

SKINVISIBLE INC
Form 10-K/A
February 08, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A
Amendment No. 1

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT

For the transition period from _____ to _____

Commission file number: 000-25911

Skinvisible, Inc.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation or organization) 88-0344219
(I.R.S. Employer Identification No.)

6320 South Sandhill Road, Suite 10, Las Vegas, NV
(Address of principal executive offices) 89120
(Zip Code)

Registrant's telephone number: 702.433.7154

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
none	not applicable

Securities registered under Section 12(g) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value \$0.001	not applicable

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

Check whether the Issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2)

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has been subject to such filing requirements for the past 90 days. Yes [X] 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. Yes [] No [X]

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 [] Smaller reporting company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

State 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, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. \$120,360

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 84,095,888 as of December 31, 2008.

EXPLANATORY NOTE

The purpose of this Amendment No. 1 to the Annual Report on Form 10-K, previously filed with the United States Securities and Exchange Commission on April 15, 2009, is to correct the beneficial ownership table.

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PART I

Item 1. Business

Company Overview

We develop innovative polymer delivery vehicles and related compositions that hold active ingredients on the skin for extended periods of time when applied topically. We designed a process for combining water soluble and insoluble polymers that is specifically formulated to carry water insoluble active ingredients in water-based products without the use of alcohol, silicones, waxes, or other organic solvents. This enables active agents the ability to perform their intended functions for an extended period of time. Our polymer delivery vehicles, trademarked Invisicare®, allow normal skin respiration and perspiration. The polymer compositions we develop wear off as part of the natural exfoliation process of the skin's outer layer cells.

We believe Invisicare® offers the following benefits:

- § Displays superior skin adherence for extended time periods
- § Non-occlusive yet resists water wash-off, respiration and perspiration
 - § Increased efficacy of active ingredients
- § Allows for lower use levels of actives with increased persistence of effect
 - § Offers advantage of controlled and/or sustained time-release
 - § Highly compatible with a variety of actives and bases
 - § Easy to emulsify
 - § Formulates well at a cream, lotion, or spray viscosity
- § Non-irritating emulsion dries quickly with no greasy after-feel
- § Non-occlusive film forms protective barrier against environmental irritants
 - § Broad polymer selection to meet application requirements
- § Offers “Life Cycle” management to core products with potential for new patent
 - § Simplified manufacturing process

Products that successfully incorporate Invisicare to date include antimicrobial hand sanitizer lotions, suncare products, skincare moisturizers, sunless tanning products as well as various dermatology products for various skin disorders. On an ongoing basis, we are seeking to develop polymer formulations that can successfully be incorporated into other products.

Our primary objective is to license Invisicare to established brand manufacturers and marketers of prescription and over-the-counter products in the dermatological, medical, cosmetic, and skincare markets. With the exception of sales to one vendor, our management’s policy is to only sell Invisicare to vendors that have executed a license agreement with us. We conduct our research and development in-house. We engage an outside party that currently handles all of our manufacturing and distribution needs.

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Recent Developments

Our core business is the research and development of products formulated with our patented technology Invisicare. This year we have added a strategic focus on the sale and marketing of these products and developing new Invisicare technologies. Our focus has allowed us to expand our reputation amongst key dermatology, consumer goods and medical/surgical companies around the globe. It has also allowed us to branch out beyond dermatology into other medical areas that require topically delivered products.

Leadership

We have brought on key people this year with specific skills to assist us with our growth strategy. Mr. Brian Piwek became a member of our Board of Directors early in the year. He was selected not only for his excellent business acumen but also his vast experience in the international retail / personal goods marketplace. He was President of Overwaitea Foods supermarket in Canada from 1991 until 1997. Prior to retiring in 2005, Brian served as the President and Chief Executive Officer of A&P Foods, one of North America's oldest retail food chains.

Internally, we hired a Vice President of Business Development and Marketing - Ms. Doreen McMorran. She brings over seven years of international dermatology marketing experience to our company. We believe having a person solely focused on revenue generation and with excellent dermatology industry contacts will assist our expansion plans.

In the fall of 2008, we appointed Dr. Geert Cauwenbergh PhD. to head our International Advisory Board and to spearhead further extension into international markets. Dr. Cauwenbergh has vast dermatology experience having held senior executive positions with Barrier Therapeutics, Johnson & Johnson and Janssen Pharmaceutica. Dr. Cauwenbergh assists us with dermatology research and development knowledge.

Product Developments

We intend to expand our product offerings. Currently we have over 30 topical products formulated with Invisicare available for licensing. Our products range from acne formations to sunscreens to surgical products. A key addition to our portfolio in 2008 was our UVA/UVB sunscreen with Parsol 1789. Parsol 1789 is the most used UVA filter in sunscreens in the US and the only ingredient approved by the US FDA that is not proprietary. Our studies show a minimum of eight hour photostability compared to the industry average of two hours. In addition, most sunscreens, even those that indicate they are water resistant, do not remain on the skin after swimming. With our Invisicare technology, sunscreens remain on the skin for 8 to 12 hours and resist wash-off and rub-off. For the international market, we have developed new sunscreens using a proprietary sunscreen UVA filter from CIBA Specialty Chemicals. While this ingredient is not yet approved for sale in the US, it is used internationally and we are working with sunscreen companies in Europe and Latin America on this new development.

