013. At December 31, 2013, the Company recognized no dividends due because of the full conversion of preferred stock to common stock as of December 31, 2013.

During the three months ended March 31, 2013 there were 593,000 shares of the Company's redeemable preferred stock that converted into 593,000 shares of the Company's common stock. During the three months ended June 30, 2013 there were 403,520 shares of the Company's redeemable preferred stock that converted into 403,520 shares of the Company's common stock. During the three months ended September 30, 2013 there were 734,999 shares of the Company's redeemable preferred stock that converted into 734,999 shares of the Company's common stock. During the three months ended December 31, 2013 there were 746,666 shares of the Company's redeemable preferred stock that converted into 746,666 shares of the Company's common stock. At December 31, 2013 there was no 8% Convertible Preferred Stock outstanding.

(e) On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of \$2,550,000 of Units at a purchase price of \$0.75 per Unit. Each Unit consists of one share of Series A 8% Convertible Preferred Stock, par value \$.001 per share, and a warrant to purchase one and one-quarter shares of the Company's common stock, par value \$.001 per share (subject to adjustment) at an exercise price of \$1.00 per whole share (subject to adjustment). The total Series A 8% Convertible Preferred Stock issued was 3,400,001 shares, and the total warrants were 4,250,000. The Company used the net proceeds of the private placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

The Company determined that warrants issued in February, 2013 with the Series A 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share.

The preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be

bifurcated and classified as a liability. The proceeds received from the issuance of the preferred stock were first allocated to the fair value of the warrants with the remainder allocated to the preferred stock. The fair value of the preferred stock if converted on the date of issuance was greater than the value allocated to the preferred stock. As a result, a beneficial conversion amount was recorded upon issuance. The fair value of the warrants recorded from the February 2013 issuance was \$1,297,950 resulting in a beneficial conversion amount of \$1,025,950. The beneficial conversion has been recorded as a deemed dividend as of March 31, 2013 and is included in dividends on preferred stock on the consolidated statements of operations.

The value of the warrant liability was determined based on the Monte-Carlo Simulation model at the date the warrants were issued. The warrant liability is then revalued at each subsequent quarter. During the three months ended December 31, 2013, 2,400,000 of the warrants included in the warrant liability were exercised, resulting in 2,400,000 common shares being issued. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the warrants exercised of \$2,016,000 was reclassified into additional paid-in capital. For the year ended December 31, 2013 there was a loss recognized from the revaluation of the warrant liability of \$3,886,360. During the three months ended March 31, 2014, 1,650,000 of the warrants included in the warrant

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liability were exercised. During the three months ended June 30, 2014, 200,000 of the warrants included in the warrant liability were exercised, which is the remainder of the 2013 warrants. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the warrants exercised in 2014 of \$4,047,116 was reclassified into additional paid-in capital. For the year ended December 31, 2014 there was a loss recognized from the revaluation of the warrant liability of \$878,806.

Dividends on the Series A 8% Convertible Preferred Stock accrued at an annual rate of 8% of the original issue price and are payable in either cash or common stock. If the dividend is paid in common stock, the number of shares of common stock will equal the quotient of the amount of cash dividends divided by the market price of the stock on the dividend payment date. The dividends are payable quarterly on the 15th day after the quarter-end. The Company paid the dividends in common stock although was required to pay the initial dividends due in cash. The Company has a deficit and, as a result, the dividends are recorded against additional paid-in capital. At March 31, 2013, the Company recognized dividends of \$29,063 which are included in dividends on preferred stock on the consolidated statement of operations and were paid in April 2013. At June 30, 2013, the Company recognized dividends of \$50,860 which are included in dividends on preferred stock on the consolidated statement of operations. In July 2013, the Company issued 79,401 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of July 15, 2013. At September 30, 2013, the Company recognized dividends of \$28,104 which are included in dividends on preferred stock on the consolidated statement of operations. In October 2013, the Company issued 32,033 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of October 15, 2013. At December 31, 2013, the Company recognized no dividends due because of the full conversion of preferred stock to common stock as of January 15, 2014. In 2014, the Company recognized no dividends because of the conversion of all outstanding preferred stock to common stock as of January 15, 2014.

During the three months ended September 30, 2013 there were 441,667 shares of the Company's Series A 8% Convertible Preferred Stock that converted into 441,667 shares of the Company's common stock. During the three months ended December 31, 2013 there were 2,925,000 shares of the Company's Series A 8% Convertible Preferred Stock that converted into 2,925,000 shares of the Company's common stock. In January 2014 there were 33,334 shares of the Company's Series A 8% Convertible Preferred Stock that converted into 33,334 shares of the Company's common stock. As of January 15, 2014, there were no shares of Series A 8% Convertible Preferred Stock outstanding.

*Common Stock Purchase Agreements*

(f) In December 2010, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, pursuant to which the Company could, in our sole discretion, direct Lincoln Park to purchase up to an additional \$30,000,000 of our common stock over the 30-month term of the purchase agreement at no less than \$0.75 per share. On June 23, 2013, our agreement with Lincoln Park Capital Fund, LLC expired.

On July 22, 2013 the Company entered into a Purchase Agreement with Alpha Capital Anstalt pursuant to which the Company may, in the Company's sole discretion, direct the purchase up to \$30,000,000 of the Company's common stock over the 30-month term of the Purchase Agreement. From time to time during the term of the Purchase Agreement, the Company may, in its sole discretion direct the purchase up to 100,000 shares of the Company's common stock at a per share purchase price equal to the lesser of (i) the lowest sale price of the Company's common stock reported on the OTCQB or NYSE MKT on the purchase date and (ii) the arithmetic average of the three lowest closing sale prices for the Company's common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date. The Company may, under certain circumstances, at its discretion, increase the amount of common stock that it sells on each purchase date. The committed obligation under any single regular purchase shall not exceed \$250,000, unless the parties mutually agree to increase the dollar amount of any regular purchase. In no event may Alpha Capital Anstalt purchase shares of the Company's common stock for less than

\$0.75 per share. In consideration of entering into the Purchase Agreement and making the commitment to purchase the Purchase Shares, the Company issued 250,000 shares of the Company's common stock to Alpha Capital Anstalt. Costs charged to operations for this commitment fee were \$162,500. The Purchase Agreement may be terminated by the Company at any time, at its discretion, without cost to the Company. As of December 31, 2015, the Company had the full amount of the Purchase Agreement available for use. On January 22, 2016, our agreement with Alpha Capital Anstalt expired.

