



# Melanovus Oncology, Inc.

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## Business Plan

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## **SUMMARY**

Melanovus Oncology, Inc. is a late pre-clinical stage biotechnology company that has discovered and is developing innovative new therapies and diagnostics for late stage melanoma. Founded in 2012 and headquartered in Jensen Beach, Florida, the company has been undertaking the studies necessary for experimental drugs leading to investigational new drug (IND) status from the Food and Drug Administration (FDA) for its compounds.

The company's portfolio includes five compounds with demonstrated pre-clinical activity in various stages of melanoma. The core technology was licensed from the Penn State Research Foundation. These first-in-class compounds are known as *Multi-Target Inhibitors*<sup>™</sup> (MTIs) as a result of their unique ability to selectively inhibit multiple pathways expressed in melanoma with a single agent. Nanilipolee-007 is the most advanced of these MTI compounds and could enter Phase I clinical trials in mid-2013. A companion diagnostic is also in development. The long-range plan for the company is to develop these unique compounds through Phase 2 clinical trials (either alone or with a strategic partner) and to identify partners that can help Melanovus to realize the full commercial potential of each compound in the U.S. and abroad. A full range of collaboration opportunities will be considered.

## **Vision, MISSION, AND STRATEGY**

To become a recognized leader in melanoma and skin cancers, and a partner of choice for licensing and commercialization, with world class products that diagnose, treat and ultimately prevent melanoma and other skin cancers, the company will leverage its unique scientific approach and library of proven compounds to develop new therapeutics for late stage melanoma through Phase 2 clinical trials. The company's small and highly qualified internal staff will lead scientific and commercial initiatives, and will establish strategic relationships with leading companies and consultants for support in clinical, finance, regulatory, legal and manufacturing. The company will seek partners for collaborations in research, development and commercialization.

Melanovus will help shape the market prior to commercialization through interaction with thought leaders in melanoma, and will highlight published data in respected journals that demonstrate the effectiveness and safety of the company's products. At the appropriate time, and in cooperation with our commercialization partners, direct-to-patient initiatives with internet support, as well as collaborations with non-profit melanoma foundations, will focus on raising awareness and help expand markets by encouraging regular checkups and earlier detection of the disease.

Reimbursement by third party payers will be key to the use and adoption of the company's products. Clinical trials and other pre-commercialization efforts will generate solid economic data as a basis for reimbursement discussions with major payers and Medicare.

## **MANAGEMENT**

The Melanovus management team and research staff includes individuals with proven success in research, product development, clinical development, and product commercialization. Members of the core team have successfully managed and arranged financing for an early stage oncology company through Phase I. Using a capital efficient model, the core team is

supported by a network of seasoned professionals with extensive legal, regulatory, financial and manufacturing expertise with early stage companies.

## **INDUSTRY AND ENVIRONMENT**

### **INDUSTRY OUTLOOK**

According to the American Cancer Society's 2011 Cancer Facts and Figures report, over 70,000 Americans were diagnosed with melanoma in 2011, and almost 9,000 died of the disease. Melanoma is the fifth leading cause of cancer in men, and the seventh leading cause of cancer in women. If diagnosed early, treatment can be successful. Because melanoma can often become aggressive, once it metastasizes to other organs, it can become fatal. The incidence of melanoma is increasing faster than any other solid tumor cancer. Current approaches to disease management can be costly, including surgery, radiation, immunotherapy, chemotherapy or combinations of several approaches. The five year survival rate for localized disease is 91%, and for regionalized disease is 62%, however, for distant (metastasized) disease the survival rate is just 15%.

In addition to the treatment of melanoma, the company will develop drugs, currently in our pipeline, that could ultimately prevent melanoma and other skin cancers.

### **REGULATORY ENVIRONMENT**

Melanovus expects a comprehensive review by the FDA for its therapeutics and diagnostics, and will be prepared to meet all regulatory requirements as they relate to clinical, manufacturing and other submissions. With IND approval, the company will initiate its Phase I trial in late stage melanoma. A regulatory pathway for the company's companion diagnostic will also be pursued, utilizing the expertise of a strategic diagnostic partner.

Melanoma is classified as an orphan disease. With IND approval, the company will seek Orphan Drug status for its lead compound.

Because there is a significant unmet medical need in melanoma, the company will seek Fast Track and expedited review status as supporting data become available.

### **TECHNOLOGY**

Targeting the multiple key pathways involved in melanoma using a single agent represents a new and novel approach. Melanovus has developed a library of first-in-class compounds which are referred to as *Multi-Target Inhibitors™ (MTIs)*. This unique approach inhibits not one but multiple processes leading to tumor development and spread including inhibition of proliferation, triggering of apoptosis, reduction in migration and metastasis and limiting tumor vascularization. This multifaceted approach could lead to slowing tumor growth and decreasing probability of developing drug resistance that will ultimately change the course of disease progression.

The company's compounds uniquely attack the tumor through the PI3 kinase, MAP kinase, STAT and other key pathway(s) in melanoma development. By targeting the pathways that are primarily overactive in melanoma cells, these highly specific agents could provide better efficacy and less damage to surrounding/normal tissues.

The effectiveness of this approach has been observed in early animal studies. Not only did the disease no longer progress, but tumor shrinkage and reversal of progression was clearly observed.

## **MARKET**

The market for new compounds in melanoma is large, growing, and largely unsatisfied. Despite the recent introduction of new compounds, current approaches often result in treatment failures, disease recurrence, and drug resistance. Effective new alternatives are necessary if we ever hope to change the course of this disease.

The global market potential for products to treat melanoma could exceed \$7.5 billion in 2015 according to Med Track 2011 projections. Sales in the U.S. could exceed \$3 billion.

