

SKINVISIBLE INC
Form 10KSB
April 14, 2005

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

FORM 10-KSB

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

For the fiscal year ended December 31, 2004

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

88-033442219

(State or other jurisdiction of incorporation or
organization)

(I.R.S. Employer
Identification No.)

6320 South Sandhill Road, Suite 10

Las Vegas, Nevada

(Address of principal executive offices)

89120

(Zip Code)

Issuer's telephone number (702) 433-7154

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

Title of each class

None

Name of each exchange on which registered

Not Applicable

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

Common Stock

(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 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

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State issuer's revenue for its most recent fiscal year: \$519,972

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. \$3,817,947 as of March 22, 2005.

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date.

56,725,248 Common Shares as of March 22, 2005

Transitional Small Business Disclosure Format (Check One): Yes: ; No

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We were organized as a Nevada corporation on March 5, 1998 under the name "Microbial Solutions, Inc." On February 26, 1999, we changed our name to "Skinvisible, Inc."

We conduct our business through the following wholly owned subsidiaries:

NAME OF SUBSIDIARY	DATE OF INCORPORATION	JURISDICTION OF INCORPORATION
Skinvisible Pharmaceuticals, Inc. f/k/a Manloe Laboratories, Inc.	June 30, 1995	Nevada
Skinvisible Pharmaceuticals (Canada) Inc.	October 20, 1998	Canada

We conduct our primary business activities such as research and development and marketing of our products through Skinvisible Pharmaceuticals, Inc., a Nevada corporation. We conduct our marketing activities in Canada through the Canadian entity Skinvisible Pharmaceuticals (Canada) Inc.

Description of Business

We develop innovative polymer delivery vehicles and related compositions that when topically applied hold active ingredients on the skin for up to four hours. 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 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 our polymer delivery vehicles to date include antimicrobial hand sanitizers, sunscreen products, skincare moisturizers, sunless tanning sprays, incontinence lotion, anti-fungals, and acne. We are in the process of developing polymer formulations that can successfully be utilized in insect repellents and liquid bandages.

Our primary objective is to license our polymer delivery vehicles 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 our polymers to vendors that have executed a license agreement with us. We conduct our research and development in-house and continuously are engaged in developing additional applications for our polymer delivery vehicles.

Manufacture and Distribution

We previously manufactured our polymer delivery vehicles and products that incorporate our polymer delivery on-site at our facility at 6320 South Sandhill Road, Unit #10, Las Vegas, Nevada 89120. We also formerly distributed these manufactured products from our facility. We engaged an outside party that currently handles all of our manufacturing

and distribution needs. At the present time, we only perform research and development at our facility.

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Description of Current Products and Agreements

Antibacterial/Antimicrobial Hand Sanitizer

On July 9, 2003 our wholly-owned subsidiary, Skinvisible Pharmaceuticals, Inc. ("Skinvisible") signed a letter of intent with Health First Distributors North America, Inc. of British Columbia, Canada ("Health First") to grant Health First the exclusive marketing and distribution rights to the antimicrobial hand sanitizer product we manufacture that which utilizes the active ingredient Triclosan 1% (the "Product") in the North American countries of Canada, United States, and Mexico. Due to Health First's failure to satisfy certain conditions set forth in the letter of intent, we never entered into a formalized License Agreement and no further negotiations occurred.

Our management continued its attempts to license the exclusive marketing and distribution rights to our antimicrobial hand sanitizer which utilizes the active ingredient Triclosan 1% and entered into a letter of intent with Dermal Defense, Inc. ("Dermal Defense") on or about March 24, 2004. On February 21, 2005, we entered into a definitive distribution agreement with Dermal Defense. Under the terms of 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.

Dermal Defense acquired these rights for the purchase price of \$1,000,000. Dermal Defense has already paid \$475,000 of this purchase price. The remaining balance is due and payable on a quarterly basis in the amount of \$75,000 or 5% of gross revenue from sales of the licensed product, whichever is greater until paid in full.

In addition and under the terms of the agreement, Dermal Defense is also 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. Under the terms of this agreement, Dermal Defense is prohibited from manufacturing, marketing, distributing, or selling any competing product while this agreement is in full force and effect.

Dermal Defense was granted an option to acquire the exclusive marketing and distribution rights for our antimicrobial hand sanitizer globally. This option expired on March 30, 2005. If this option was exercised, Dermal Defense would have been required to pay us \$1 Million and a 5% royalty on all sales of the licensed product globally. We are currently negotiating with Dermal Defense an extension to the termination date of this option.