*Public Offerings of Common Stock and Warrants*

(g) On June 24, 2015, the Company completed a public offering of common stock and warrants for gross proceeds of \$13,151,250 (the Offering). The Offering consisted of 17,500,000 shares of common stock and warrants to purchase 17,500,000 shares of common stock with a public offering price of \$0.75 for a fixed combination of one share of common

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stock and a warrant to purchase one share of common stock. Investors received five year fully vested warrants to purchase up to 100% of the number of shares purchased by the investors in the Offering. The warrants have an exercise price of \$0.85 per share. The warrants met the criteria for equity treatment. At the closing, the underwriters exercised their over-allotment option with respect to warrants to purchase up to an additional 2,625,000 shares of common stock at \$0.01 per warrant. The warrants issued in the Offering began trading on the NYSE MKT on June 22, 2015, under the ticker symbol PVCTWS. The Company used the proceeds of the Offering for clinical development, working capital and general corporate purposes. Maxim Group LLC acted as sole book-running manager for the Offering. In connection with the Offering, the Company paid \$1,052,100 to Maxim Group LLC. As of December 31, 2015, 20,125,000 tradable warrants are outstanding.

**4. Stock Incentive Plan and Warrants**

The Company maintained two long-term incentive compensation plans which have been terminated; namely, the Provectus Pharmaceuticals, Inc. 2002 Stock Plan, which provided for the issuance of 18,450,000 shares of common stock pursuant to stock options, and the 2012 Stock Plan, which provided for the issuance of up to 20,000,000 shares of common stock pursuant to stock options. Currently, the Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan provides for the issuance of up to 20,000,000 shares of common stock pursuant to stock options for the benefit of eligible employees and directors of the Company.

Options granted under the 2002 Stock Plan and under the 2012 Stock Plan were either incentive stock options within the meaning of Section 422 of the Internal Revenue Code or options which were not incentive stock options. Options granted under the 2014 Equity Compensation Plan are either incentive stock options within the meaning of Section 422 of the Internal Revenue Code or options which are not incentive stock options. The stock options are exercisable over a period determined by the Board of Directors (through its Compensation Committee), but generally no longer than 10 years after the date they are granted.

For stock options granted to employees during 2015, 2014 and 2013, the Company has estimated the fair value of each option granted using the Black-Scholes option pricing model with the following assumptions:

|  | 2015    |     | 2014    |     | 2013    |     |
|--|---------|-----|---------|-----|---------|-----|
| Weighted average fair value per options granted                                  | \$ 0.38 |     | \$ 0.77 |     | \$ 0.57 |     |
| Significant assumptions (weighted average) risk-free interest rate at grant date | 0.25%   |     | 0.25%   |     | 0.25%   |     |
| Expected stock price volatility  | 90%     | 92% | 85%     | 92% | 83%     | 85% |
| Expected option life (years)   | 10      |     | 10      |     | 10      |     |

One employee of the Company exercised 18,750 options at an exercise price of \$0.32 per share of common stock for \$6,000 and 25,000 options at an exercise price of \$0.60 per share of common stock for \$15,000 during the three months ended June 30, 2013. One former non-employee member of the board forfeited 25,000 stock options on May 29, 2013. On August 19, 2013, the Company issued 250,000 stock options to its re-elected members of the board. All of the stock options issued in 2013 vest on the date of grant and have an exercise price equal to the fair market price on the date of issuance.

One employee of the Company exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750, 14,248 options at an exercise price of \$0.75 per share of common stock for \$10,686 and 600,000 options at



an exercise price of \$0.93 per share of common stock for \$558,000 during the three months ended March 31, 2014. Another employee of the Company exercised 300,000 options at an exercise price of \$1.10 per share of common stock for \$330,000 during the three months ended March 31, 2014. Another employee of the Company exercised 189,624 options at an exercise price of \$1.10 per share of common stock for \$208,586 during the three months ended March 31, 2014. One employee of the Company forfeited 300,000 stock options on February 26, 2014. One employee of the Company exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750 during the three months ended June 30, 2014. Another employee of the Company exercised 100,000 options at an exercise price of \$1.25 per share of common stock for \$125,000 during the three months ended June 30, 2014. A former non-employee member of the board of directors exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750 during the three months ended June 30, 2014. One employee of the Company forfeited 25,000 stock options on May 27, 2014. On July 29, 2014, the Company issued a total of 150,000 stock options to its three re-elected non-employee members of the board of directors. All of the stock options issued in 2014 vested on the date of grant and have an exercise price equal to the fair market price on the date of issuance. One employee of the Company exercised 96,875 options at an exercise price of \$0.64 per share of common stock for \$62,000, and 126,361 options at an exercise price of \$0.64 per share of common stock for \$80,871 during the three months ended December 31, 2014. Three employees of the Company had options rescinded during the three months ended December 31, 2014 due to the terms of the settlement discussed in Note 9.

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One employee of the Company exercised 185,000 options at an exercise price of \$1.02 per share of common stock for \$188,700 during the three months ended March 31, 2015. Another employee of the Company exercised 76,764 options at an exercise price of \$0.64 per share of common stock for \$49,129 during the three months ended March 31, 2015. Another employee of the Company exercised 33,334 options at an exercise price of \$0.75 per share of common stock for \$25,000 and 29,786 options at an exercise price of \$0.94 per share of common stock for \$27,999 during the three months ended March 31, 2015. One employee of the Company forfeited 300,000 stock options on January 7, 2015. Two employees and a former non-employee member of the board of the Company each forfeited 25,000 stock options on May 19, 2015 for a total of 75,000 options. Two employees of the Company each forfeited 300,000 stock options on May 25, 2015 for a total of 600,000 options. Two employees of the Company each forfeited 200,000 stock options on December 9, 2015 for a total of 400,000 options. One employee of the Company exercised 120,000 options at an exercise price of \$1.02 per share of common stock for \$122,400 during the three months ended December 31, 2015. Another employee of the Company exercised 145,214 options at an exercise price of \$0.94 per share of common stock for \$136,502 during the three months ended December 31, 2015. On December 9, 2015, the Company issued a total of 150,000 stock options to its three re-elected non-employee members of the board of directors and a total of 1,600,000 stock options to its four executive officers then in office. All of the stock options issued in 2015 vested on the date of grant and have an exercise price equal to \$0.75 per share of common stock which is greater than the fair market price on the date of issuance.

The compensation cost relating to share-based payment transactions is measured based on the fair value of the equity or liability instruments issued. For purposes of estimating the fair value of each stock option on the date of grant, the Company utilized the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company's common stock (as determined by reviewing its historical public market closing prices). Included in the results for the year ended December 31, 2015, is \$670,576 of stock-based compensation expense which relates to the fair value of stock options vested in 2015. Included in the results for the year ended December 31, 2014, is \$115,645 of stock-based compensation expense which relates to the fair value of stock options vested in 2014. Included in the results for the year ended December 31, 2013, is \$142,310 of stock-based compensation expense which relates to the fair value of stock options vested in 2013.