There are currently no satisfactory therapies available for the long term treatment of melanoma. Annually, there are over 70,000 new cases of melanoma diagnosed in the United States from which approximately 10,000 people will die. Any effective new therapy therefore has the potential to have a profound impact in the United States and around the world.

## **MANAGEMENT TEAM**

### **President and Chief Executive Officer: Thomas S. Lytle, MBA**

Tom, age 66, is a pharmaceutical and biotechnology executive with a demonstrated track record and over 35 years of progressive experience in commercializing products in multiple markets and therapeutic categories at market-leading companies.

He began his extensive career in the healthcare industry at Pfizer in 1971. In 20+ years with that company he gained a broad range of industry and commercial experience in a series of sales, marketing, and management positions including Group Product Manager and Vice President, Marketing and Business Development.

Tom joined Amgen in 1997 and led efforts to build new capabilities in market research, corporate accounts, and competitive analysis. His efforts resulted in improved planning and new ways to use information for strategic and competitive advantage. He was promoted to Vice President of New Products in 1999 where his responsibilities included the shaping of markets and products for launch and developing plans for the commercialization of new products. In 2002 he became Vice President, Strategic Marketing and Business Development and led efforts to bring innovative and forward-looking business solutions to customer and market problems. These efforts helped create and realize significant value in several key areas.

Following a brief retirement from Amgen, he joined Cytogen Corporation in 2004 as Senior Vice President, Sales and Marketing where he leveraged his pharmaceutical and biotechnology experience to create a new business model and to build a new commercial capability in support of the company's cancer portfolio. In this role he was instrumental in the company achieving double-digit revenue growth.

In January 2006 Tom launched Strategic Choices, LLC, a well-networked healthcare consulting practice focused on helping a select group of small and emerging companies build core strategies, develop options, and make the hard choices necessary to achieve key objectives.

In December 2006 Tom was elected to the Board of Directors of Neogenix Oncology, Inc., a clinical stage oncology therapeutics and diagnostic company focusing on pancreatic and other cancers, where he also served as Chief Operating and Administrative Officer until January 2011. His responsibilities included a full range of business development and commercialization activities. Neogenix is now in Phase I trials and is a public reporting company. He left Neogenix in November of 2011 to establish Melanovus.

Tom is an Adjunct Professor at the University of the Sciences in Philadelphia, teaching graduate level courses in Pharmaceutical Sales and Marketing, Brand Management, and Competitive Analysis and Business Strategy. He earned his Bachelor's degree in marketing at Western Michigan University in 1968 and his MBA at LaSalle University in Philadelphia in 1981.

In 1993 Tom retired from the US Army Reserve as a Colonel, after 25 years of active and reserve service. He successfully served in senior command and staff positions including Assistant Division Commander and Division Chief of Staff. He has been awarded the Legion of Merit, the Bronze Star, and numerous other decorations. He is a graduate of the Command and General Staff College, the War College, and senior service schools.

**Chief Scientific Officer: Gavin P. Robertson, PhD**

Gavin, age 48, is a Professor of Pharmacology, Pathology, Dermatology and Surgery at Penn State University, Director of the Penn State Melanoma Center, and Director of the Foreman Foundation Melanoma Research Laboratory in the Department of Pharmacology and the Penn State Cancer Institute. His research focuses on malignant melanoma. The central goal of his program is to unravel the biology and signaling pathways involved in melanoma tumor development in order to develop the next generation of therapeutic agents to treat this disease. Specifically, it involves identification and validation of novel therapeutic targets, discovery and development of new therapies and clinical evaluation of these drugs in patients. Generally, the types of studies conducted in the Robertson laboratory are as follows: first, genetic, cell culture, animal, as well as human models are used to identify and validate the involvement of candidate melanoma-causing genes in this disease. A recent example is the discovery of Akt3 involvement in ~70% of human melanomas; second, drug screens and medicinal chemistry are used to identify and develop new therapeutic agents. A recent example is the melanoma-treating drug ISC-4, which targets Akt3 signaling; third, nanotechnology and bioengineering are used to deliver experimental agents into cancer cells. A recent example of this is the use of nanoliposomes and ultrasound that deliver therapeutic siRNA into melanoma cells; and finally, agents are tested in the clinic for toxicity and tumor inhibitory efficacy. A recent example is a killed mycobacterium called CADI-5 that is being evaluated in clinical trials. The ultimate goal of Gavin's translational research program is to develop better therapeutics for the treatment of melanoma based on the biology of the disease.

Gavin earned a PhD from the University of California, Riverside in 1997, and completed his Postdoctoral Training at the Ludwig Institute for Cancer Research in San Diego in 2000. He earned his Bachelor's degree from California State University in 1988.

**Chief Medical Officer: Rogerio I. Neves, MD, PhD**

Rogerio, age 51, is a Professor of Surgery, Dermatology, Pharmacology and Medicine at Penn State University College of Medicine in Hershey, Pennsylvania. He is the deputy director of the Penn State Hershey Melanoma Center, director of the Skin Oncology Program and clinical science leader of the Melanoma Therapeutics Program of The Penn State Cancer Institute.

Rogério received his medical degree from Faculdade de Medicina do ABC in Sao Paulo, Brazil in 1985. He completed his residencies in general and plastic and reconstructive surgery at the Hospital das Clínicas of the University of Sao Paulo School of Medicine. He then continued with two research fellowships at Penn State University College of Medicine, Hershey Medical Center, and at Memorial Sloan-Kettering Cancer Center in New York, and earned a doctorate in medicine (surgery) at the University of Sao Paulo in 1997.

Rogério is a member of the American Society of Clinical Oncology, Plastic Surgery Research Council, Society of Surgical Oncology, the New York Academy of Sciences, the Society for Melanoma Research, and the International Dermoscopy Society, among others. In addition, he serves on several university and hospital-related committees.

