



January 2013

Dear Shareholder:

As we welcome a new year, we would like to take this time to reflect on Skinvisible Pharmaceutical's many important accomplishments of 2012 and to provide you with our vision and goals for 2013.

Last year we were focused on helping our licensees with additional studies and support as well as making the tough decisions regarding cancelling some of the agreements. We also had a number of significant accomplishments that added value to our company including the granting of three new patents, the submission of our orphan drug candidate to the European Medical Agency, the achievement of additional key testing for DermSafe hand sanitizer and the completion of a significant financing to ensure the long-term viability of various projects that are underway.

Skinvisible's mission is to provide its shareholders with increased value and to this end, we continue to focus on our high value assets which include increased patent protection, our orphan drug candidate, maximizing the efforts of current licensees and the licensing of our patent protected products that have completed development.

## 2012 Skinvisible Highlights:

### Increased Patent Protection – Three Noteworthy Patents Granted

Skinvisible's value, both corporately and for its individual products, increases with the granting of new patents. Skinvisible's current patent portfolio includes fourteen patents, including eight international patents for Invisicare® which cover three diverse areas of protection (manufacturing, composition and use). This past year Skinvisible received two product specific patents for sunscreens and retinoids (acne) and an additional US Invisicare® technology patent.

For pharmaceutical companies product patent protection is key when licensing a product from Skinvisible. A patent is required to maintain revenues and profit margins. Losing patent protection can result in a 90% drop in sales due to generics entering the market. Pharmaceutical companies seek products and technologies (like Invisicare®) that can extend their patent life and thereby protect them from major revenue losses.

#### **March 7, 2012**

[Skinvisible Granted US Sunscreen Patent for UVA Absorber - Broad Spectrum UVA / UVB Sunscreens with Invisicare® Offer Eight Hours of Photostability](#)

In March, Skinvisible was granted a patent for its unique sunscreen formulations. Avobenzene is the approved sun filter used in the USA to obtain the important UVA sun protection. Avobenzene however is notorious for breaking down in the sun; usually within two hours. Skinvisible has been granted a patent due to the ability of Invisicare® to "photo-stabilize" this sunscreen for eight hours; a significant advantage over other sunscreens in the marketplace. In addition, recently the U.S. Food & Drug Administration (FDA) implemented new regulations in respect to what claims can be made regarding a sunscreen. Skinvisible's sunscreens not only surpass these new regulations for broad-spectrum sunscreens, they

have been developed with a formula which does not conflict with other sunscreen patents on the market. Skinvisible is currently in discussions for the licensing of these sunscreen formulations.

**November 27, 2012**

[Skinvisible Granted US Patent for Stabilizing Retinoids - Intellectual Property Portfolio Strengthens](#)

Acne is one of the largest dermatology conditions that Skinvisible targets, with worldwide sales of prescription acne products reaching \$600 million annually. Both prescription and over-the-counter products can individually generate multi-millions of dollars of revenue. A key acne product developed by Skinvisible contains retinoic acid, a derivative of vitamin A. In November Skinvisible was granted a US patent due to its ability to protect retinoic acid from breaking down during manufacturing. Retinoic acid breaks down when exposed to light and oxygen, however when formulated in Skinvisible's Invisicare®, this drug is protected by the stabilizing effect of Invisicare®. This patent protection extends until 2029.

**December 4, 2012**

[Skinvisible Granted US Patent for Topical Drug Delivery Technology - Invisicare® Patent Protection Extends to Year 2029](#)

The foundation of every product developed by Skinvisible is Invisicare®. Invisicare® is a combination of several different hydrophobic and hydrophilic polymers which form a unique "system"



for delivering drugs and other ingredient to the skin. This system can be formulated to deliver a greater release of the drug to the skin while at the same time decreasing irritation and dryness. Invisicare® also binds products to the skin for a longer therapeutic effect. As evident by the two product patents granted this past year, Invisicare® can also provide added benefits depending on the ingredients and the desired outcome.

Skinvisible is pleased that this year the U.S. Patent Office granted the third division of its Invisicare® patent. This patent protects the composition of Invisicare® so that no duplications can be made. This is in addition the two patents already granted covering manufacturing and the "precursor" (the pre-mix which is the first step of making Invisicare®.) This new patent extends Invisicare's patent protection until 2029.

## **Skinvisible's Orphan Drug Candidate**

**February 23, 2012**

[Skinvisible Formulation Submitted to European Union for Orphan Drug Designation - Invisicare® Formulation for Netherton Syndrome Under Review](#)

Skinvisible has developed a product that has the potential ability to help patients suffering from a rare disease called Netherton Syndrome. Nethertons is a generic disorder that has a huge impact on the children and families that suffer from this disease due to its devastating symptoms. Patients with Nethertons have a genetic defect which prevents the skin from forming a continuous protective layer. Skinvisible undertook the development of a protective cream which delivers an ingredient that inhibits the breakdown of the skin and provides additional skin barrier protection with Invisicare®.

Following its application to the US Orphan Drug Committee, Skinvisible presented its findings to the European Medicine Agency this past year. Skinvisible is currently undertaking a further proof-of-concept study in the disease itself. These findings will be submitted along with its original applications in the US and Europe. Due to previous feedback from these agencies, Skinvisible feels confident that this additional data will provide the final evidence required for orphan drug status.