The following table summarizes the options granted, exercised, outstanding and exercisable as of December 31, 2013, 2014 and 2015:

|  | Shares     | Exercise Price<br>Per Share |      | Weighted<br>Average<br>Exercise<br>Price |
|--|------------|-----------------------------|------|--|
| Outstanding at January 1, 2013                   | 15,140,956 | \$ 0.32                     | 1.50 | \$ 0.97                                  |
| Granted  | 250,000    | \$                          | 0.67 | \$ 0.67                                  |
| Exercised  | (43,750)   | \$ 0.32                     | 0.60 | \$ 0.48                                  |
| Forfeited  | (25,000)   | \$                          | 0.60 | \$ 0.60                                  |
| Outstanding and exercisable at December 31, 2013 | 15,322,206 | \$ 0.62                     | 1.50 | \$ 0.97                                  |
| Outstanding at January 1, 2014                   | 15,322,206 | \$ 0.62                     | 1.50 | \$ 0.97                                  |

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|  |             |    |      |      |         |
|--|-------------|----|------|------|---------|
| Granted  | 150,000     | \$ | 0.88 | \$   | 0.88    |
| Settlement (Note 9)                              | (2,800,000) | \$ | 0.93 | 1.00 | \$ 0.97 |
| Exercised  | (1,502,108) | \$ | 0.64 | 1.25 | \$ 0.96 |
| Forfeited  | (325,000)   | \$ | 0.95 | 1.10 | \$ 1.09 |
| Outstanding and exercisable at December 31, 2014 | 10,845,098  | \$ | 0.64 | 1.50 | \$ 0.97 |
| Outstanding at January 1, 2015                   | 10,845,098  | \$ | 0.64 | 1.50 | \$ 0.97 |
| Granted  | 1,750,000   | \$ | 0.75 |      | \$ 0.75 |
| Exercised  | (590,098)   | \$ | 0.64 | 1.02 | \$ 0.93 |
| Forfeited  | (1,375,000) | \$ | 0.62 | 0.94 | \$ 0.77 |
| Outstanding and exercisable at December 31, 2015 | 10,630,000  | \$ | 0.67 | 1.50 | \$ 0.96 |

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The following table summarizes information about stock options outstanding at December 31, 2015 in order of issuance from oldest to newest.

| <b>Exercise Price</b> | <b>Number Outstanding at December 31, 2015</b> | <b>Weighted Average Remaining contractual Life</b> | <b>Outstanding Weighted Average Exercise price</b> | <b>Number Exercisable at December 31, 2015</b> | <b>Exercisable Weighted Average Exercise Price</b> |
|-----------------------|--|--|--|--|--|
| \$1.02                | 3,830,000                                      | 0.50 years   | \$ 1.02  | 3,830,000                                      | \$ 1.02  |
| \$1.50                | 200,000  | 1.50 years   | \$ 1.50  | 200,000  | \$ 1.50  |
| \$1.16                | 50,000   | 2.42 years   | \$ 1.16  | 50,000   | \$ 1.16  |
| \$1.00                | 150,000  | 2.50 years   | \$ 1.00  | 150,000  | \$ 1.00  |
| \$1.04                | 250,000  | 3.50 years   | \$ 1.04  | 250,000  | \$ 1.04  |
| \$1.16                | 250,000  | 4.50 years   | \$ 1.16  | 250,000  | \$ 1.16  |
| \$1.00                | 1,600,000                                      | 4.50 years   | \$ 1.00  | 1,600,000                                      | \$ 1.00  |
| \$1.04                | 250,000  | 5.50 years   | \$ 1.04  | 250,000  | \$ 1.04  |
| \$0.99                | 50,000   | 5.50 years   | \$ 0.99  | 50,000   | \$ 0.99  |
| \$0.93                | 1,600,000                                      | 5.67 years   | \$ 0.93  | 1,600,000                                      | \$ 0.93  |
| \$0.93                | 50,000   | 6.38 years   | \$ 0.93  | 50,000   | \$ 0.93  |
| \$0.84                | 200,000  | 6.50 years   | \$ 0.84  | 200,000  | \$ 0.84  |
| \$0.67                | 250,000  | 7.71 years   | \$ 0.67  | 250,000  | \$ 0.67  |
| \$0.88                | 150,000  | 8.67 years   | \$ 0.88  | 150,000  | \$ 0.88  |
| \$0.75                | 1,750,000                                      | 9.96 years   | \$ 0.75  | 1,750,000                                      | \$ 0.75  |
|                       | 10,630,000                                     | 4.92 years   | \$ 0.96  | 10,630,000                                     | \$ 0.96  |

The weighted-average grant-date fair value of options granted during 2015 was \$0.38. The total intrinsic value of options exercised during the year ended December 31, 2015 which were in the money was \$16,151.

The weighted-average grant-date fair value of options granted during 2014 was \$0.77. The total intrinsic value of options exercised during the year ended December 31, 2014 which were in the money was \$1,327,300.

The weighted-average grant-date fair value of options granted during 2013 was \$0.57. The total intrinsic value of options exercised during the year ended December 31, 2013 which were in the money was \$7,000.

The following is a summary of nonvested stock option activity for the year ended December 31, 2015:

|                                | <b>Number of Shares</b> | <b>Weighted Average Grant-Date Fair Value</b> |
|--------------------------------|-------------------------|---|
| Nonvested at December 31, 2014 |                         | \$  |
| Granted                        | 1,750,000               | \$ 0.38                                       |
| Vested                         | (1,750,000)             | \$ 0.38                                       |
| Canceled                       |                         |   |

|                                |    |
|--------------------------------|----|
| Nonvested at December 31, 2015 | \$ |
|--------------------------------|----|

As of December 31, 2015, there was no unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan.

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The following is a summary of the aggregate intrinsic value of shares outstanding and exercisable at December 31, 2015. The aggregate intrinsic value of stock options outstanding and exercisable is defined as the difference between the market value of the Company's stock as of the end of the period and the exercise price of the stock options which are in the money.

|  | Number of Shares | Aggregate Intrinsic Value |
|--|------------------|---------------------------|
| Outstanding and Exercisable at December 31, 2015 | 10,630,000       | \$ 0                      |

The following table summarizes the warrants granted, exercised, outstanding and exercisable as of December 31, 2013, 2014 and 2015.