Rogério has received numerous grants for scientific and clinical research studies. Co-editor of a textbook on dermoscopy and co-author of various textbook chapters, his work has been widely published in peer-reviewed journals, and he serves on the editorial boards of three medical journals. He is a frequent invited lecturer as well as a presenter at national and international medical and scientific meetings around the world.

**Chief Financial Officer: Peter Gordon, MBA**

Peter, age 62, has 25 years of experience in management, finance, and accounting activities. He is also the President of 1st U.S. Capital Markets, Inc., a financial advisory and general management consulting firm. He previously served as a Founder, Board Member, Chief Financial Officer and Corporate Secretary of Neogenix Oncology, Inc., a biotechnology firm developing products for the treatment of pancreatic and colorectal cancer. He served as Vice President of Finance for Concrete Media, a pioneering e-commerce firm; CFO of Bennett X-Ray, a medical device manufacturer; CFO of Cornwall Securities, Inc., a registered broker/dealer; and CFO of US Tele-Com, Inc., the third largest private payphone service in the U.S. He also served as Vice President of Finance for Time-in-Motion, Inc., a custom timepiece manufacturer, and was Director of Business Planning for the Loris Products Division of the Hattori-Seiko Corporation.

Peter received an AAS degree in Mechanical Engineering from the College of Aeronautics in 1971, a Bachelor of Science degree from Lehman College in 1981, and an MBA from Pace University in 1986.

**Vice President of Product and Business Development: Antony Brazzale**

Tony, age 38, began his career at Abbott Laboratories in 1996 as a research scientist in the area of medicinal drug discovery. In 1999 he moved to Wyeth to continue his drug development career. He is an inventor on numerous patents and an author of a number of published peer-reviewed journal articles in the areas of chemistry and drug discovery in the antibiotic and women's health therapeutic areas. He left the lab in 2003 to pursue operations, sales, and business development positions in the life sciences with companies including Biotage, Argonaut Technologies, and BIA Separations, where he spent three years as the Vice President of Business Development for North America and special advisor to the Board of Directors.

In 2011 Tony founded Biotech Business Development, Inc., a corporate strategy and finance advisory focused on the global life sciences industry. The company's mission is to add and create value for therapeutic and technology-based companies by implementing operational improvements and business development strategies.

Tony is a member of a number of scientific and professional societies including the Licensing Executives Society and the American Chemical Society (ACS), where he will be the 2013 Chairman of the Division of Business Development and Management. He is also an advisor to the Entrepreneurial Resource Center, part of the Entrepreneurial Initiative, within the ACS.

Tony earned a Bachelor of Science degree in chemistry from Southern Illinois University in 1996.

## **BOARD OF DIRECTORS**

### **Thomas S. Lytle, Chair**

See bio above

### **Gavin P. Robertson**

See bio above

### **Richard A. Mafrica**

Rick has over 28 years of sales, marketing and executive leadership experience in pharmaceutical, device and biotechnology businesses with both development stage and fully commercialized companies. He currently advises clients on commercial strategy.

As Chief Business Officer at One Oncology, Senior Vice President Commercial at Idenix Pharmaceuticals and Vice President Global Commercial at Maxim Pharmaceuticals, he built teams, brands and commercial capability, while at the executive committee level defined strategy, portfolio and business development and licensing decision-making, established policy and compliance guidelines, re-structured and executed a successful reverse merger.

Over 14 years at Amgen, Inc. he led national teams in sales and marketing, corporate accounts, payer relations and strategic planning. At Amgen Rick was accountable for over \$3 billion in annual sales and over 300 people. He played a central role in establishing Amgen's early commercial oncology presence and the successful launch of three blockbuster products.

Prior to Amgen he held sales positions in the device industry representing Siemens-Pacesetter (pacemakers), Cryolife (human vascular tissue for transplant) and Wyeth-Ayerst (pharmaceuticals).

### **John Cushard**

John had a successful 37 year career in Pharmaceutical Sales and Marketing. From 2004 until 2008, John was Amgen's Director of Corporate Accounts Payor and Reimbursement Organization comprised of Managed Care and Medicaid sales managers in the North East and Mid-Atlantic Regions. After joining Amgen in 2002, John worked with Key National and Regional Accounts in Managed Care. Before Amgen, John worked for Novartis Pharmaceuticals and CibaGeigy Pharmaceuticals as an Associate Director in Managed Care leading account teams for National Managed Care Organizations for over seven years. Prior to Novartis, John worked in Managed Care and various sales management capacities for Boehringer Ingelheim and Searle Pharmaceuticals.

### **Phillip G. Foreman**

Phil is the Founder and the Chairman of the Foreman Foundation at the Hershey Medical Center, a 501(c)3 charitable organization dedicated to raising funds for medical research that will lead to a cure for melanoma cancer. He is the President of the Foreman Group Companies



which include Foreman Architects Engineers, Inc., Foreman Program and Construction Managers, Inc., Foreman Building Commissioning, PerFOREMANce Roofing Specialists, and RAPOSAP®.

#### **SCIENTIFIC ADVISORY BOARD**

The company's scientific board will provide guidance and advice regarding agent development, Phase I trial development and decision-making regarding prioritization of agents for development.

