



January 2012

Dear Shareholder:

I am pleased to present to you today a 2011 review for Skinvisible Pharmaceuticals, Inc. and discuss some of those achievements that are positioning us for an exciting and prosperous 2012. During the last year the market has been challenging however I believe we have been able to increase the value of Skinvisible this past year with many exciting, important developments and some key agreements which have the potential of generating significant future revenue. The key highlights include: a development agreement with the second largest pharmaceutical company in the world, two key patents were allowed, Skinvisible applied for its first "orphan drug", the first Skinvisible product was approved in Europe, the first Skinvisible prescription product was launched in the USA, a Skinvisible OTC product was launched in Canada and a Skinvisible product received a notable recommendation from a distinguished group of dermatologists.

### **2011 Skinvisible Highlights:**

#### **Development Agreement with Novartis, AG – A Major Opportunity**

In February Skinvisible entered into a feasibility agreement with Novartis Pharma AG, one of the largest pharmaceutical companies in the world. The purpose of the agreement was for Skinvisible to assess the technical feasibility of incorporating our Invisicare® technology into a new topical formulation with an undisclosed active ingredient ("the drug" or "API"). This formulation, still in development, would leverage the benefits of Invisicare by providing controlled release of the active ingredient. After the initial agreement was completed, a new feasibility agreement was entered into in November 2011 and Skinvisible continues to work in conjunction with Novartis to develop a viable formulation.

Why is this agreement a major opportunity? Should Skinvisible's development be successful, the agreement includes the option for Skinvisible and Novartis to enter into a future exclusive licensing agreement which would include a licensing fee and royalties based on sales. As I stated in our news release, *"It is important to us to pursue markets that can have a significant impact on our bottom-line."*

#### **Two Key Patents Allowed**

In 2011, Skinvisible was allowed two key patents; Canada and Europe. These two patents, like our other six international patents, offer very comprehensive protection for Skinvisible formulations. The patent covers three distinct areas including how the Invisicare is manufactured, the composition of Invisicare and what skin / medical condition it is used for.

In February we were granted this all-inclusive patent for our Invisicare technology in Canada. Canada is significant for Skinvisible as many potential licensees cover the North American market. This patent along with the US Invisicare patents already granted, gives North American licensees complete patent protection.

In September Skinvisible was allowed the Invisicare patent for Europe. This patent also covers all three areas. The European patent approval is a significant milestone for Skinvisible as multi-national pharmaceutical and consumer goods companies seeking products for global distribution will now have protected products to license from Skinvisible on four continents, covering over twenty-two countries, thereby increasing the value of these licenses.

## **Skinvisible's First Orphan Drug Application**

This past year Skinvisible entered into a new disease area which it had not addressed with any prior formulations. During our research and development process we discovered that we developed a product that may have a significant impact on those people that suffer from a debilitating disease called Netherton Syndrome. Netherton's is a sub-type of ichthyosis which can affect any age and has some level of dry, thickened, scaly, cracked or flaky skin, with symptoms ranging from mild to life threatening.

In March 2011, Skinvisible submitted an application to the United States Orphan Drug Division in order to receive an Orphan Drug Product Designation for the Company's product formulated with Invisicare to treat Netherton Syndrome. An adjunct to the original application was submitted in November 2011. In conjunction with this application, Skinvisible has also filed a patent application with the US Patent Office.

Skinvisible is pursuing this product as the United States Orphan Drug Act provides significant incentives to pharmaceutical companies to develop products for patients suffering from rare diseases. In the United States, a rare disease is defined as a condition which has less than 200,000 people with the disease. Receiving this orphan drug designation would add considerable value to this formulation which could result in a multimillion dollar license fee for Skinvisible. The benefits of achieving orphan drug status for this product include:

- seven years of market exclusively for the product;
- a waiver of all FDA fees;
- tax incentives;
- a potential for grants to fund clinical trials;
- some orphan drugs also receive an expedited review if the disease is severe or life-threatening.

Upon approval, the next steps would include seeking a licensee or partnership with a pharmaceutical company in order to get the product approved by the FDA and then commercialized.

The United States Orphan Drug Department responded to the application and indicated that (1) they accept Netherton Syndrome as an orphan disease and (2) they reviewed the data submitted and have requested that Skinvisible provide an additional specific set of data. Skinvisible is pleased with the feedback of the application so far and has begun putting into place a study that will meet the requirements specified by the FDA.

## **Skinvisible's DermSafe® / HandSafe™ Receives Its First European Approval**

Skinvisible's licensee, RHEI Pharmaceuticals NV with offices in Belgium and China, received marketing authorization from the Federal Agency for Medicines and Health Products in Belgium for HandSafe™, Skinvisible's unique chlorhexidine hand sanitizer made without alcohol. HandSafe™, referred to as DermSafe® in the US and Canada, is Skinvisible's patent pending hand sanitizer formulated with 4% chlorhexidine gluconate and Skinvisible's patented polymer delivery system Invisicare®. HandSafe™ is made without alcohol so it will not dry the skin.