|  | Warrants     | Exercise Price Per Warrant |      | Weighted Average Exercise Price |
|--|--------------|----------------------------|------|---------------------------------|
| Outstanding at January 1, 2013                   | 30,038,017   | \$ 0.68                    | 2.00 | \$ 1.05                         |
| Granted  | 53,675,050   | \$ 0.68                    | 1.12 | \$ 1.00                         |
| Exercised  | (8,379,845)  | \$ 0.68                    | 1.25 | \$ 0.93                         |
| Forfeited  | (2,295,806)  | \$ 0.68                    | 1.12 | \$ 0.87                         |
| Outstanding and exercisable at December 31, 2013 | 73,037,416   | \$ 0.68                    | 2.00 | \$ 1.03                         |
| Outstanding at January 1, 2014                   | 73,037,416   | \$ 0.68                    | 2.00 | \$ 1.03                         |
| Granted  | 9,415,673    | \$ 1.00                    | 3.00 | \$ 1.61                         |
| Exercised  | (17,524,498) | \$ 0.68                    | 1.50 | \$ 1.01                         |
| Forfeited  | (1,692,635)  | \$ 0.95                    | 1.25 | \$ 1.07                         |
| Outstanding and exercisable at December 31, 2014 | 63,235,956   | \$ 0.68                    | 3.00 | \$ 1.12                         |
| Outstanding at January 1, 2015                   | 63,235,956   | \$ 0.68                    | 3.00 | \$ 1.12                         |
| Granted  | 23,145,962   | \$ 0.85                    | 1.25 | \$ 0.88                         |
| Forfeited  | (6,260,323)  | \$ 0.95                    | 1.50 | \$ 1.10                         |
| Outstanding and exercisable at December 31, 2015 | 80,121,595   | \$ 0.68                    | 3.00 | \$ 1.05                         |

The following table summarizes information about warrants outstanding at December 31, 2015.

**Exercise Price**

|        | <b>Number Outstanding<br/>and Exercisable<br/>at<br/>December 31,<br/>2015</b> | <b>Weighted Average<br/>Remaining<br/>Contractual Life in<br/>Years</b> | <b>Weighted Average<br/>Exercise<br/>Price</b> |
|--------|--|---|--|
| \$0.68 | 134,994  | 0.00  | \$ 0.68  |
| \$0.85 | 20,125,000   | 4.50  | \$ 0.85  |
| \$1.00 | 47,125,026   | 2.61  | \$ 1.00  |
| \$1.12 | 1,337,035  | 1.33  | \$ 1.12  |
| \$1.25 | 8,176,540  | 2.82  | \$ 1.25  |
| \$1.50 | 400,000  | 0.83  | \$ 1.50  |
| \$1.75 | 200,000  | 0.00  | \$ 1.75  |
| \$2.00 | 323,000  | 1.25  | \$ 2.00  |
| \$2.50 | 300,000  | 3.33  | \$ 2.50  |
| \$3.00 | 2,000,000  | 3.33  | \$ 3.00  |
|        | 80,121,595   | 3.08  | \$ 1.05  |

## 5. Related Party Transactions

The Company paid one non-employee member of the board \$54,000 for consulting services performed as of December 31, 2013. The Company paid another non-employee member of the board \$75,000 for consulting services performed as of December 31, 2013. The Company paid a third non-employee member of the board \$75,000 for consulting services performed as of December 31, 2013.

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The Company paid one of the Company's directors \$6,000 as of March 31, 2014, all of which was paid as part of his overall compensation of an aggregate of \$85,000 for board and committee service.

On March 15, 2016, the Audit Committee made the following findings related to travel expense advances to its former Chief Executive Officer and Chairman of the Board of Directors, Dr. Dees: (1) in 2015, Dr. Dees received \$898,430 in travel expense advances but submitted receipts totaling only \$297,170, most of which did not appear to be authentic; (2) in 2014, Dr. Dees received \$819,000 for travel expense advances, for which no receipts were submitted; and (3) in 2013, Dr. Dees received \$752,034 for travel expense advances; no receipts were submitted by Dr. Dees for \$698,000 of these expenses and \$54,034 of submitted receipts did not appear to be authentic. The Company intends to pursue collection efforts on all of Dr. Dees' unsubstantiated travel expenses, including those which did not appear to be authentic. The travel expense advances to Dr. Dees could be deemed to be in violation of Section 402 of the Sarbanes-Oxley Act of 2002. If it were determined that these advances violated the prohibitions of Section 402 from making personal loans to executive officers or directors, we could be subject to investigation and/or litigation that could involve significant time and costs and may not be resolved favorably. The Company is unable to predict the extent of its ultimate liability with respect to these advances.

**6. Income Taxes**

Reconciliations between the statutory federal income tax rate and the Company's effective tax rate follow:

| Years Ended December 31,          | 2015           |        | 2014           |        | 2013           |        |
|-----------------------------------|----------------|--------|----------------|--------|----------------|--------|
|                                   | Amount         | %      | Amount         | %      | Amount         | %      |
| Federal statutory rate            | \$ (8,331,000) | (34.0) | \$ (3,483,000) | (34.0) | \$ (9,417,000) | (34.0) |
| State taxes                       | (1,103,000)    | (4.5)  | (461,000)      | (4.5)  | (1,246,000)    | (4.5)  |
| Adjustment to valuation allowance | 9,490,000      | 38.7   | 4,862,000      | 47.7   | 5,015,000      | 18.1   |
| Non-deductible compensation       |                |        |                |        |                |        |
| (Gain) loss on warrant liability  | (56,000)       | (0.2)  | (918,000)      | (9.2)  | 5,648,000      | 20.4   |
| Actual tax benefit                | \$             |        | \$             |        | \$             |        |

The components of the Company's deferred income taxes are summarized below:

| December 31,                      | 2015          | 2014          |
|-----------------------------------|---------------|---------------|
| Deferred tax assets               |               |               |
| Net operating loss carry-forwards | \$ 42,457,000 | \$ 34,046,000 |
| Theft loss                        | 963,000       |               |
| Stock-based compensation          | 6,602,000     | 6,344,000     |
| Warrants for services             | 5,633,000     | 5,421,000     |
| Deferred tax asset                | 55,655,000    | 45,811,000    |
| Deferred tax liabilities          |               |               |
| Patent amortization               | (1,121,000)   | (1,380,000)   |
| Valuation allowance               | (54,534,000)  | (44,431,000)  |



|                    |    |    |
|--------------------|----|----|
| Net deferred taxes | \$ | \$ |
|--------------------|----|----|

A valuation allowance against deferred tax assets is required if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company is in the development stage and realization of the deferred tax assets is not considered more likely than not. As a result, the Company has recorded a full valuation allowance for the net deferred tax asset.

Since inception of the Company on January 17, 2002, the Company has generated tax net operating losses of approximately \$110 million, expiring in 2022 through 2035. The tax loss carry-forwards of the Company may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carry-forwards. The Company completed a Section 382 study for the period from inception through the year ended December 31, 2014 and recorded a limitation of \$3.2 million to their net operating loss carry-forward.

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The Company has determined that there are no uncertain tax positions as of December 31, 2015 or 2014 and does not expect any significant change within the next year.

**7. 401(K) Profit Sharing Plan**

Contributions made by the Company totaled approximately \$212,000, \$320,000 and \$226,000 in 2015, 2014 and 2013, respectively.