#### **Chair - Gavin P. Robertson, PhD**

See Gavin's bio above

#### **Vincent Chau, PhD**

Professor of Cellular and Molecular Physiology, Penn State College of Medicine

#### **Webster Cavenee, PhD**

Professor of Medicine and Cell & Molecular Medicine, Cancer Biology Program, Director - Ludwig Center for Cancer Research, Member Of National Academy of Sciences, University of California at San Diego

#### **Meenhard Herlyn, DVM, DSc**

Casper Wistar Professor in Melanoma Research, Director - The Wistar Institute & Melanoma Research Center, Professor and Co-Program Leader - Tumor Microenvironment & Metastasis Program

#### **Sanjiv S. Agarwala, MD**

Professor of Medicine - Temple University School of Medicine, Chief - Oncology & Hematology - St. Luke's Cancer Center

#### **BUSINESS ADVISORY BOARD**

The company's business advisory board will provide guidance and advice regarding strategic business direction.

#### **Chair - Peter Gordon, MBA**

See Peter's bio above

#### **James Laird, MBA**

Jim has held senior positions in sales, marketing, business development, and international general management over his 20 years at GlaxoSmithKline. In 1995, Jim formed his own consulting firm specializing in identifying and executing business growth strategies for early-stage and middle-market life sciences companies. Through his contracted assignments from 1995 through 2001 he served in interim senior management positions such as Executive Director of a national IT solutions provider, COO for an emerging dot-com company, COO of a regional healthcare data and informatics service provider, and President of a regional business accelerator. In September 2001, he co-founded ParagonRx, now a subsidiary of inVentiv Health, a leader in the design and implementation of FDA sanctioned Risk Evaluation and Mitigation Strategies (REMS) programs.

In 2005 Jim joined Ashton Tweed Ltd. as a full equity partner and redirected the firm's core service offerings to support exclusively the life sciences industry. He created and branded The Life Sciences Talent Bank™ comprising executive level industry veterans who are available for interim employment or selective consulting assignments. Jim also created and served as CEO of BioPortUSA, a wholly owned subsidiary of Ashton Tweed launched in 2007 to assist foreign-based life sciences firms establish a business entity in the USA by employing a virtual organization model drawing upon the Talent Bank to fulfill mission critical roles in a cost-effective format for their international clients.

Jim earned a Bachelor of Science degree in Pharmacology & International Marketing in 1975 and an MBA in 1977 from The University of Western Ontario.

### **Steven Terreri**

Steve has 22 years of experience at Amgen with increasing levels of responsibility, where he successfully launched every oncology brand in the company's history. During his last 10 years at Amgen he held the position of Executive Director of Oncology Sales, where he participated in numerous strategic corporate projects and initiatives and received many awards and honors.

Steve earned a Bachelor of Science degree in Animal Science from the University of Vermont in 1981.

### **Richard Slattery**

Rick is an expert in clinical research with over 44 years in the healthcare industry. For the past 22 years he has been the owner and president of Clinical Marketing Consortium, a leader in the CRO field. He also has experience in significant areas of market research and healthcare advertising. He has worked for companies such as Smith Kline & French, Pfizer, Pipeline Research, Barnum, and CDA. He has tracked or launched over 100 compounds, invented the clinical model known as "Clinical Experience Study (CES)," and executed more than 40 post-marketing trials including strict Phase 4 studies and CESs. Rick continues to consult to both pharmaceutical firms and the FDA on REMS programs.

Rick earned a bachelor's degree from Lemoyne College in 1965.

### **Philip Goodman**

Phil is the Managing Director of Investment Banking at Joseph Gunnar & Company, a 100+ person broker/dealer and investment bank. He also serves as the Managing Member of 30 Broad Group, which operates the Genesis Bridge Fund. He is a director of American Fund Advisors Private Equity Fund I, a co-founder and, until recently, a director of Ardent Acquisition Corporation, which was merged into AVANTAIR (AAIR). At Ardent he also served as a member of the audit committee. He is a member of the board of directors of Oxford Biomedical Technologies, Inc. and serves as Strategic Advisor to that company's President and CEO. He served as a board observer and long term advisor to the CEO of InClinix, Inc., a clinical trial enrollment company. Inclinix was turned around and then more than tripled sales and profits in just 2½ years.

In addition to his broad experience in angel, venture capital, and private equity investing, Phil is a successful serial entrepreneur. He also has done numerous turnarounds and restructurings on behalf of investors such as Warren Avis, Principal Financial, and Bulldog Capital. Phil co-founded and was Chairman of the Board of FastComm Communications Corporation, which achieved a \$160 million market capitalization in the early 1990's. He was the Fund Consultant for Greyhound Fund LP, advising the CEO and COO on all new private technology investments,

early stage and mezzanine, as well as turnarounds and restructurings of the fund's portfolio companies. He was a founder of Control Transaction Corporation via a leveraged buyout, serving as both an officer and director. The company was successfully merged with GEAC, at that time an \$800 million conglomerate. He also served as Vice President, Sales and Marketing of Digital Computer during its years of maximum growth. Phil assisted Central Florida Innovation Corporation (CFIC) as Entrepreneur in Residence on a consulting basis, helping to set the strategy for two new technology companies in the Orlando area; Theseus Logic and TeraNex.

He has served, and serves, as a director of both public and private companies including Ardent Acquisition, Oxford Biomedical Technologies, Inc., Transidyne General, Control Transaction, AFA Private Equity Fund, and AIFFL.

Phil earned an Associate of Arts degree in Liberal Arts in 1955 from the University of Chicago, a Bachelor of Arts in Anthropology in 1959 from Miami University, and a Bachelor of Science in Mechanical Engineering in 1960 from Case Western University.

Additional members will be added to bring experience in financing, IP and business development.

#### **SUPPORT STAFF**

The company will operate with only the internal lab and administrative staff required to achieve key milestones and objectives. Lab facilities have been made available through Penn State and through the Hershey Center for Applied Research (HCAR). Highly skilled and experienced researchers are in position to help conduct Melanovus' research. These PhD level individuals have worked extensively in Dr. Robertson's lab, and some have been principal investigators on previously completed IND-enabling studies. Located in close proximity to both the Penn State Medical School and Medical Center, the Melanovus research team will be supplemented with graduate level researchers who have experience with our products, and who have already contributed to early efficacy, safety, and formulation work.

