SKINVISIBLE INC
Form 10KSB
April 02, 2007

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

FORM 10-KSB

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

For the fiscal year ended December 31, 2006

[ ] 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.
(Name of small business issuer in its charter)

Nevada	88-0344219
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6320 South Sandhill Road Suite 10, Las Vegas, Nevada	89120
(Address of principal executive offices)	(Zip Code)

Issuer'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:

Common Stock, par value $0.001
(Title of class)

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

Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB [ ]

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 issuer's revenue for its most recent fiscal year. $691,452

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of a specified date within the past 60 days. $13,699,320 as of March 28, 2007

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date. 64,443,778 Common Shares as of December 31, 2006

Transitional Small Business Disclosure Format (Check One): Yes [ ] No [X]

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PART I

Item 1. Description of Business

Overview

We develop innovative polymer delivery vehicles and related compositions that hold active ingredients on the skin for up to four hours 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.

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.

Description of Current Products and Agreements

Cosmetics and Personal Care Markets

On October 7, 2005, we entered into a Master Sales, Collaboration and Distribution Agreement (“Agreement”) with EMD Chemicals Inc. (“EMD”), a New York corporation and affiliate of Merck KGaA of Darmstadt, Germany. Under the terms of this Agreement, we granted EMD the exclusive right to distribute and sell our patented polymer delivery system, Invisicare, for the cosmetics and personal care markets in the entire world. EMD will be entitled to commission income based upon the gross revenues from the sale of sublicensing agreements as well as the polymers. The initial term of this Agreement is until December 31, 2008 and this Agreement will automatically renew for successive three year terms unless either party provides fourteen months advance notice of its intention to terminate or not renew the Agreement.

As part of the consideration of the Agreement, we granted EMD options to purchase shares of our common stock. We executed a stock option agreement on February 27, 2006 where we granted EMD the option to purchase 5,817,525 shares of common stock at the exercise price of $0.172 per share exercisable until December 31, 2006. These options expired and were not exercised.

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Antibacterial/Antimicrobial Hand Sanitizer Lotion

On February 21, 2005, we entered into a definitive distribution agreement with Dermal Defense, Inc. ("Dermal Defense"). Pursuant to this agreement, Dermal Defense acquired the exclusive marketing and distribution rights in the United States of America, Canada and Mexico for our antimicrobial hand sanitizer lotion composition which utilizes the active ingredient Triclosan 1% and incorporates our patented Invisicare® polymer delivery system (the "Product").

Dermal Defense acquired these rights for the purchase price of $1,000,000 which has been paid in full. Under the terms of this agreement, Dermal Defense is obligated to pay us a royalty fee quarterly in the amount of $20,000 or 5% of gross revenues generated by Dermal Defense from sales of the product in the quarter, whichever is greater.

During the second quarter of 2005 and with our approval, Dermal Defense entered into an exclusive sub-distribution agreement with JD Nelson & Associates of Columbus Ohio ("JD Nelson") and transferred all of its rights to distribute, market, and sell our antimicrobial hand sanitizer lotion in the United States of America, Canada and Mexico. Under the terms of the sub- distribution agreement, JD Nelson will pay a license fee and royalty on product sales to Dermal Defense and Dermal Defense will continue to pay us as agreed in the Distribution Agreement of February 21, 2005. As a result, the fees and royalties that we are due under this agreement remain unchanged. Currently, all required fees and royalties due in accordance with this agreement are paid and current. Dermal Defense and JD Nelson & Associates are prohibited under this agreement from manufacturing, marketing, distributing, or selling any competing product while the Distribution Agreement is in full force and effect.

In December 2006, we entered into an Amended Distribution Agreement to revise the terms of the marketing and distribution rights granted to Dermal Defense and those rights provided to JD Nelson as a sub-distributor. In the Amended Distribution Agreement, we expanded the product for which rights were conferred to include our antimicrobial hand sanitizer lotion composition which utilizes the active ingredient Triclosan 1% and any other active ingredients included in the FDA Monograph exclusive of Chlorhexidine, Chlorhexidine gluconate or iodine or any combinations of iodine or Chlorhexidine gluconate or Chlorhexidine. In accordance with the Amended Distribution Agreement, JD Nelson must now pay all royalties under this arrangement directly to us.