**8. Fair Value of Financial Instruments**

The FASB's authoritative guidance on fair value measurements establishes a framework for measuring fair value, and expands disclosure about fair value measurements. This guidance enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. Under this guidance, assets and liabilities carried at fair value must be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are measured and reported on a fair value basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. The fair value of certain of the Company's financial instruments which are considered Level 1, including Cash and cash equivalents and Accounts payable, approximates the carrying value due to the relatively short maturity of such instruments. The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. The warrant liability is a derivative instrument and is classified as Level 3. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. Significant assumptions used are as follows:

|   | December 31, 2015 | December 31, 2014 | December 31, 2013 |
|---|-------------------|-------------------|-------------------|
| <b>2010 Warrants:</b>                                 |                   |                   |                   |
| Weighted average term                                 | N/A               | 0.2 years         | 1.2 years         |
| Probability the warrant exercise price would be reset | N/A               | 5%                | 5%                |
| Volatility  | N/A               | 63.7%             | 66.5% to 69.5%    |
| Risk free interest rate                               | N/A               | 0.03% to 0.04%    | 0.13% to 0.38%    |
| <b>2011 Warrants:</b>                                 |                   |                   |                   |
| Weighted average term                                 | 0 years           | 1.0 years         | 2.0 years         |
| Probability the warrant exercise price would be reset | 5%                | 5%                | 5%                |
| Volatility  | 40.4%             | 159.2%            | 64.7%             |
| Risk free interest rate                               | 0.13%             | 0.25%             | 0.38% to 0.78%    |
| <b>2013 Warrants:</b>                                 |                   |                   |                   |
| Weighted average term                                 | N/A               | N/A               | 4.1 years         |

|   |     |     |                |
|---|-----|-----|----------------|
| Probability the warrant exercise price would be reset | N/A | N/A | 5%             |
| Volatility  | N/A | N/A | 67.2%          |
| Risk free interest rate                               | N/A | N/A | 0.78% to 1.78% |

At December 31, 2015 there are no remaining 2010 or 2013 warrants and therefore no associated warrant liability.

The warrant liability measured at fair value on a recurring basis is as follows:

|  | Total      | Level 1 | Level 2 | Level 3    |
|--|------------|---------|---------|------------|
| Derivative instruments:                |            |         |         |            |
| Warrant liability at December 31, 2015 | \$         | \$      | \$      | \$         |
| Warrant liability at December 31, 2014 | \$ 146,560 | \$      | \$      | \$ 146,560 |

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A reconciliation of the warranty liability measured at fair value on a recurring basis with the use of significant unobservable inputs (Level 3) from January 1, 2014 to December 31, 2015 follows:

|                                  |                |
|----------------------------------|----------------|
| Balance at January 1, 2014       | \$ 12,866,572  |
| Issuance of warrants             |                |
| Net gain included in earnings    | (2,384,393)    |
| Exercise of warrants             | (10,335,619)   |
| <br>Balance at December 31, 2014 | <br>\$ 146,560 |
| <br>Balance at January 1, 2015   | <br>\$ 146,560 |
| Issuance of warrants             |                |
| Net gain included in earnings    | (146,560)      |
| Exercise of warrants             |                |
| <br>Balance at December 31, 2015 | <br>\$         |

**9. Litigation***Kleba Shareholder Derivative Lawsuit*

On January 2, 2013, Glenn Kleba, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against H. Craig Dees, Timothy C. Scott, Eric A. Wachter, and Peter R. Culpepper (collectively, the Executives), Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, together with the Executives, the Individual Defendants), and against the Company as a nominal defendant (the Shareholder Derivative Lawsuit). The Shareholder Derivative Lawsuit alleged (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on Mr. Kleba's allegations that the defendants authorized and/or accepted stock option awards in violation of the terms of the Company's 2002 Stock Plan (the Plan) by issuing stock options in excess of the amounts authorized under the Plan and delegated to defendant H. Craig Dees the sole authority to grant himself and the other Executives cash bonuses that Mr. Kleba alleges to be excessive.

In April 2013, the Company's Board of Directors appointed a special litigation committee to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee conducted its investigation, and proceedings in the case were stayed pending the conclusion of the committee's investigation. The Company has established a reserve of \$100,000 for potential liabilities because such is the amount of the self-insured retention of its insurance policy. On February 21, 2014, an Amended Shareholder Derivative Complaint was filed which added Don B. Dale (Mr. Dale) as a plaintiff.

On March 6, 2014, the Company filed a Joint Notice of Settlement (the Notice of Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Notice of Settlement are Mr. Kleba, Mr. Dale and the Individual Defendants.

On June 6, 2014, the Company, in its capacity as a nominal defendant, entered into a Stipulated Settlement Agreement and Mutual Release (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company and the Individual Defendants, Plaintiffs Glenn Kleba and Don B. Dale are parties to the Settlement.

By entering into the Settlement, the settling parties have resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the settling plaintiffs have not admitted that any claims or allegations lack merit or foundation. Under the terms of the Settlement, (i) the Executives each agreed (A) to re-pay to the Company \$2.24 Million of the cash bonuses they each received in 2010 and 2011, which amount equals 70% of such bonuses or an estimate of the after-tax net proceeds to each Executive; provided, however, that subject to certain terms and conditions set forth in the Settlement, the Executives are entitled to a 2:1 credit such that total actual repayment may be \$1.12 Million each; (B) to reimburse the Company for 25% of the actual costs, net of recovery from any other source, incurred by the Company as a result of the Shareholder Derivative Lawsuit; and (C) to grant to the Company a first priority security interest in 1,000,000 shares of the Company's common stock owned by each such Executive to serve as collateral for

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the amounts due to the Company under the Settlement; (ii) Drs. Dees and Scott and Mr. Culpepper agreed to retain incentive stock options for 100,000 shares but shall forfeit 50% of the nonqualified stock options granted to each such Executive in both 2010 and 2011. The Settlement also requires that each of the Executives enter into new employment agreements with the Company, which were entered into on April 28, 2014, and that the Company adhere to certain corporate governance principles and processes in the future. Under the Settlement, Messrs. Fuchs and Smith and Dr. McMasters have each agreed to pay the Company \$25,000 in cash, subject to reduction by such amount that the Company's insurance carrier pays to the Company on behalf of such defendant pursuant to such defendant's directors and officers liability insurance policy. The Settlement also provides for an award to plaintiffs' counsel of attorneys' fees and reimbursement of expenses in connection with their role in this litigation, subject to Court approval.

On July 24, 2014, the Court approved the terms of the proposed Settlement and awarded \$911,000 to plaintiffs' counsel for attorneys' fees and reimbursement of expenses in connection with their role in the Shareholder Derivative Lawsuit. The payment to plaintiff's counsel was made by the Company during October 2014 and was recorded as other current assets at December 31, 2014. The Company is seeking reimbursement of the full amount from insurance and if the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants. The amount was reclassified to long-term receivable at December 31, 2015. A reserve for uncollectibility of \$227,750 was established at December 31, 2015 in connection with the resignation of Dr. Dees.