The initial budget assumes that two technicians (one animal, and one wet lab) may be required to support the remaining pre-IND studies. Melanovus will initially hire only one technician who can function in both areas. As work demand escalates, consideration will be given to employment of a second technician. However, if a CMO or CRO can provide these services, that is the preferred approach versus hiring internal staff.

#### **RETAINING KEY PERSONNEL**

All team members are deeply committed to discover more effective treatments for skin cancer. Competitive wages and benefits will be instituted to ensure the retention of key talent and expertise. As the company develops, an attractive package of salaries, incentives and benefits will be developed. The company's core philosophy is to "pay for performance", with salaries being competitive but in the median range for comparable positions in the industry. Significant upside potential will be offered through stock options and bonuses for achieving and exceeding key milestones.

## **MARKETING PLAN**

### **PRODUCT DEVELOPMENT**

The core technology for the products in Melanovus' pipeline was developed under the auspices of the Penn State Research Foundation, and funded by a combination of grants and other funding provided by Penn State University. Melanovus acquired a global license to the patents, related IP, and know-how associated with these products in March of 2012. Melanovus also has a right of first refusal on any future improvements or developments related to licensed technology.

The company's lead compound, Nanolipolee-007, is a late pre-clinical stage product with the majority of IND enabling studies having been completed successfully. The company will complete the remaining studies, complete GLP and GMP manufacturing, and file for IND approval in preparing for initiating a Phase I trial in late stage melanoma.

Company co-founder Gavin Robertson, the discoverer of the technology, provides the company's scientific leadership. A network of industry-leading Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs) will manage clinical trials and products production, in addition to ensuring regulatory compliance.

Leveraging the work that has already been completed, CROs and CMOs will be utilized to synthesize multiple batches of clinical grade material and conduct toxicology, pharmacokinetics and pharmacodynamics studies in multiple animal models. The CMO will complete manufacturing in preparation for Phase I testing.

The company's Chief Medical Officer, Rogerio Neves, will coordinate protocol development and participate in discussions with IRBs and other organizations reviewing and approving protocols.

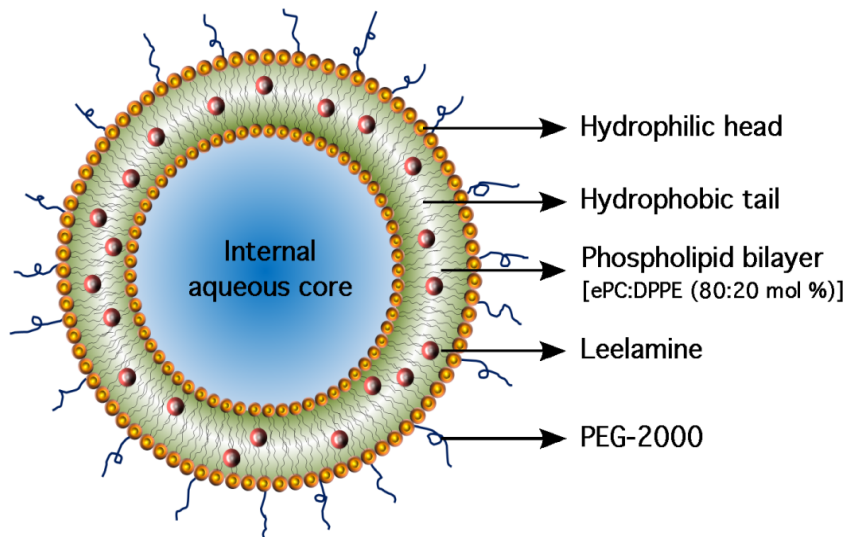
A similar process will be followed in development of the companion diagnostics. The company will rely heavily on a diagnostic partner for this expertise.

### **LEAD PRODUCT CANDIDATE DEVELOPMENT - NANOLIPOLEE-007**

Malignant melanoma is the most deadly form of skin cancer. Multiple pathways such as STAT, MAP and PI3 kinase are deregulated in the development of melanoma. Cross-talk between these pathways has been implicated in development of drug resistance and disease recurrence. Simultaneous targeting of these multiple pathways could be a better strategy to effectively treat this deadly disease, an approach which has been supported in multiple recent peer-reviewed published scientific articles. A natural product library was screened to identify compounds that targeted these multiple pathways. Leelamine, a product derived from the bark of pine trees, was identified for further study. A nanoliposomal formulation of this compound, Nanolipolee-007, was chosen for drug development and IND-enabling studies.

The benefits of the nanoliposomal formulation, which has been shown to be stable at room temperature for one month and at 4°C for one year, are many and include the "enhanced permeability and retention" (EPR) effect which allows for greater concentration, or accumulation, of the active agent within the tumor.

## Schematic of leelamine loaded liposome (Nanolipolee-007)



An agent of this type does not currently exist for melanoma, making this product highly innovative with the potential to satisfy a real need in the market.

In the next phase of development, further IND enabling studies will (1) establish a LC-MS/MS method for measuring levels of leelamine contained in Nanolipolee-007 in the serum or tissues of animals over time following intravenous administration to establish dosing for therapeutic efficacy, toxicokinetics, pharmacokinetic and pharmacokinetic studies of the agent, and (2) conduct escalating dose and 10-day repeated intravenous dosing studies in rats and dogs followed by measurement of leelamine levels present in the serum and tissues of the animals. Collectively, these discoveries are expected to form a crucial portion of the foundation to obtain IND status for systemic Nanolipolee-007 treatment from the FDA to enable evaluation in a Phase I clinical trial.