In May 2005, we entered into a Distribution Agreement ("Agreement") with Safe4Hours, Inc. ("Safe4Hours"), a Nevada corporation. Under the terms of this Agreement, we granted Safe4Hours the exclusive right to distribute, market, sell, and promote our antimicrobial hand sanitizer lotion that utilizes the active ingredient Triclosan 1% in every country in the world except Canada, the United States, and Mexico. The Agreement prohibited Safe4Hours from manufacturing, marketing, distributing, or selling any competing product while the Agreement was in full force and effect. Safe4Hours acquired these rights for an up-front fee of $1,000,000, of which only $100,000 was received. The remaining $900,000 balance was to be paid in quarterly installments based upon a predetermined formula until the remaining balance is received, and a royalty fee of no less than 5% of gross revenue of all sales. Safe4Hours did not pay any quarterly installments under the terms of the Agreement and we were negotiating with

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Safe4Hours to revise the payment terms for the remaining $900,000 due under this Agreement. Following these negotiations, we were unable to reach an agreement and terminated the Agreement as a result of Safe4Hours' failure to materially perform its obligations under the Agreement. We are currently negotiating with JD Nelson to acquire these rights. We have extended an option to JD Nelson to acquire these rights by March 31, 2007 for consideration of $500,000 and a 10% royalty payment. We can provide no assurance that we will execute an agreement with JD Nelson for these rights.

Sunless Tanning Spray Product

On June 9, 2004, our wholly-owned subsidiary, Skinvisible Pharmaceuticals, Inc., entered into a Trademark License Agreement and Distribution Agreement ("Distribution Agreement") with Cross Global, Inc. ("Cross Global"), a Delaware corporation, to grant Cross Global the exclusive right to distribute, market, sell, and promote our proprietary sunless tanning spray products in Canada, the United States, Mexico, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom, and Israel. Cross Global is also utilizing our proprietary polymer formula to manufacture nine additional sun care related products.

Pursuant to the terms of the Distribution Agreement, Cross Global paid us the license fee of $1,000,000. Under the terms of this agreement, we are to receive a minimum royalty fee quarterly of not less than 5% of gross revenue of all sales of our proprietary sunless tanning spray products or $25,000, whichever is greater. We extended the minimum royalty payments terms on 3 different occasions in an effort to accommodate and assist Cross Global in the early stage of their operations. Despite our efforts, Cross Global remains delinquent for the minimum payments due at the present time in the amount of $120,000. We have the ability to terminate the Distribution Agreement as a result of this material breach upon providing notice to Cross Global. We are negotiating with Cross Global regarding this matter and have taken no further action at this time. Cross Global is prohibited under this agreement from manufacturing, marketing, distributing, or selling any competing product while the Distribution Agreement is in full force and effect.

Sunscreen and Skin Care Products

We developed and successfully tested the application of Invisicare in sunscreen products with SPF 15 and SPF 30, sunless tanning lotions, moisturizing creams, aloe after-sun products, and other skin care products. We currently offer Invisicare for incorporation into these products on a private label basis and have multiple agreements in place.

During the reporting period, we developed two additional sunscreen products. One of the products utilizes the active ingredient Parsol 1789. The other product utilizes the active ingredient Tinasorb which has been approved for distribution in Europe, Japan, Australia and recently Canada. Tinasorb has not yet have approval in the US. Tinasorb is a broad spectrum UVA/UVB ingredient. The manufacturer of Tinasorb is Ciba Chemicals. It is our intention to license out the distribution of both of these formulas where approved.