Sunless Tanning Sprays

On June 9, 2004, our wholly-owned subsidiary, Skinvisible Pharmaceuticals, Inc. ("Skinvisible"), 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 Skinvisible's 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 utilizing our proprietary polymer formula to manufacture nine additional suncare related products.

The Distribution Agreement provides that Cross Global must pay Skinvisible an up-front royalty in the amount of \$1,000,000. Cross Global has paid us \$700,000. The remaining \$300,000 is due on May 30, 2005.

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Under the terms of the Distribution Agreement, Cross Global is prohibited 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 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 our polymer delivery vehicles for incorporation into these products on a private label basis and have multiple agreements in place.

Description of Other Applications for which no Agreements are Currently in Place

We have developed and successfully tested the application of our polymer delivery vehicles in the following products:

- Incontinence lotion
- Anti-fungal
- Anti-acne
- Anti-Inflammatory
- Dermal Abrasion/Cosmetic

Skin Care

- Anti-microbial Wound Care

Our management is seeking to offer our polymer delivery vehicles for incorporation into these products on a private label basis.

Status of Research and Development for New Applications

We are continuing our research and development toward developing additional applications for our polymer delivery vehicles. We are currently researching the following potential applications for our polymer delivery vehicles:

- Insect repellants
- Liquid bandages
- New antibacterial/antimicrobial

hand sanitizer

In the event that these studies determine that we can successfully incorporate our topical polymer-based delivery system into any of these products set forth below, we will move forward to secure all appropriate governmental approvals for the distribution of this product in the United States. It is our anticipation that the process to complete all studies and secure all government approvals will take approximately twelve (12) to eighteen (18) months from the beginning of each study.

Insect Repellants

We are in the process of developing a mosquito repellent that incorporates our topical polymer-based delivery systems. The approximate cost of the outside study is \$100,000 and our management is seeking to negotiate a deal with a third party where they would pay the cost of the study in exchange for licensing rights.

We expect to commence outside studies on this product once a deal is in place to provide funding for the outside study.

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New Antibacterial/Antimicrobial Hand Sanitizer

We have developed and sold the exclusive marketing and distribution rights to an antimicrobial hand sanitizer product that utilizes the active ingredient Triclosan 1%. We have developed and a currently testing a new antimicrobial hand sanitizer product that utilizes the active ingredient Chlorhexadine. Chlorhexadine is the active agent in scrub soaps currently used in the operating rooms of most hospitals in North America and Europe.

We have received positive results from the first study we commissioned and are currently in the process of a second study. We anticipate that the results of the second study will be available before the end of the second quarter of fiscal 2005. This product may require us filing of a New Drug Application with the US FDA because the drug Chlorhexadine is not an approved drug for Hand Sanitizers in the US under the FDA Tentative Final Monograph. If we are required to file a New Drug Application with the US FDA, the development of this product may be both time and cost prohibitive for us. Under such circumstance, we would seek a pharmaceutical partner to fund the remaining studies.

Competition

In terms of our current focus and long-term strategy, our primary products have been identified as the licensing of our polymer-based delivery system technologies and sale of our delivery systems as ingredients for topically administered finished product applications in the prescription Rx and OTC treatment, cosmetic, and skincare formulations. 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 *Invisicar*® 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). Our patent applications on Topical Compositions and Methods of Use are still 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 March 22, 2005, we did not receive any response.

We also have two patents currently pending, which cover our sunless tanning spray formula and sunscreen formulas.

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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*."

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 full-time employees including our President, Chief Executive Officer, and Chief Financial Officer, Terry Howlett.

Research and Development

We incurred research and development expenditures for the fiscal years ended December 30, 2003 and 2004 in the amount of \$3,500 and \$17,300 respectively.

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.

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

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 owned subsidiary, owns the manufacturing and laboratory equipment at this location.

Item 3: Legal Proceedings

Subsequent to the reporting period on March 8, 2005, we initiated litigation in the U.S. District Court for the District of Nevada against Health First Distributors North America, Inc., a British Columbia corporation ("HFD"). The complaint seeks declaratory relief to the effect that the parties must arbitrate a dispute between them in Las Vegas, Nevada, as required by the parties' July 9, 2003, letter of intent as amended by a subsequent letter dated October 29, 2003. The underlying dispute concerns whether we must return what we contend was a non-refundable deposit of \$100,000 USD towards North American distribution rights for our products. HFD has claimed in demand letters that we must return the deposit and has threatened to bring suit in British Columbia if we fail to do so. We disagree with HFD's position and have demanded that the dispute be arbitrated in Las Vegas, Nevada, as required by the parties' agreement. HFD has refused. Our

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lawsuit seeks only a declaration from the court that arbitration is required and that it must take place in Las Vegas, Nevada. We served the summons and complaint on March 17, 2005. As of March 31, 2005, HFD had not answered or otherwise responded to the litigation.