The Phase I trial will likely be a multi-center trial, with the centers in the Pennsylvania Melanoma Consortium (Penn State University, Thomas Jefferson University and the University of Pennsylvania) as one possible location. Other sites will be considered based on availability of patients and speed with which the trial can be completed. Depending on the availability of financing, we expect that the trial will begin in mid to late 2013.

### **PRODUCTS, SERVICES, AND CUSTOMERS**

Melanovus is in the business of discovering and developing products for melanoma and skin cancers through Phase 2 clinical development. The longer term goal is to identify pharmaceutical or biotech partners that can continue clinical development to FDA approval, and that can work with Melanovus successfully to commercialize the products in key markets.

As trials progress and as data is gathered supporting proof of concept, efficacy and safety, the company will aggressively pursue partnership discussions to secure licensing and collaboration agreements and provide a revenue stream to Melanovus in the form of upfront payments, milestone payments, and royalties.

Products include therapeutics for treatment, diagnostics to help identify patients who are likely to respond to treatment (i.e. have the markers present that are targeted by our drugs), and products that could help prevent melanoma or other skin cancers altogether.

The company does not plan to offer services of any kind, except that we may collaborate on future research once resources and capabilities permit.

Our primary customers will be companies that can bring what we have discovered and developed through to successful commercialization, i.e. pharmaceutical and biotech companies in the melanoma/skin cancer space.

Our pre-licensing “customers” are the regulatory bodies that will review and approve our products and plans, the thought leaders who will lend support to our scientific approach, and the investors that will help finance our research and development work.

## **COMPETITION**

While two recently approved new compounds - - Vemurufinab (Zelboraf) from Roche, and Ipilumimab (Yervoy) from Bristol-Myers Squibb - - offer some promise their utility may be limited for long-term disease management. Vemurufinab (<sup>V600E</sup>BRAF inhibitor PLX-4032) is active against approximately half of tumors found in melanoma (those containing mutant <sup>V600E</sup>BRAF), but because it targets a single protein, recurrent resistant disease develops to this agent. In clinical studies, survival was extended by approximately three to five months. Ipilumimab may be effective in only 10% to 20% of melanoma patients. While initially effective, the formation of tumors resistant to the agent is likely, as occurs with other immune system modulators. This is equally true of most currently available therapeutic strategies for metastatic melanoma patients, including surgery, immuno-, radio- and chemotherapy, which are ineffective long-term treatments for individuals suffering from advanced disease.

## **COMPETITIVE STRENGTHS**

The Melanovus approach is both novel and unique in targeting the multiple key pathways involved in melanoma using a single agent. These first-in-class compounds are referred to as *Multi-Target Inhibitors™ (MTIs)*. The unique approach regulates the multiple processes leading to tumor development and spread including inhibition of proliferation, triggering of apoptosis, reduction in migration and metastasis and limiting tumor vascularization. This multifaceted approach could lead to slowing tumor growth, more effective tumor inhibition and a decrease in the probability of developing drug resistance that will ultimately change the course of disease progression.

Melanovus' compounds uniquely attack the tumor through the PI3K(Akt3), MAPK(Erk), STAT(STAT3) and other key pathways in melanoma development. By targeting the pathways that are primarily over-expressed in melanoma cells, these highly specific agents could provide better efficacy and less damage to surrounding normal tissues.

The effectiveness of this approach has been observed in animal studies. Not only did the disease no longer progress, but tumor shrinkage and reversal of progression was clearly observed.

## COMPETITORS

The National Comprehensive Cancer Network (NCCN) and the American Society for Clinical Oncology (ASCO) guidelines suggest healthcare providers consider a range of therapeutic alternatives, depending on the stage of the disease. Early stage disease can be treated with surgery or radiation, while guidelines for later stage disease recommend chemotherapy, interferon, and other products.

Melanoma is a complex disease which is characterized by tumors that present with multiple pathways. According to the 2012 Pharmaceutical Manufacturers and Research Association annual report on products in development, over 50 products are in some stage of development for melanoma. The failure rate, however, is extremely high.

Because it is a complex disease, researchers have taken multiple approaches as a basis for their research. These approaches include Immune System Modulators (ISMs), MAP kinase pathway inhibitors, and Oncolytic Viruses. The ISMs include Monoclonal antibody (Mab) tumor targeting therapies, and second generation IL2s. The MAP kinase pathway inhibitors include drugs that inhibit Raf, MEK, Tyrosine kinase, B-Raf, and FAK. There are currently no approaches that we are aware of, other than those of Melanovus, that target multiple pathways with a single agent.

Currently marketed products for late stage melanoma are listed in the table below. A common characteristic is that these agents typically attack only a single pathway, which can result in treatment failures and disease recurrence and drug resistance.

Product	Status	Route of Administration	Pathway/Target	Published Outcomes	Estimated Cost
Zelboraf (Genentech /Roche)	Launched 2011	Oral	BRAF	Extends survival by an average of 6 months	\$61,000 per year
Yervoy (BMS)	Launched 2011	IV	BRAF	Increased 1 year survival from 25 to 40%	\$120,000 per 4 month treatment
Sylatron (Merck)	Launched 2011	Injectable (self- SQ)	ISM	Delayed recurrence by 9 months	\$40,000 per 8 week treatment followed by maintenance

A variety of products are in the later phases of development. A listing of the later stage products is included in the following table. As indicated, results of efficacy and safety have yet to be published, and Melanovus continues to monitor the progress of these programs through all available sources. It should be noted, however, that like currently available products, none of

the products in development appears to attack multi-pathways in a manner associated with Melanovus compounds.