On October 3, 2014, the Settlement was effective and stock options for Drs. Dees and Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$900,000 was repaid by the Executives as of December 31, 2015. The first year payment due has been paid. The remaining cash settlement amounts will continue to be repaid to the Company over a period of four years with the second payment due in total by October 2016 and the final payment is expected to be received by October 3, 2019. \$103,969 of the settlement discount was amortized as of December 31, 2015. The remaining balance due the Company as of December 31, 2015 is \$2,511,735, including a reserve for uncollectibility of \$870,578 in connection with the resignation of Dr. Dees, with a present value discount remaining of \$197,686. As a result of his resignation, Dr. Dees is no longer entitled to the 2:1 credit, such that his total repayment obligation of \$2,040,000 (the total \$2.24 million owed by Dr. Dees pursuant to the Settlement less the \$200,000 that he repaid as of December 31, 2015) plus Dr. Dees's proportionate share of the litigation costs is immediately due and payable. The Company sent Dr. Dees a notice of default in March 2016 for the total amount he owes the Company.

*Class Action Lawsuits*

On May 27, 2014, Cary Farrah and James H. Harrison, Jr., individually and on behalf of all others similarly situated (the Farrah Case), and on May 29, 2014, each of Paul Jason Chaney, individually and on behalf of all others similarly situated (the Chaney Case), and Jayson Dauphinee, individually and on behalf of all others similarly situated (the Dauphinee Case) (the plaintiffs in the Farrah Case, the Chaney Case and the Dauphinee Case collectively referred to as the Plaintiffs), each filed a class action lawsuit in the United States District Court for the Middle District of Tennessee against the Company, H. Craig Dees, Timothy C. Scott and Peter R. Culpepper (the Defendants) alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Specifically, the Plaintiffs in each of the Farrah Case, the Chaney Case and the Dauphinee Case allege that the Defendants are liable for making false statements and failing to disclose adverse facts known to them about the Company, in connection with the Company's application to the FDA for Breakthrough Therapy Designation (BTD) of the Company's melanoma drug, PV-10, in the Spring of 2014, and the FDA's subsequent denial of the Company's application for BTD.

On July 9, 2014, the Plaintiffs and the Defendants filed joint motions in the Farrah Case, the Chaney Case and the Dauphinee Case to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered

an order consolidating the Farrah Case, the Chaney Case and the Dauphinee Case (collectively and, as consolidated, the Securities Litigation ) and transferred the Securities Litigation to the United States District Court for the Eastern District of Tennessee.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint ) in the Class Action Case, alleging that Provectus and the other individual defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTB, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

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On June 5, 2015, Provectus filed its Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss ). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response ). Pursuant to order of the Court, Provectus replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions are continuing. On January 28, 2016, a settlement terms sheet (the Terms Sheet ) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Federal Class Actions.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Federal Class Actions, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier will pay the total amount of \$3.5 Million (the Settlement Funds ) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Federal Class Actions. The Company has determined that it is probable that the Company will pay \$1.85 Million of the total, which has been accrued at December 31, 2015. The insurance carrier will pay \$1.65 Million of the total directly to the plaintiff's trust escrow account and it will not pass through the Company. Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Federal Class Actions will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Federal Class Actions and the Federal Class Actions will be fully concluded. If the court does not give final approval of the Settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the Settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and provides for the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Federal Class Action. The court in the Federal Class Action has set April 7, 2016 for a hearing on preliminary settlement approval. If the Settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

### *Hurtado Shareholder Derivative Lawsuit*

On June 4, 2014, Karla Hurtado, derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ), and against the Company as a nominal defendant (the Hurtado Shareholder Derivative Lawsuit ). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) abuse of control, both claims based on Ms. Hurtado's allegations that the Individual Defendants (a) recklessly permitted the Company to make false and misleading disclosures and (b) failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the case to the United States District Court for the Eastern District of Tennessee and, in light of the pending Securities Litigation, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado Shareholder Derivative Lawsuit pending a ruling on the Motion to Dismiss filed by Provectus in the Class



Action Case.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado Shareholder Derivative Lawsuit.

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### *Montiminy Shareholder Derivative Lawsuit*

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit ) against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ). Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy's allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that the Company's melanoma drug, PV-10, would qualify for BTM. As a practical matter, the factual allegations and requested relief in the Montiminy Shareholder Derivative Lawsuit are substantively the same as those in the Hurtado Shareholder Derivative Lawsuit.

On December 29, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order consolidating the Hurtado Shareholder Derivative Lawsuit and the Montiminy Derivative Lawsuit. On February 25, 2015, the parties submitted a proposed agreed order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits until the Court issues a ruling on the anticipated motion to dismiss the amended consolidated complaint to be filed in the Securities Litigation. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado Shareholder Derivative Lawsuit, no relief is sought against the Company itself; the action is against the Individual Defendants only.

### *Foley Shareholder Derivative Complaint*

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ), and against the Company as a nominal defendant (the Foley Shareholder Derivative Lawsuit ). The Foley Shareholder Derivative Lawsuit was brought by the same attorney as the Montiminy Shareholder Derivative Lawsuit, Paul Kent Bramlett of Bramlett Law Offices. Other than the difference in the named plaintiff, the complaints in the Foley Shareholder Derivative Lawsuit and the Montiminy Shareholder Derivative Lawsuit are identical. On March 6, 2015, the Chancery Court of Knox County, Tennessee entered an Order staying the Foley Derivative Lawsuit until the United States District Court for the Eastern District of Tennessee issues a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado and Montiminy Shareholder Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

### *Donato Shareholder Derivative Lawsuit*

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against H. Craig Dees, Timothy C. Scott, Jan. E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ), and against the Company as a nominal defendant (the Donato Shareholder Derivative Lawsuit ). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company's purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. We are not in a position at this time to

give you an evaluation of the likelihood of an unfavorable outcome, or an estimate of the amount or range of potential loss to the Company.