Subsequent to the reporting period, Skinvisible Pharmaceuticals, Inc. and our Chief Executive Officer, Terry Howlett, were named as defendants in a lawsuit initiated in the U.S. District Court for the Eastern District of Michigan on March 11, 2005. The lawsuit seeks a judgment against all defendants jointly and severally in the amount of \$1,025,000 plus other costs, interest and expenses as the court finds appropriate. The underlying dispute concerns the circumstances under which the plaintiffs purchased common stock in Dermal Defense, Inc., a Nevada corporation. We believe that the lawsuit against Skinvisible Pharmaceuticals, Inc. and our Chief Executive Officer is without merit and plan to file a motion to dismiss.

Item 4: Submission of Matters to a Vote of the Security Holders

No other matters were submitted to our security holders for a vote during the reporting period.

Subsequent to the reporting period on January 10, 2005, we held our annual shareholder meeting. The meeting was called for the purpose of electing directors to the board of directors and to transact any other business that may properly come before the meeting. The number of votes present in person or by proxy was sufficient to constitute a quorum. A majority of the shareholders elected Terry Howlett, Jost Steinbruchel, and Greg McCartney to serve on the board of directors until the next annual meeting of the shareholders, or until removed by other action as allowed by the corporate bylaws. The tabulation of the votes was as follows:

Nominee	Votes Cast For	Votes Cast Against	Votes Abstained
Terry Howlett	8,422,052	0	0
Jost Steinbruchel	8,422,052	0	0
Greg McCartney	8,422,052	0	0

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Our common stock is currently quoted on the OTC Bulletin Board, which is sponsored by the National Association of Securities Dealers ("NASD"). The OTC Bulletin Board 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 OTC Bulletin Board 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 NASD OTCBB. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Fiscal Year Ending December 31, 2004

<u>Quarter</u> <u>Ended</u>	<u>High \$</u>	<u>Low \$</u>
March 31, 2004	0.20	0.12
June 30, 2004	0.15	0.10
September 30, 2004	0.08	0.06
December 31, 2004	0.09	0.06

Fiscal Year Ending December 31, 2003

<u>Quarter</u> <u>Ended</u>	<u>High \$</u>	<u>Low \$</u>
March 31, 2003	0.11	0.03
June 30, 2003	0.23	0.07
September 30, 2003	0.23	0.08
December 31, 2003	0.29	0.10

On March 22, 2005 closing price per share of our common stock, as reported by the NASD OTC Bulletin Board, was \$0.19.

Penny Stock

Until our shares qualify for inclusion in the Nasdaq system, the public trading, if any, of our common stock will be on the OTC Bulletin Board. As a result, an investor may find it more difficult to dispose of, or to obtain accurate quotations as to the price of, the common stock offered. Our common stock is subject to provisions of Section 15(g) and Rule 15g-9 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), commonly referred to as the "penny stock rule." Section 15(g) sets forth certain requirements for transactions in penny stocks, and Rule 15g-9(d) incorporates the definition of "penny stock" that is found in Rule 3a51-1 of the Exchange Act. The SEC generally defines "penny stock" to be any equity security that has a market price less than \$5.00 per share, subject to

certain exceptions. If our common stock is deemed to be a penny stock, trading in the shares will be subject to additional sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. "Accredited investors" are persons with assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse. For transactions covered by these rules, broker-dealers must make a special suitability determination for the purchase of such security and must have the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the first transaction, of a

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risk disclosure document, prepared by the SEC, relating to the penny stock market. A broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative, and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information for the penny stocks held in an account and information on the limited market in penny stocks. Consequently, these rules may restrict the ability of a broker-dealer to trade and/or maintain a market in our common stock and may affect the ability of our shareholders to sell their shares.

Holders of Our Common Stock

As of March 31, 2005, there were 174 registered holders of our common stock.

Dividends

There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statutes, however, do prohibit us from declaring dividends where, after giving effect to the distribution of the dividend:

1. we would not be able to pay our debts as they become due in the usual course of business; or
2. our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of shareholders who have preferential rights superior to those receiving the distribution.

We have not declared any dividends, and we do not plan to declare any dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plans as of December 31, 2004

	A	B	C
Plan Category	Number of securities to be issued upon exercise		