With hand sanitizer sales in Europe for the healthcare market alone is valued at over \$1.7 billion in 2007 and growing 25% annually, Skinvisible believes that there is a very profitable market in Europe. Skinvisible has been working with RHEI to successfully expand this approval and launch in Europe.

## **First Prescription Product Launched in the USA**

In July of 2011, Skinvisible's licensee, Women's Choice Pharmaceuticals LLC (Gilbert, Arizona) launched ProCort®, Skinvisible's first prescription product in the United States. The product, called ProCort®, is

made of a combination of hydrocortisone acetate and pramoxine hydrochloride along with the Invisicare technology. ProCort® is a topical treatment for hemorrhoids. The US hemorrhoid market is estimated at \$85 million (2006) and growing.

Womens Choice Pharmaceuticals has thirty-five sales representatives that focus on the women's health market. They are pleased with the first six months sales and anticipate continued growth. Skinvisible received its first royalty for the third quarter of 2011 and looks forward to Womens Choice's continued success and increasing royalty revenue from this product.

### **Skinvisible's R&D Highlighted in US Publication**

Skinvisible's new research and development was featured in an article in Drug Development & Delivery Journal (July/August, page 26 <http://www.drugdeliverytech-online.com/drugdelivery/20110708#pg23>). Skinvisible is developing transdermal (penetrate through the skin) and mucosal (adhere to moist surfaces ie/ inside the mouth) methods using the Invisicare technology for new products.

### **DermSafe® Launches in Canada**

This past September Skinvisible's DermSafe® hand sanitizer was launched in Canada by Alto Pharmaceuticals, based in Toronto, Canada. Alto has the exclusive "personal commercial" use rights to DermSafe made with 4% chlorhexidine gluconate, an ingredient used in hospitals worldwide due to its effectiveness against a wide range of germs and its persistence. DermSafe hand sanitizer lotion has no alcohol and therefore does not dry the skin like other sanitizers; instead it delivers protection in a lotion formulation that defends the skin from outside irritants.

Alto completed the first manufacturing of DermSafe in Canada and will act as a manufacturer for other licensees around the world including Europe and Asia. Skinvisible continues to leverage this value-added option to potential international licensees.

### **Seal of Approval Awarded to Skinvisible Product**

Skinvisible's DermSafe® Hand Sanitizing Lotion has received the "Seal of Approval" from an independent panel of dermatologists that reviews scientific data for non-prescription products in order to authenticate a product's claims. The Dermatology Review Panel ("DRP") is comprised of key dermatologists from across Canada. These physicians were selected based on their expertise in skin care, geographical diversity and dedication to the mission of this program. See [www.dermatologyreviewpanel.ca](http://www.dermatologyreviewpanel.ca) for more information.

Skinvisible's scientific data was reviewed by the DRP dermatologists who evaluated and validated the following claims for DermSafe Hand Sanitizer:

- DermSafe is alcohol-free,
- It offers protection from harmful bacteria,
- It resists wash-off
- It provides a moisture barrier for the hands.



DermSafe, marketed by Alto Pharmaceuticals in Canada, uses the DRP Seal on its promotional materials and website. This Seal of Approval is also used by Skinvisible to show the results of an independent review of its product to potential licensees.

## LOOKING AHEAD TO 2012

The successes of 2011 will provide us with many potential opportunities which we will be focused on monetizing in 2012. The announcements of the past year have generated interest from pharmaceutical companies around the globe, many of which you would recognize. We have proven there is a need for the Invisicare technology based on the number of pharmaceutical companies looking for a cost-effective means to provide “life-cycle management” for their products coming off patent. Invisicare, with its international patents, is a solution that is resonating with these companies as more and more drugs continue to lose their market share to competitors and generics.

Our research and development efforts of 2011 have been very significant to date. We are committed to monetizing these developments through new licensing agreements and partnerships. We are also continually focused on the bottom-line. We are dedicated to being fiscally responsible, with operating expenses kept at a minimum and all necessary cutbacks being made. Skinvisible’s goal is always to increase shareholder value.

## SUMMARY

We are excited about the strong foundation we have created for our future growth. We believe there is unlimited potential for Skinvisible as we look forward to 2012. The pharmaceutical markets we pursue have a considerable need for our Invisicare technology. We have intellectual property and a pipeline of over 40 product formulations which we believe will enhance our position long term. We have become stronger and more focused in our development and sales efforts this past year and will continue to do so in 2012. Finally, we have an excellent team in place of employees and advisors to execute our plans and achieve our goals for the company and its shareholders.

I would like to thank you for your continued support of Skinvisible. We are committed to making every effort to deliver results for our shareholders.

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 10K for the quarter ending October 31, 2011).