As in the Hurtado, Montiminy, and Foley Shareholder Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

## **10. Subsequent Events**

The Company has evaluated subsequent events through the date of the filing of these financial statements. As of December 28, 2015, we had outstanding Existing Warrants to purchase an aggregate of 59,861,601 shares of Common Stock, which were issued between January 6, 2011 and November 1, 2015 in transactions exempt from registration under the Securities Act. Each Existing Warrant has an exercise price of between \$1.00 and \$3.00 per share (not taking into account the discounted exercise price), and expires between January 6, 2016 and November 1, 2020. On December 31, 2015, we offered pursuant to an Offer Letter/Prospectus 59,861,601 shares of our Common Stock for issuance upon exercise of the Existing Warrants. The shares issued upon exercise of the Existing Warrants are unrestricted and freely transferable. There is no established trading market

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for the Existing Warrants. The Offer was to temporarily modify the terms of the Existing Warrants so that each holder who tendered Existing Warrants during the Offer Period for early exercise were able to do so at a discounted exercise price of \$0.50 per share. The modification of the exercise price of the Existing Warrants and the Replacement Warrants are treated as an inducement to enter into the exchange offer and will be accounted for as of the closing date. Each Existing Warrant holder who tendered Existing Warrants for early exercise during the Offer Period received, in addition to the shares of Common Stock purchased upon exercise, an equal number of Replacement Warrants. Each Replacement Warrant has a cash exercise price of \$0.85 per share and will expire on June 19, 2020, unless sooner exercised. The exchange offer expired at 4:00 p.m., Eastern Time, on March 28, 2016. Approximately \$4.0 Million in gross proceeds were received upon closing of the exchange offer.

Under the terms of the Amended and Restated Executive Employment Agreement entered into by Craig Dees and the Company on April 28, 2014 (the Agreement), Dr. Dees is owed no severance payments as a result of his resignation on February 27, 2016 as the Company's Chief Executive Officer and Chairman of the Board of Directors. Dr. Dees's employment terminated with his resignation without Good Reason as that term is defined in the Agreement. Under section 6 of the Agreement, Effect of Termination, a resignation by Dr. Dees without Good Reason terminates any payments due to Dr. Dees as of the last day of his employment. As reported in the Company's press release furnished with the Company's Current Report on Form 8-K filed with the Commission on February 29, 2016, in connection with the resignation of Dr. Dees as the Company's Chief Executive Officer and Chairman of the Board of Directors, which was effective February 27, 2016, the Audit Committee conducted a review of Company procedures, policies and practices, including travel expense advancements and reimbursements. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. On March 15, 2016, the Audit Committee completed this investigation and made the following findings: (1) in 2015, Dr. Dees received \$898,430 in travel expense advances but submitted receipts totaling only \$297,170, most of which did not appear to be authentic; (2) in 2014, Dr. Dees received \$819,000 for travel expense advances, for which no receipts were submitted; and (3) in 2013, Dr. Dees received \$752,034 for travel expense advances; no receipts were submitted by Dr. Dees for \$698,000 of these expenses and \$54,034 of submitted receipts did not appear to be authentic. The Company intends to pursue collection efforts on all of Dr. Dees' unsubstantiated travel expenses, including those which did not appear to be authentic. The Company treats all relevant travel expenses of Dr. Dees as a theft loss and therefore any uncollectible amounts will be treated as income to Dr. Dees and a Form 1099 MISC will be issued by the Company to him in 2016 in that regard.

**11. Selected Quarterly Financial Data (Unaudited)**

The following tables present a summary of quarterly results of operations for 2015 and 2014:

|   | <b>Three Months Ended</b>             |                          |                               |                              |
|---|---------------------------------------|--------------------------|-------------------------------|------------------------------|
|   | <b>March 31,<br/>2015</b>             | <b>June 30,<br/>2015</b> | <b>September 30,<br/>2015</b> | <b>December 31,<br/>2015</b> |
|   | (in thousands, except per share data) |                          |                               |                              |
| <b>Consolidated Statement of Operations Data:</b>     |                                       |                          |                               |                              |
| Gain on settlement net of discount                    | \$                                    | \$                       | \$                            | \$                           |
| Total operating loss not including gain on settlement | (4,620)                               | (4,592)                  | (5,779)                       | (9,663)                      |
| Other income (expense), net                           | 95                                    | 47                       | (1)                           | 11                           |

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|  |            |            |            |            |
|--|------------|------------|------------|------------|
| Net income (loss)  | (4,525)    | (4,545)    | (5,780)    | (9,652)    |
| Net income (loss) applicable to common stockholders                    | \$ (4,525) | \$ (4,545) | \$ (5,780) | \$ (9,652) |
| Basic and diluted income (loss) per common share                       | \$ (0.02)  | \$ (0.02)  | \$ (0.03)  | \$ (0.05)  |
| Weighted average number of common shares outstanding basic and diluted | 185,196    | 187,793    | 204,610    | 204,735    |

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|  | <b>Three Months Ended</b>                    |                          |                               |                              |
|--|--|--------------------------|-------------------------------|------------------------------|
|  | <b>March 31,<br/>2014</b>                    | <b>June 30,<br/>2014</b> | <b>September 30,<br/>2014</b> | <b>December 31,<br/>2014</b> |
|  | <b>(in thousands, except per share data)</b> |                          |                               |                              |
| <b>Consolidated Statement of Operations Data:</b>                      |  |                          |                               |                              |
| Gain on settlement net of discount                                     | \$   | \$                       | \$                            | \$ 4,178                     |
| Total operating loss not including gain on settlement                  | (4,382)                                      | (4,160)                  | (3,826)                       | (4,443)                      |
| Other income (expense), net  | (2,285)                                      | 3,517                    | 77                            | 1,081                        |
| Net income (loss)  | (6,667)                                      | (643)                    | (3,749)                       | 816                          |
| Net income (loss) applicable to common stockholders                    | \$ (6,667)                                   | \$ (643)                 | \$ (3,749)                    | \$ 816                       |
| Basic and diluted income (loss) per common share                       | \$ (0.04)                                    | \$ (0.00)                | \$ (0.02)                     | \$ 0.00                      |
| Weighted average number of common shares outstanding basic and diluted | 168,860                                      | 175,554                  | 179,089                       | 182,057                      |