<b>Product</b>	<b>Status</b>	<b>Route of Administration</b>	<b>Pathway/Target</b>	<b>Published Outcomes</b>
<b>Nexavar (Bayer)</b>	<b>Phase 3</b>	<b>Oral</b>	<b>MAP</b>	<b>TBD</b>
<b>Abraxene (Celgene)</b>	<b>Phase 3</b>	<b>IV</b>	<b>ISM</b>	<b>TBD</b>
<b>GSK 2118436 (dabrafenib) (GSK)</b>	<b>Phase 3</b>	<b>Oral</b>	<b>BRAF</b>	<b>2012/2013</b>
<b>GSK1120212 (trametinib) (GSK)</b>	<b>Phase 3</b>	<b>Oral</b>	<b>MAP</b>	<b>2012/2013</b>
<b>Allovetin (Vical)</b>	<b>Phase 3</b>	<b>IM</b>	<b>ISM</b>	<b>2013</b>
<b>OncoVex (Amgen)</b>	<b>Phase 3</b>	<b>Injected into tumor</b>	<b>MKP</b>	<b>2013</b>
<b>Masitinib (AB Science)</b>	<b>Phase 3</b>	<b>Oral</b>	<b>OMAP</b>	<b>2013</b>
<b>NuLuesin (3 S Bio)</b>	<b>Phase 3</b>	<b>Sub Q</b>	<b>ISM</b>	<b>2013</b>

While researchers continue to search for a better solution, a significant opportunity exists for a better and more effective approach to therapy. Melanovus' Multi-Target Inhibitors are designed to meet that need.

#### **PRICING**

Costs for currently available products for late stage melanoma can be high, ranging from \$40,000 to almost \$120,000 per course of therapy, or per year for oral and injectable treatments. Still, treatment outcomes are far from certain.

Although detailed pricing models have yet to be developed for Nanoliopolee-007, our base case scenarios assume a per course of treatment price of \$50,000.

The company recognizes that with the implementation of healthcare reform there will continue to be downward pressure on pricing for all categories of products including oncology products. Clinical studies and economics studies will be included in the development plan and a value proposition will be developed as clinical data is developed. With established efficacy, a single



MTI could perhaps replace current combination therapy, thereby lowering the overall cost of care.

The company will continue to look for manufacturing and other efficiencies to ensure a cost efficient model that ensures adequate margins.

### **SALES ESTIMATES AND REVENUE MODEL**

According to the MedTrack Epidemiology Report “2011 Incidence of Melanoma” it is projected that there will be approximately 74,000 people in the U.S. diagnosed with melanoma in 2016. This same report, and corresponding NIH/SEER reports, indicate that approximately 30% of these patients will have late stage melanoma, addressable by Melanovus products. We estimate that 50% of these patients will present with the multiple targets treatable with Nanolipolee-007. With an estimated price per treatment of \$50,000, annual revenues for the therapeutic will approach \$750 million.

Focused thus far on Nanoipolee-007, the company has not yet developed estimates for its follow-on therapeutics, nor its products for prevention. A product that could prevent melanoma would participate in what could be a substantial market, depending on how it is formulated and delivered (e.g. sun screen, other topical formulation, etc.).

The company does not intend to commercialize these products alone, but plans to collaborate with a commercial partner that can develop and commercialize the products to ensure that their full commercial value is reached.

Revenue in the early stages will derive from up-front licensing payments and milestone payments for achieving clinical and development objectives. Future revenues will derive from royalties and sales. Detailed estimates will be developed based on published data and on the stage at which the products are licensed and the nature of the agreements. Royalties could range from a low of 3-5% of sales to a high of 14-16%.

### **LOCATION**

The company’s executive offices are located in Jensen Beach, Florida, approximately 40 miles north of West Palm Beach. Its research facilities are currently located in the Hershey Center for Applied Research (HCAR) in Hershey, Pennsylvania. HCAR has a collaborative relationship with the Penn State Milton S. Hershey Medical Center and the Penn State College of Medicine, which contribute to HCAR's community of business and research resources – a distinct advantage for a suburban research park.

The company is open to relocating its research to another biotech-friendly area based on access to capital, tax incentives, and proximity to recognized research institutes and availability of key talent.

As the company grows, every effort will be made to remain a lean organization. Space and equipment will be leased and third parties utilized whenever it is more efficient in terms of cost and timing.

## ADVERTISING






Melanovus will raise awareness among potential investors, research collaborators, and pharmaceutical/biotech partners through a variety of initiatives, including the company website ([www.melanovus.com](http://www.melanovus.com)), attendance at key medical meetings addressing melanoma, presentations at major cancer meetings, and attendance at BIO meetings and various partnering conferences. An aggressive schedule of presentations will position the company with potential investors.

Press releases will be issued as the company achieves its milestones. Background articles and publications will be authored to raise awareness of the shortfall of current therapies and the need for new therapies that attack multiple pathways.

The most effective approach will likely center on the activities of the company's senior management with industry influencers and decision-makers to gain access to the partners and collaborators that would best fit with the company and its objectives.

## GROWTH STRATEGIES

The company's growth will come from the ability to mine its pipeline for additional therapeutics, preventatives, and diagnostics. Our ability to execute a long range plan will be driven almost entirely by financing and resources; there are no scientific limitations that would prevent establishing a full development program for any of the compounds in the pipeline. The following table summarizes the pipeline and current stage of development.

Product	Indication	Pre-Clinical	Pre-IND/IND	Phase 1	Phase 2
Nanolipolee-007	Late Stage Melanoma				
ISC 4	Early Melanoma				
Selenocoxib Sela-1-GSH	Melanoma & Skin Cancer				
PBISe	Melanoma & Skin Cancer				
MXO-005 Diagnostic	Melanoma & Skin Cancer				

## PRODUCTION AND OPERATIONS PLANS

### FACILITY

In its early stages, the company will require minimal office or administrative space, and will utilize lab space at HCAR near Penn State. Every effort will be made to minimize the requirements for additional space.