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Status of Research and Development for New Applications

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:

- Insect repellent
- Sunscreens
- Antifungal
- Acne
- Topical analgesic
- Atopic dermatitis
- Antimicrobial hand sanitizer

Insect Repellents

We are in the process of developing an insect repellent with an active ingredient that incorporates our topical polymer-based delivery systems and are presently undergoing in-house research. We anticipate that our research will be completed during the second quarter of 2007. Our current research efforts are being devoted to producing a stick application for this product. In the event that we are successful in developing an effective insect repellent that incorporates our topical polymer-based delivery systems, the rights to distribute and sell the developed product will be subject to the terms of an Agreement with EMD Chemicals, the owner of the active ingredient. There can be no assurance that we will be successful in developing a viable insect repellent that incorporates our topical polymer-based delivery systems and the active ingredient.

Sunscreen

We developed and successfully tested the application of our polymer delivery vehicles in sunscreen products with SPF 15 and SPF 30, sunless tanning lotions, moisturizing creams, aloe after-sun products, and other skin care products. We currently offer Invisicare for incorporation into these products on a private label basis and have multiple agreements in place.

During the reporting period, we developed two additional sunscreen products. One of the products utilizes the active ingredient Parsol 1789. The other product utilizes the active ingredient Tinasorb which has been approved for distribution in Europe, Japan, Australia and recently Canada. Tinasorb has not yet have approval in the US. Tinasorb is a broad spectrum UVA/UVB ingredient. The manufacturer of Tinasorb is Ciba Chemicals. It is our intention to license out the distribution of both of these formulas.

Antifungal

We have an oral agreement with a pharmaceutical company relating to the development of an antifungal product that incorporates Invisicare with the active ingredient Clotrimazole. We have completed our initial research and development of this product and are awaiting the results of

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this study. If this pharmaceutical company is satisfied with the study, we would expect to execute a licensing agreement with this company. A definitive licensing agreement would require the company to pay us an upfront license fee plus ongoing royalty payments based on territorial sales of the product. There can be no assurance that we will be successful in executing a license agreement for this product.

Acne

We have an oral agreement with a pharmaceutical company relating to the development of an acne product that incorporates Invisicare with the active ingredient retinoic acid. We have completed our initial research and development of this product and are waiting the results of this study. If this pharmaceutical company is satisfied with the study, we would expect to execute a licensing agreement with this company. A definitive licensing agreement would require the company to pay us an upfront license fee plus ongoing royalty payments based on territorial sales of the product. There can be no assurance that we will be successful in executing a license agreement for this product.

Topical Analgesic

We have an agreement with an OTC pharmaceutical company relating to the development of an analgesic that incorporates Invisicare with the active ingredient menthol. We have completed our research and development of this product and are expecting to execute a licensing agreement with this company. A definitive licensing agreement would require the company to pay us an upfront license fee plus ongoing royalty payments based on territorial sales of the product. There can be no assurance that we will be successful in executing a license agreement for this product.

Non-steroidal atopic dermatitis

During the three months ended June 30, 2006, we developed a non-steroidal atopic dermatitis product, also referred to as hydro-gel, for atopic dermatitis that incorporates Invisicare for a pharmaceutical company. In July 2006, we were notified of a change in the FDA's approval process and the pharmaceutical company declined to proceed forward following this change. We are now seeking to make this product available to a pharmaceutical company that can successfully secure FDA approval for the marketing and distribution of this product. There can be no assurance that this product will receive FDA approval. We are presently working with a pharmaceutical company in Canada to obtain approval to market and distribute this product in Canada.

Antimicrobial Hand Sanitizer Lotion

We have developed and are currently testing a new antimicrobial hand sanitizer lotion that utilizes the active ingredient Chlorhexidine ("Chlorhexidine antimicrobial hand sanitizer"). Chlorhexidine is the active agent in scrub soaps currently used in the operating rooms of most hospitals worldwide.

