SKINVISIBLE INC
Form 10-K
April 14, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended **December 31, 2015**

[ ] 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	**88-0344219**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6320 South Sandhill Road, Suite 10, Las Vegas, NV	**89120**
(Address of principal executive offices)	(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
Common Stock, par value $0.001

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

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 [X]

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 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 [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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.

[ ] Large accelerated filer [ ] Accelerated filer
[ ] Non-accelerated filer [X] Smaller reporting company

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. $3,431,692

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 117,001,969 common shares as of February 18, 2016

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PART I

Item 1. Business

Company Overview

We, through our wholly owned subsidiary Skinvisible Pharmaceuticals Inc., are a pharmaceutical research and development ("R&D") company that has developed and patented an innovative polymer delivery system, Invisicare® and formulated over forty topical skin products, which we out-license globally. We were incorporated in 1998, and target an estimated $80 billion global skincare and dermatology market and a $30 billion global over-the-counter market as well as other healthcare / medical and consumer goods markets.

With the research and development complete on forty products and numerous patents issued (technology and product patents), we are ready to monetize our investment. Our business model will continue to be to out-license our patented prescription and over-the-counter ("OTC") products featuring Invisicare to established manufacturers and marketers of brands internationally and to maximize profits from the products we have already out-licensed. We have also formed a commercial subsidiary, Kintari USA Inc., in order to take our cosmeceutical and select OTC products with Invisicare to market.

The opportunity for us to license our products continues to be a viable model as the need for pharmaceutical companies to access external R&D companies for new products due to their own down-sizing or elimination of internal R&D departments. The demand for our products is enhanced due to the granting of key US and international patents and the completed development of a number of unique products.

Our Flagship Product

Pivotal to our success is our patented polymer delivery system technology Invisicare. Invisicare is a patented polymer delivery system that enhances the delivery of active ingredients for topically applied skin care products. Its patented technology has a unique formula and process for combining active ingredients with a delivery system that extends the duration of time the product remains on the skin and active.

Invisicare is specifically formulated to carry water insoluble active and certain cationic active ingredients in water-based products without the use of alcohol, silicones, waxes, or other organic solvents. Products utilizing Invisicare have the proven ability to bond active ingredients to the skin for up to four hours and longer. They are non-occlusive and allow normal skin respiration and perspiration while moisturizing and protecting against exposure

from a wide variety of environmental irritants.

When topically applied, these formulated products adhere to the skin's outer layers, forming a protective bond, resisting wash-off, and delivering targeted levels of therapeutic or cosmetic skincare agents to the skin. They allow enhanced delivery performance for a variety of skincare agents resulting in improved efficacy, longer duration of action, reduced irritation and lower dosage of active agent required. The "invisible" polymer compositions wear off as part of the natural exfoliation process of the skin's outer layer cells.

The advantage of products formulated with Invisicare is (1) Invisicare’s ability to bind active ingredients (the drug) to the skin, forming a protective bond on the skin, for extended periods of time - some up to eight hours or more; (2) Invisicare can deliver targeted levels (high or low) of therapeutic or cosmetic ingredients to the skin in a controlled release; (3) Invisicare can help to reduce the irritation of some active ingredients due to how it controls the slower

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release of that active ingredient; and (4) Invisicare science proves that it provides a protective skin barrier which helps retain the natural moisture content of the skin, while still allowing it to breathe. These benefits present an excellent opportunity for clear scientific advantages and marketing messages which resonate with physicians and consumers.

The Market

The dermatology market is large, with over 80% of Americans affected by some kind of skin condition in their lifetime. The worldwide market for dermatology products including prescription, OTC and cosmeceuticals is estimated at $80 billion.

Company History

We formed Skinvisible Pharmaceuticals, Inc. (“Skinvisible”), in March 1998 and purchased the exclusive worldwide manufacturing and marketing rights for a polymer delivery system invention now called Invisicare® from the inventor for $2 million. We have continued to develop the Invisicare technology and subsequent product development resulting in over seven series of Invisicare and over forty unique, patented formulations offering distinctive benefits that differentiate them significantly from other leading products in the marketplace.