In the third quarter of 2009, we intend to begin marketing our Chlorhexidine Hand Sanitizer Lotion "DermSafe" in Canada where we have received approval from Health Canada. We expect to file for US FDA approval with a marketing partner in 2009. We believe this is a unique product that is needed immediately in all healthcare settings from hospitals to nursing homes. DermSafe stays bound to the hands, even after frequent washings, for up to 4 hours while killing both bacteria and viruses; a real plus for doctors and nurses as they move from patient to patient.

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Patent Developments

We intend to continually to generate new patents (intellectual property) on our dermatology and medical products. Every product we formulate is protected by one or more patents. Patent approvals are sought (initially in the U.S. and later internationally) for all products developed. Currently there are 5 patents approved including the US, Australia, India and this year Japan, 9 U.S. patents pending in addition to 34 PCT's internationally, with many more to be filed. Some of these PCT patents cover up to 5 products. All patents with Invisicare are owned by Skinvisible.

Patent protection is important to our company. Pharmaceutical companies are pursuing new or improved revenue streams along with protecting their own intellectual properties. Invisicare allows companies to sell a patent-protected product that has been revitalized with new benefits, giving them a new story to help combat generic competitors. A prescription dermatology product can generate \$100 plus million per year; some even \$200 plus million – and that is why we believe the investment into a license with an Invisicare formulation is a very viable option for these companies.

We continue to submit for patent protection worldwide for products formulated with Invisicare.

License Agreements

Our current licensees: JD Nelson with Safe4Hours®, DRJ Group with Stopain® and Sunless Beauty with Solerra® all remain focused on expanding their markets in the US and Solerra globally. In 2008, we added two new licensees. Our first addition was for two acne formulations made with adapalene for Panalab Internacional S.A. for the territory of Latin America. Panalab is a multi-national dermatology company headquartered in Panama with subsidiaries and partners in most Latin American countries. Under the terms of the agreement, Panalab will be responsible for filing and obtaining marketing approval in the countries they have licensed. We received a research and development fee plus a licensing fee allocated as an upfront fee plus milestone payments. In addition, we will receive royalties based on revenues generated by the sale of the products. According to the agreement, Panalab will have the right to manufacture, distribute, market, sell and promote the Adapalene formulations in the specified territory. Panalabs expect to be selling in their territory by late fall 2009.

In addition, two more prescription acne products (clindamycin and retinoic acid) were licensed to Embil Pharmaceuticals for Turkey, parts of Asia (Indonesia, Malaysia, and the Philippines) and Azerbaijan, Kazakhstan, Kyrgyzstan, Turkmenistan, and Uzbekistan. Embil is a multi-national dermatology company headquartered in Istanbul, Turkey with subsidiaries and partners in S.E. Asia. Under the terms of the agreement, Embil will be responsible for filing and obtaining marketing approval in the countries they have licensed. We have received a research and development fee plus a licensing fee allocated as an upfront fee plus milestone payments. In addition, we will receive royalties based on revenues generated by the sale of the products.

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According to the agreement, Embil will have the right to manufacture, distribute, market, sell and promote the Clindamycin HCL and Retinoic Acid formulations for acne in the specified territory.

In January 2009, we signed an agreement with RHEI Pharmaceuticals NV, a Belgium based pharmaceutical company that in-licenses drugs for sale in China. This agreement gives RHEI the first option to license the exclusive rights for Skinvisible's dermatology products for the territory of China, Hong Kong and Taiwan. Specifically the agreement is for over-the-counter and prescription dermatology products formulated with Invisicare that have been approved in a reference country. As part of the agreement, RHEI will augment its existing product lines by seeking approval and then marketing and manufacturing Skinvisible's Invisicare dermatology products in the approved territory.

The Chinese pharmaceutical market represents a huge opportunity with an estimated \$22.6 billion spent on pharmaceutical drugs in 2007 and growing at an annual rate of nearly 20%. To address this huge growth, the Chinese government has implemented a more effective approval process, one that fits advantageously into the strategic plans of both Skinvisible and RHEI.