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| <b>Exhibit<br/>No.</b> | <b>Description</b>   |
|------------------------|--|
| 3.1                    | Certificate of Incorporation of Provectus Biopharmaceuticals, Inc. (the Company ) (incorporated by reference to Exhibit 3.1 of the Company s annual report on Form 10-K filed with the SEC on March 13, 2014)  |
| 3.2                    | Certificate of Amendment to Certificate of Incorporation of Provectus Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 3.2 of the Company s annual report on Form 10-K filed with the SEC on March 12, 2015)   |
| 3.3                    | Certificate of Designation for the Company s 8% Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Company s annual report on Form 10-K filed with the SEC on March 13, 2014)  |
| 3.4                    | Certificate of Designation for the Company s Series A 8% Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 of the Company s annual report on Form 10-K filed with the SEC on March 13, 2014)   |
| 3.5                    | Bylaws of the Company (incorporated by reference to Exhibit 3.4 of the Company s annual report on Form 10-K filed with the SEC on March 13, 2014)  |
| 4.1                    | Specimen certificate for the Company s common shares, \$.001 par value per share (incorporated by reference to Exhibit 4.1 of the Company s annual report on Form 10-KSB filed with the SEC on April 15, 2003).  |
| 4.2                    | Form of Series A Warrant issued to each of the purchasers identified on the signature pages of the Securities Purchase Agreement dated as of January 13, 2011 (incorporated by reference to Exhibit 4.1 of the Company s current report on Form 8-K filed with the SEC on January 13, 2011). |
| 4.3                    | Form of Series B Warrant issued to each of the purchasers identified on the signature pages of the Securities Purchase Agreement dated as of January 13, 2011 (incorporated by reference to Exhibit 4.2 of the Company s current report on Form 8-K filed with the SEC on January 13, 2011). |
| 4.4                    | Form of Series C Warrant issued to each of the purchasers identified on the signature pages of the Securities Purchase Agreement dated as of January 13, 2011 (incorporated by reference to Exhibit 4.3 of the Company s current report on Form 8-K filed with the SEC on January 13, 2011). |
| 4.5                    | Form of Warrant issued to Lincoln Park Capital, LLC (incorporated by reference to Exhibit 4.1 of the Company s current report on Form 8-K filed with the SEC on December 23, 2010).  |
| 4.6                    | Form of Warrant issued to investors in connection with the offering of the Company s 8% Convertible Preferred Stock (incorporated by reference to Exhibit 10.2 of the Company s current report on Form 8-K filed on March 12, 2010).   |
| 4.7                    | Form of Warrant issued to investors in connection with the offering of the Company s Series A 8% Convertible Preferred Stock (incorporated by reference to Exhibit 10.2 of the Company s current report on Form 8-K filed on February 28, 2013).   |
| 4.8                    | Warrant Agency Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.1 to the Company s current report on Form 8-K, filed with the SEC on June 19, 2015)  |

- 4.9 First Amendment to Warrant Agency Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.3 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015)
- 4.10 Form of Warrant Certificate (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 19, 2015)
- 4.11 Exchange and Escrow Agent Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.5 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015)
- 10.1\* Amended and Restated 2012 Stock Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed on April 30, 2012).



**Table of Contents****Exhibit**

| <b>No.</b> | <b>Description</b>  |
|------------|---|
| 10.2*      | Confidentiality, Inventions and Non-competition Agreement dated as of November 26, 2002 between the Company and H. Craig Dees (incorporated by reference to Exhibit 10.8 of the Company's annual report on Form 10-KSB filed on April 15, 2003).  |
| 10.3*      | Confidentiality, Inventions and Non-competition Agreement dated as of November 26, 2002 between the Company and Timothy C. Scott (incorporated by reference to Exhibit 10.9 of the Company's annual report on Form 10-KSB filed on April 15, 2003).   |
| 10.4*      | Confidentiality, Inventions and Non-competition Agreement dated as of November 26, 2002, between the Company and Eric A. Wachter (incorporated by reference to Exhibit 10.10 of the Company's annual report on Form 10-KSB filed on April 15, 2003).  |
| 10.5       | Material Transfer Agreement dated as of July 31, 2003 between Schering-Plough Animal Health Corporation and the Company (incorporated by reference to Exhibit 10.15 of the Company's quarterly report on Form 10-QSB filed on August 14, 2003).   |
| 10.6       | Securities Purchase Agreement dated as of January 13, 2011, by and between the Company and the purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on January 13, 2011).  |
| 10.7       | Purchase Agreement dated as of December 22, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed on December 23, 2010).   |
| 10.8       | Registration Rights Agreement dated as of December 22, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed on December 23, 2010).  |
| 10.9       | Form of Securities Purchase Agreement by and among the Company and the investors set forth on the signature pages affixed thereto used in connection with the offering of the 8% Convertible Preferred Stock and related warrants (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on March 12, 2010).                |
| 10.10      | Form of Registration Rights Agreement by and among the Company and the stockholders set forth on the signature pages affixed thereto used in connection with the offering of the 8% Convertible Preferred Stock and related warrants (incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K filed on March 12, 2010).             |
| 10.11      | Form of Securities Purchase Agreement by and among the Company and the investors set forth on the signature pages affixed thereto used in connection with the offering of the Series A 8% Convertible Preferred Stock and related warrants (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on February 28, 2013).    |
| 10.12      | Form of Registration Rights Agreement by and among the Company and the stockholders set forth on the signature pages affixed thereto used in connection with the offering of the Series A 8% Convertible Preferred Stock and related warrants (incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K filed on February 28, 2013). |
| 10.13*     | Executive Employment Agreement by and between the Company and H. Craig Dees, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.13 of the Company's annual report on Form 10-K filed with the SEC on April 30, 2014).   |

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- 10.14\* Executive Employment Agreement by and between the Company and Eric Wachter, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.14 of the Company's annual report on Form 10-K filed with the SEC on April 30, 2014).
- 10.15\* Executive Employment Agreement by and between the Company and Timothy C. Scott, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.15 of the Company's annual report on Form 10-K filed with the SEC on April 30, 2014).
- 10.16\* Executive Employment Agreement by and between the Company and Peter Culpepper dated April 28, 2014 (incorporated by reference to Exhibit 10.16 of the Company's annual report on Form 10-K filed with the SEC on April 30, 2014).

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**Exhibit**

| <b>No.</b> | <b>Description</b>   |
|------------|--|
| 10.17      | 2014 Equity Compensation Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed on April 30, 2014).  |
| 10.18      | Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on April 30, 2014).   |
| 10.19      | Stipulated Settlement Agreement and Mutual Release, dated June 6, 2014, by and among the Company as nominal defendant, H. Craig Dees, Timothy C. Scott, Eric A. Wachter, Peter R. Culpepper, Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV, as defendants, and Glenn Kleba and Don B. Dale, as plaintiffs (Exhibits Omitted) (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed on August 7, 2014).   |
| 10.20      | Consent and Waiver of Rights, between Provectus Biopharmaceuticals, Inc. and Alpha Capital Anstalt (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 24, 2015)  |
| 14         | Code of Ethics (incorporated by reference to Exhibit 14 of the Company's annual report on Form 10-K filed on March 16, 2011).  |
| 21         | Subsidiaries of the Company (incorporated by reference to Exhibit 21 of the Company's annual report on Form 10-K filed on March 16, 2011).   |
| 23         | Consent of Independent Registered Public Accounting Firm   |
| 31         | Certification of Interim CEO and CFO pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.   |
| 32         | Certification Pursuant to 18 U.S.C. Section 1350.  |
| 101        | The following financial information from Provectus Biopharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2015, filed with the SEC on March 10, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheet as of December 31, 2015 and December 31, 2014; (ii) the Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013; (iii) the Consolidated Statements of Equity for the years ended December 31, 2015, 2014 and 2013; (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013; and (v) Notes to Consolidated Financial Statements. |

Filed herewith.

Furnished herewith.

\* Indicates a management contract or compensatory plan or arrangement.