What We Do

We have positioned ourselves in the $80 billion worldwide prescription and over-the-counter dermatology and skincare market. We generate revenue by:

- **LICENSING**: We develop topical prescription and over-the-counter products enhanced with Invisicare to license to pharmaceutical and consumer goods companies around the world for an upfront fee and ongoing royalties;
- **DIRECT SALES**: We develop topical over-the-counter products enhanced with Invisicare to sell directly into the market through our wholly-owned subsidiary, Kintari USA Inc.
- **CO-DEVELOPMENT**: We assist pharmaceutical clients in the early development of the most optimal formulation, which they then take forward into clinical testing;
- **LIFE CYCLE MANAGEMENT**: We provide cost-effective solutions to global pharmaceutical companies by reformulating their products coming off patent with a new Invisicare patent and new product benefits and line extensions. Pharmaceutical companies are under a lot of pressure to develop innovative strategies to counteract the revenue loss from their drugs coming off patent.

Corporate Ownership

We are a publicly traded company under the symbol SKVI, listed on the OTC Bulletin Board since February 1999 and currently trading on the OTCQB in the US.

We carry on business primarily through our wholly owned subsidiaries: Skinvisible Pharmaceuticals, Inc. and Kintari USA Inc., both Nevada corporations.

Patents

We have fourteen patents granted, including comprehensive patents on Invisicare, the foundation of all of our products; three in the US, and internationally in Canada, Europe (4), China, India, Australia, Hong Kong, Japan and Korea. The Invisicare patents cover manufacturing, composition and use. Additionally, we have been granted three product specific patents in the US for dermal barrier products, sunscreens (photostability of avobenzone) and retinoids (stabilization). There are a number of U.S. and international (PCT) patents pending, with many more patent applications in progress. Some of these patents cover up to five products.

Our value lies in our ability to continually generate new IP on dermatology and medical products formulated with Invisicare. Patent approvals are sought (initially in the U.S. and later internationally) for all products developed. All patents with Invisicare are owned by us.

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Trademarks

When developing new products using Invisicare, we file for both patent and trademark protection. We have been granted trademarks in the U.S. and Canada for the following names:

- Skinvisible® w Invisicare® w JUSTCARE® w Work Gluv® w Bare Sunless Tanning® w Kintari® w Skinbrella®

Revenue generation: We receive a combination of five revenue streams including:

- Research and development fees;;
- Upfront license fee;
- Ongoing royalties based on product sales;
- Licensees purchase Invisicare polymers from us. The polymers make up 6-8% of each final product formulation for OTC and cosmetic formulas and less for prescription formulas.
- Sales of our cosmeceutical product line through our wholly-owned subsidiary, Kintari USA Inc.

Strategic Growth Opportunities

Our growth strategy is to:

1. Generate revenue from direct sales of our cosmeceutical/OTC product line;

2. Capitalize on the success of current licensees;

3. Increase the value of our current pipeline; and

4. Boost licensing revenues by securing additional licensees globally and develop a robust royalty revenue stream that will finance our future growth.

1. ***Kintari USA Inc.:***

On September 9, 2014, we formed Kinatri USA Inc., a new wholly-owned subsidiary of Kintari International Inc., wholly-owned subsidiary of Skinvisible Inc., to market a premium line of scientifically formulated skincare products powered by our patented Invisicare® technology. The company was officially launched January 15, 2015. As part of our strategic focus on revenue generation and creating shareholder value, Kintari USA Inc. products will be sold via network marketing. The products will be sold initially in the US and then in Canada in 2016.

The Kintari product portfolio consists of 2 anti-aging products to help fight the signs of aging and a broad spectrum sunscreen along with our newest product: Kintari's Hand & Body lotion. All products are made with our patented Invisicare technology.

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Our anti-aging products have been developed using proven anti-aging ingredients with scientific evidence of their effectiveness at reducing the look of fine lines and wrinkles resulting in youthful looking skin. These potent ingredients will be powered by patented Invisicare technology, providing consumers with unique, effective products which we believe cannot be duplicated.