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As a part our development efforts to develop the Chlorhexidine antimicrobial hand sanitizer lotion, we developed a research plan that comprises of several studies. The first and second studies were in-vitro tests designed to gauge the effectiveness of the Chlorhexidine antimicrobial hand sanitizer lotion when exposed to certain bacteria. We received positive results from the first study. The results of the second study indicated that further strengthening of the product could improve the product's effectiveness. Our research department implemented the appropriate improvements and commenced a third study on viruses during the fourth quarter. The third study was conducted by Retroscreen Virology Ltd. ("RVL"), a research company that is a division of St. Bartholomew's Hospital and the Royal London Hospital based in London, England, and designed to test the effectiveness of the Chlorhexidine antimicrobial hand sanitizer lotion in killing the H5N1 virus also known as the bird flu virus or avian flu. In-vitro testing conducted by RVL confirmed that the Chlorhexidine antimicrobial hand sanitizer lotion got a greater than 99.9% inactivation/kill on the H5N1 virus at the following four points: 15 seconds, 30 seconds, 1 minute, and 5 minutes following contact. This in-vitro study was conducted by placing the Chlorhexidine antimicrobial hand sanitizer lotion in a dish and then exposing the H5N1 virus at the forgoing time intervals. Based upon these positive results, we retained RVL to conduct a further ex-vivo study to provide data on the effectiveness of the Chlorhexidine antimicrobial hand sanitizer when exposed to the H5N1 virus over an extended period of time. This ex-vitro study was conducted by applying the Chlorhexidine antimicrobial hand sanitizer lotion to dead skin specimens, simulating normal conditions of wash-off and skin perspiration, and then exposing the H5N1 virus to the skin specimen at various extended time intervals.

This ex-vivo study confirmed that the Chlorhexidine antimicrobial hand sanitizer lotion got a greater than 98% inactivation/kill on the H5N1 virus at various intervals following application up to four hours. This study verifies that the patented polymer delivery system Invisicare® successfully holds the active ingredient Chlorhexidine on the skin for extended periods of time. Additional in-vitro studies performed by RVL using the Chlorhexidine antimicrobial hand sanitizer lotion confirmed a greater than 99.9% inactivation/kill on the seasonal flu virus Influenza A (H1 and H3) as well as Influenza B. We have suspended further studies until such time that we are able to enter into an agreement with a potential licensee for this product.

We also commissioned another study referred to as a human repeat insult patch test (HRIPT). This study exposes a minimum of 100 persons to the Chlorhexidine antimicrobial hand sanitizer to determine if continued use and exposure to the product will result in skin complications or sensitivities. This study was completed and indicated that 5 people out of the 100 tested experienced a mild sensitization to the product. This study used a method that kept the product moist and occluded which was inconsistent with the product's intended use. We are preparing a further study to test the product under normal use conditions.

In the event that the Chlorhexidine antimicrobial hand sanitizer lotion proves to be a viable product, we may be required to file a New Drug Application with the US FDA because the drug Chlorhexidine is not presently an approved drug under the FDA Tentative Final Monograph (TFM) for Hand Sanitizers. We may also be required to seek similar regulatory approvals in other foreign jurisdictions. If we are required to file a New Drug Application with the US FDA, further development of this product may be both time and cost prohibitive for us. It is our intention to seek a pharmaceutical partner to fund there additional studies required to obtain FDA

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approval. There can be no assurance that we will successfully complete the research and development of this product and/or receive approval to make the Chlorhexidine antimicrobial hand sanitizer lotion available for sale in the United States or other foreign jurisdictions.

We filed a patent application on the Chlorhexidine Hand Sanitizer Lotion formula with the United States Patent and Trademark Office. We can provide no assurance that we will receive patent approval for the Chlorhexidine Hand Sanitizer Lotion formula.

We have retained a consultant in China to assist us in securing regulatory approval for this product within China. Our efforts to secure regulatory approval for this product in China are ongoing and we can provide no assurance that we will successfully receive the required approval to market and distribute this product within China.

In December 2006, the Chlorhexidine antimicrobial hand sanitizer has received approval for marketing in Canada.