## **EQUIPMENT**

Minimal equipment (e.g. computers, printers, etc.) will be required in the early phases, with the company relying on its outsourcing partners to provide the equipment required for pre-clinical and IND enabling studies. Some equipment may be available through the HCAR facility.

## **PRODUCTION**

A contract manufacturer (CMO) will provide process development, GLP and GMP manufacturing, and regulatory support for FDA submissions. The company will engage a CMO with deep experience in nanoparticle and liposomal development.

## **QUALITY CONTROL**

Quality control will be primarily the responsibility of the CMO; detailed plans shall be developed with strategic partners.

## **INVENTORY CONTROL**

Inventory control will be primarily the responsibility of the CMO; detailed plans shall be developed in the future.

## **LEGAL ENVIRONMENT**

The company is a Delaware "C" corporation.

Mark H. Mirkin, Esq., a partner at Hicks, Motto, & Ehrlich, P.A. in Palm Beach Gardens, Florida, serves as the company's corporate and securities law counsel. He has considerable expertise in representation of life sciences companies and the ability to guide the company in matters related to IP, regulatory filings, contracts, personnel and other matters.

## **INTELLECTUAL PROPERTY**

Patents have been issued, or are pending, and the company will continue to file patent applications for the company's novel compounds in an effort to expand the overall IP estate. The company acquired the exclusive global rights to these patents, related IP, and know-how from the Penn State Research Foundation in exchange for equity in the company and royalties. Key patents are shown in the following table. The patent strategy is designed to build an estate of patents that provides long-term protection for the core IP related to the products. Penn State is responsible for continuing to develop the IP estate, with full cooperation by the company. Melanovus may exercise its right to pursue patents if Penn State does not perform satisfactorily. Specific terms are outlined in the license agreement.

Technology/Compound	Primary Use	Primary Indication	Secondary Indication/Use
<p>1. Akt3 as selective therapeutic target in melanoma [<b><i>Combinatorial Methods and Compositions for Treatment of Melanoma</i></b>] – <b><u>2004-2887</u></b></p> <p>2. Development of ISC-4 Drugs for Inhibition of AKT Pathway Signaling in Cancer [<b><i>Anti-Cancer Compositions &amp; Methods (Novel ISC Drugs)</i></b>] – <b><u>2007-3330</u></b></p>	Therapeutic Prevention	Late Stage Melanoma  Early Stage Melanoma	Other Skin Cancers  Other Solid Tumors
<p>3. A selenium Derivative of PBIT to Therapeutically Target Cancer [<b><i>Anti-Cancer Compositions &amp; Methods (Selenium Derivative of PBIT)</i></b>] -<b><u>2007-3335</u></b></p>	Therapeutic Prevention	Late Stage Melanoma  Early Stage Melanoma	Other Skin Cancers  Other Solid Tumors
<p>4. Nanolipolee 007 [<b><i>Compositions and Methods Relating to Proliferative Diseases (Nanolipolee007)</i></b>] - <b><u>2010-3750</u></b></p>	Therapeutic	Late Stage Melanoma	Other Skin Cancers  Other Solid Tumors
<p>5. Using a Novel Selenium Containing Inhibitor Selenocoxib -1 GSH Inhibits Cancer Cancer Tumor Development to Inhibit Cancer Development- <b><u>2011-3805</u></b></p>	Therapeutic	Late Stage Melanoma	Other Skin Cancers  Other Solid Tumors

### **FINANCIAL PLAN**

Founders of the company made an initial investment of \$20,000 to cover basic start-up costs. Founders are prepared to invest additional amounts to finance ongoing operations up to approximately \$100,000.

SBIR grants have been applied for as an initial mechanism for funding. A successful SBIR phase I application can provide funding of up to \$300,000. Funding rates for phase I applications are 30%. A successful SBIR phase II application can provide funding of up to \$2 million. Funding rates for phase II applications are significantly higher and are around 50%.

An SBIR Phase I grant from the National Institutes of Health in the amount of \$235,000 was awarded in August 2012, to be used toward completion of the few remaining IND-enabling studies for Nanolipolee-007.

The company seeks to raise \$1 million in seed financing in Q4 2012. An additional \$20 million will be required to complete Phase I and II clinical studies, and to fund development of the diagnostics. With additional funding, development would begin for the other products in the portfolio. A more detailed listing of expenses for Nanolioplee-007 and the estimated timing is shown in the table below.

In parallel, the company will approach pharmaceutical and biotech partners known for funding biotech companies (e.g. Amgen Ventures), and business development activities will be launched to identify potential research partners that would support our early trials in exchange for a future option on our products or diagnostics.

#### **USE OF PROCEEDS**

<b>Seed Funding Round</b>	
<b>IND Enabling Studies</b>	<b>\$50,000</b>
<b>IND Filing Costs</b>	<b>250,000</b>
<b>Companion Diagnostic</b>	<b>50,000</b>
<b>SG&amp;A</b>	<b>300,000</b>
<b>Working Capital</b>	<b>350,000</b>
<b>Total</b>	<b>1 M</b>

#### **EXIT STRATEGY**

As stated previously, the purpose/goal of the company is to advance the development of its agents through Phase I trials and into Phase 2, when maximal value may be realized. Value will be attributable to the global license, the library of compounds, and to research and collaboration agreements reached with partners as the company moves forward. As the company achieves clinical and regulatory milestones, opportunities for liquidity events will be evaluated and pursued.

**APPENDIX ITEMS**

- A. Penn State License Agreement (Confidential, available upon request)**
- B. Drug portfolio of the Experimental Therapeutics Program (Confidential, available upon request)**