Status of Research and Development for New Applications

We believe that the enhancement and extension of our existing products and the development of new product categories have contributed significantly to our growth to date and are necessary for our continued growth. Our management evaluates new ideas and seeks to develop new products and improvements to existing products to satisfy industry requirements and changing consumer preferences. We seek to identify trends in consumer preferences and to generate new product ideas. Specific to the objective of generating new products, we are continuing our research and development toward developing additional applications with Invisicare. We are currently at various development stages for the following potential applications using Invisicare:

Skinvisible's Formulas with Invisicare:

ACTIVE INGREDIENT	TYPE	Availability	Patent
Acne			
Adapalene Cream & Gel (0.1% & 0.3%)	Rx	yes*	pending
Clindamycin Hydrochloride Cream (1%)	Rx	yes*	pending
Retinoic Acid Cream (0.1%)	Rx	yes*	pending
Benzoyl Peroxide (2.5%) Cream	Rx / OTC development	In	pending
Actinic Keratosis			
Imiquimod Lotion (2%,	Rx	yes	pending

3%)		
Analgesics		
Topical Spray with Menthol (6% & 8%)	OTC	yes technology
Topical Roll-On with Menthol (6% & 8%)	OTC	yes technology
Topical Cream with Salicylate (10%)	OTC	yes technology
Anti-Aging		

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Retinol Cream (0.3%)	Cosmetic	yes	technology
Anti-Fungal			
Terbinafine Cream, Gel (1%)	OTC	yes	pending
Naftifine Cream (1%)	Rx	yes	pending
Naftifine (1%) & Hydrocortisone (1%) Cream	Rx	yes	pending
Clotrimazole Cream (1%)	OTC	yes	pending
Anti-Inflammatory			
Hydrocortisone Cream (1%)	OTC	yes	technology
Triamcinolone (1%)	Rx	yes	technology
Triamcinolone Acetonide (1%)	Rx	yes	technology
Clobetasole Propionate (0.05%)	Rx	in-progress	technology
Betamethasone (1%)	Rx	yes	technology
Antimicrobial Lotions			
Triclosan Lotion (1%) with Nonoxynol-9	OTC	yes*	granted
Triclosan Lotion (1%) with Tomadol 901	OTC	yes*	granted
Benzalkonium Chloride Lotion (0.13%)	OTC	yes*	granted
Chlorhexidine Gluconate Lotion (4%)	OTC / NDA	yes	pending
Chlorhexidine Gluconate (2%) Pre-Surgical Prep	NDA	yes	pending
Atopic Dermatitis / Super Moisturizers			
Non-Steroidal Atopic Dermatitis Cream 1%	Rx / Cosmetic	yes	technology

Hyaluronic Acid			
Skin Protectant Lotion with Allantoin (1%)	OTC	yes	technology
Super Moisturizer with Ectoin	Cosmetic	yes	technology
Urea Moisturizer (25% & 30%)	Cosmetic	yes	technology
UVA / UVB Sunscreen			
Parsol 1789 - SPF 15 / 30 / 50 Lotion	OTC	yes	pending
Tinosorb S – SPF 15 / 30 / 50 Lotion	OTC	yes	pending
Other			
Scar Lotion with Onion Bulb	Cosmetic	yes	technology
Fragrance – Long Lasting Gel	Cosmetic	yes	technology
Long-lasting Sunless Tanner (2.5%, 5% & 9%)	Cosmetic	yes	technology
After Sun (Aloe) Cream	Cosmetic	yes	technology

*some

territories already licensed

Competition

While there is significant competition in the skincare products industry, our primary business objective is to license our technology and formulated products to manufacturers of Rx and OTC skincare products. Market research undertaken to date has indicated that, at present, there is reasonably limited competition for our polymer-based delivery systems and related technologies such as delivery vehicles and technologies that offer the same performance capabilities for topically administered products. Some delivery technology companies offer a new way to bring active ingredients to the skin topically such as foam technology. This is usually where it stops as Invisicare not only offers this delivery but also offers a sustained or controlled release of the active ingredient from the emulsion – a real plus if the active ingredient causes skin irritation.

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Trademarks

In January 2002, we received trademark approval in the United States for the name "Invisicare" to identify our family of polymer delivery systems. We have filed this trade name with the Cosmetic, Fragrance and Toiletries Association ("CFTA") as an ingredient for use in skincare and cosmetic formulations.

We have also applied and received trademark approval for the corporate logo "Skinvisible" and for our sunless and sun tanning products under the name "Solerra" both in the US and Canada.

We are seeking to extend the protection of our trademarks in additional countries where we currently conduct business and those additional countries where we intend to conduct business.

Employees

We currently have five employees, including our sole officer Terry Howlett. All our employees with the exception of our bookkeeper are full-time employees.

Research and Development Expenditures

We incurred research and development expenditures of \$21,780 in the fiscal year ended December 31, 2008, and \$20,291 in the fiscal year ended December 31, 2007.

Government Regulation

We are not subject to any significant or material federal or state government regulation in connection with the research and development and licensing of our innovative topical polymer-based delivery systems and technologies.

With respect to our products under development, our licensing agreements require the licensee to seek all required approvals for marketing, distribution, and sale in the jurisdictions for which it is desired to make the product available should we succeed in developing a successful product.

We are not subject to any significant or material environmental regulation in the normal operation of our business.

Subsidiaries

We conduct our operations through our wholly-owned subsidiary, Skinvisible Pharmaceuticals, Inc.

Item 1A Risk Factors

A smaller reporting company is not required to provide the information required by this Item.

Item 1B Unresolved Staff Comments

None.