The potential value of this product for Skinvisible is significant. Government incentives for an orphan drug make these products lucrative opportunities for pharmaceutical companies and viable alternatives for patients that have no other options. Incentives include seven to ten years of exclusivity in the marketplace, grants and tax incentives as well as expedited reviews.

Skinvisible is in discussions with pharmaceutical companies specializing in orphan drug approvals and commercialization and has filed an international patent application for its formulation.

## **DermSafe® Studies Prove Continuous Kill for Four Hours**

**June 28, 2012**

[Skinvisible's Hand Sanitizer Kills "Super Bug" MRSA and E. coli For Up to 4 Hours - Studies Confirm One Application of DermSafe As An Effective Long-Lasting Hand Sanitizer](#)

DermSafe®, Skinvisible's patent pending hand sanitizer formulated with 4% chlorhexidine gluconate and Skinvisible's patented delivery system Invisicare®, is made without alcohol so it will not dry the skin. Last year Skinvisible commissioned an independent laboratory to further analyze the long-term effectiveness of DermSafe® when put in contact with two bacteria; the "super bug" MRSA and E. coli, the "restaurant bug" since it is often transmitted by food and food handlers.



These evaluations were based on ASTM 2752-10 *Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products*. The long-term effectiveness of two bacteria; *Methicillin-resistant Staphylococcus aureus* or MRSA (ATCC #33591) and *Escherichia coli* or E. coli (ATCC #43888") were tested up to four hours after application. The results showed that the individual arms of subjects which had DermSafe® applied and were even rinsed prior to each bacteria challenge, showed a 95.83% reduction at the 4 hour time point for MRSA and 99.38% for E. coli.

These new studies were undertaken to benefit our licensee in Canada, Alto Pharmaceuticals and to assist in the re-licensing of DermSafe in Europe. In 2012 Skinvisible cancelled the license agreement to RHEI Pharmaceuticals and is in the process of transferring the regulatory approval in Europe to Skinvisible. The objective for 2013 is to make DermSafe available internationally to the general public and also for use in hospitals, schools, law enforcement and the military through independent distributors.

## **Fund Raising**

In order to facilitate the various projects mentioned above, Skinvisible has raised \$1 million to support and accelerate its drug-development efforts. These funds will provide the capital to maximize the value of products by allowing additional studies to be conducted and to leverage all patent protection possibilities available for our products.

## Skinvisible Licensees

This past year Skinvisible made a concerted effort to help maximize the potential of its licensees but also to make some difficult decisions regarding some of its licensees. This past year, JD Nelson and Associates, RHEI Pharmaceuticals and Panalab S.A. agreements were cancelled. Skinvisible continues to support its current licensees who remain focused on growing revenues.

This past year we announced that Women's Choice Pharmaceuticals LLC, based in Arizona, partnered with Advanced Medical Enterprises, LLC to market ProCort® in Puerto Rico. ProCort® is a topical prescription treatment for hemorrhoids formulated with Skinvisible's patented delivery system Invisicare®. With over thirty pharmaceutical sales reps calling on OBGYNs in the US, Women's Choice has been successfully growing their sales of ProCort® and we look forward to increased growth in 2013.



## Skinvisible Introduces Complete Product Lines

Invisicare® adds many benefits to products including skin barrier properties to aid skin healing by retaining moisture, superior adherence, and improved delivery of actives. Through our research and development efforts over the past year, Skinvisible has formulated complete product lines that are available for immediate licensing and launch. The product lines include: Acne, Anti-Aging, Sunless Tanning, Sun Care and Leg & Foot Care. Images of how these lines could look are below.

### ACNE



### ANTI-AGING





## Going Forward and Growing in 2013

We are very optimistic about the future of Skinvisible Pharmaceuticals. Along with on-going negotiations for license agreements and strategic partnerships, we endeavour to decrease our overhead costs. We have recently successfully renegotiated our lease and continue to find additional efficiencies. We are also focused on continuing to add intrinsic value to the Company as new patent applications get filed and granted in the US and globally. Our core research and development efforts are focused on refining our pipeline of products and maximizing the benefits and value of our Invisicare® technology.

We believe the greatest opportunities for shareholder value creation is through licensing and strategic partnerships. Skinvisible continues to discuss potential business opportunities with companies primarily in the US, Canada and Europe. The solidification of one or more of these deals will concentrate the Company's strategic focus and allow Skinvisible to deliver greater shareholder value over the coming year.

Thank you for your continued support and feedback. We look forward to the year ahead and the growth of Skinvisible for our shareholders.

Please feel free to contact me anytime.

Sincerely,



Terry Howlett  
President & Chief Executive Officer

**Skinvisible, Inc. SKVI on OTCQB ([www.otcmarkets.com](http://www.otcmarkets.com)).**

*Forward-Looking Statements: This press release contains 'forward looking' statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbors created thereby. Such statements involve certain risks and uncertainties associated with an emerging company. Actual results could differ materially from those projected in the forward looking statements as a result of risk factors discussed in Skinvisible, Inc. reports on file with the U.S. Securities and Exchange Commission (including, but not limited to, a report on Form 10Q for the quarter ending October 31, 2012).*