We have reached a verbal agreement with EMD Chemicals of Hawthorne, NY, an affiliate of Merck KGaA of Darmstadt, Germany, to joint venture the distribution of this product in Southeast Asia and are presently seeking to memorialize this agreement in a written contract.

Competition

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.

Patents, Licenses, Trademarks, Franchises, Concessions, Royalty Agreements, or Labor Contracts

Patents

On January 4, 2000, we filed a patent application for our antimicrobial dermal barrier composition. We received patent approval (US Patent No. 6,582,683) for our antimicrobial dermal barrier formulation in February 2003 and received the patent certificate in June 2003.

We filed a patent application on August 20, 2001 titled “Topical Compositions, Topical Composition Precursors, and Methods for Manufacturing and Using” for our *Invisicare®* topical compositions and our methodology for manufacturing and utilization of numerous delivery systems and related applications. The United States Patent and Trademark Office split this application into three different applications as follows: (a) Methods of Manufacturing (b) Topical Compositions and (c) Methods of Use. We received patent approval for the application on Methods of Manufacturing (US Patent No. 6,756,059). However, as the Patent approval of June 2003 already was covered on one of the polymer compositions noted in the Methods of

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Manufacturing the Patent Office further split this application into 2 distinct patents. Topical Compositions and Methods of Use are pending.

We have also filed under the Patent Cooperation Treaty (PCT) the Patent titled “Topical Compositions, Topical Composition Precursors, and Methods for Manufacturing and Using” for certain foreign countries. As of December 31, 2005, this patent application is still pending.

In addition to the United States patents currently pending on the core patent technology, we have filed 6 more patents which cover product classes including sunless tanning spray, sunless tanning lotion, sunscreens, chlorhexidine antimicrobial hand lotion, anti-fungal and acne formulations..

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.

Research and Development

We incurred research and development expenditures in the fiscal year ended December 31, 2006 of $172,764 and $57,091 for the fiscal year ended December 31, 2005.

Existing and Probable Governmental 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.

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Compliance with Environmental Laws

We did not incur any costs in connection with the compliance with any federal, state, or local environmental laws.

Employees

We currently have 6 total employees, including our sole executive officer, and all are full-time employees.

During the year ended December 31, 2006, we retained two additional chemists to provide research and product development services.

Item 2. Description of Property

Currently, we do not own any real estate. We are leasing our executive offices and research facility. We are located at 6320 South Sandhill Road, Suite 10, Las Vegas, Nevada 89120.

Skinvisible Pharmaceuticals, Inc., our wholly owed subsidiary, owns the manufacturing and laboratory equipment at this location.

Item 3. Legal Proceedings

We are not a party to any pending legal proceeding. We are not aware of any pending legal proceeding to which any of our officers, directors, or any beneficial holders of 5% or more of our voting securities are adverse to us or have a material interest adverse to us.

Item 4. Submission of Matters to a Vote of Security Holders

No matters have been submitted to our security holders for a vote, through the solicitation of proxies or otherwise, during the fourth quarter of the fiscal year ended December 31, 2006.

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PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Market Information

Our common stock is currently quoted on the OTC Bulletin Board (“OTCBB”), which is sponsored by the NASD. The OTCBB is a network of security dealers who buy and sell stock. The dealers are connected by a computer network that provides information on current "bids" and "asks", as well as volume information. Our shares are quoted on the OTCBB under the symbol “SKVI.”

The following table sets forth the range of high and low bid quotations for our common stock for each of the periods indicated as reported by the OTCBB. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Fiscal Year Ending December 31, 2006		
Quarter Ended	High $	Low $
March 31, 2006	0.72	0.18
June 30, 2006	0.62	0.362
September 30, 2006	0.37	0.30
December 31, 2006	0.75	0.24

Fiscal Year Ended December 31, 2005		
Quarter Ended	High $	Low $
March 31, 2005	0.20	0.16
June 30, 2005	0.195	0.17
September 30, 2005	0.21	0.195
December 31, 2005	0.28	0.19

Penny Stock

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a market price of less than $5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock, to deliver a st