Additionally, we sell a broad spectrum SPF 30 sunscreen known as Skinbrella®. We completed independent testing in early 2014 to validate our broad spectrum sunscreen claims according to the labeling guidelines of the FDA, which are designed to help reduce the incidents of skin cancer in the U.S. Our claims are as follows:

- Claim # 1 – Broad-Spectrum: According to the FDA, in order for a sunscreen to be labeled “broad spectrum” it must prove it protects against both UVA and UVB rays by having an SPF (Sun Protection Factor) of at least 15 and a critical wave length of at least 370 nm. Our sunscreen has surpassed both of these criteria, allowing our broad spectrum sunscreen label to also state “prevents sunburn, skin cancer and aging due to the sun.”

- Claim # 2 – Water-Resistant 80 Minutes: The FDA sunscreen water resistant claim requires that a sunscreen must have the same SPF after being in water or sweating for 40 or 80 minutes. Our testing was conducted at an independent laboratory specializing in sunscreen testing. The test involved human subjects that applied sunscreen to their arm, followed by the immersion of the arm into a Jacuzzi for 80 minutes (10 minutes in / 10 minutes out). Our sunscreen successfully completed this testing and is allowed to use “Water-resistant for 80 Minutes” on its sunscreen label, the longest length of time allowed by the FDA.

- Claim # 3 – Unique Patented Technology / Eight-Hour Photostability: As previously announced, we were granted a patent from the United States Patent and Trademark Office entitled “Sunscreen Composition with Enhanced UVA Absorber Stability and Methods”, which provides protection until November 2029. Skinvisible successfully formulated a unique Invisicare® delivery system specifically for stabilizing avobenzone; the key sunscreen used in the USA. Data submitted to the US patent office proved that our sunscreen provides a minimum of eight hours of photostability.

Our Hand & Body Lotion is formulated with five moisturizers including aloe, shea butter, glycerin, coconut oil and jojoba oil, and to help smooth your skin the powerful antioxidant Vitamin E. These ingredients restore and nourish your skin from head to toe.

2. ***Capitalize On Current Licensees:***

We have licensees around the globe. Two of these licensees are currently in the marketplace: Avon Products globally and Women's Choice Pharmaceuticals in the United States.

We continue to work diligently with our licensees to ensure they have a smooth manufacturing process, ongoing R&D support and marketing feedback.

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Avon Products, Inc:

Product: We have a long-term contract with Avon globally for over ten years to provide Invisicare polymer for their long-lasting lipsticks.

Sales: Invisicare polymers are purchased directly from Skinvisible.

Women's Choice Pharmaceuticals:

Product: ProCort®, long lasting prescription hemorrhoid cream launched in the United States August 2011.

Sales and Royalties: Skinvisible receives a royalty based on net sales of ProCort. This past year Women's Choice Pharmaceuticals LLC partnered with Advanced Medical Enterprises, LLC to market ProCort® in Puerto Rico. 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 2016. Women's Choice is seeking to form other strategic alliances in order to increase its sales efforts by targeting new territories and targeting medical specialists which previously were not called upon.

Product Updates:

We have additional information on specific products which add value to Skinvisible's product pipeline.

DermSafe® Hand Sanitizer

Skinvisible's hand sanitizer formulated with Invisicare® and chlorhexidine gluconate has received registration in Belgium on behalf of Skinvisible. This registration allows Skinvisible to make DermSafe® available in most of Europe through a simple registration process. We are currently seeking licensees and/or distributors to begin the sale of DermSafe in the EU. This registration has recently been granted for a ten year term to expire in 2024. We expect that the product will be sold through Kintari Canada Inc. when it launches in 2016.

Sunless Tanning Products: We have developed a new sunless tanning mousse / foam which uses a unique foam with Invisicare®, developed specifically for its foaming properties. This adds to Skinvisible's line of sunless tanning products which includes sunless tanning lotions (light, medium and dark), pre-sun moisturizer and after-sun moisturizer along with sunless tanning spray products for commercial use. The addition of a sunless tanning mousse enhances this line of products.

Sunscreen Products: We have developed 3 broad spectrum sunscreens, with SPF 15, 30 and 50 (the highest SPF allowed by the FDA). All are formulated with Avobenzone, the only UVA sun filter allowed under the US FDA monograph. This UVA/UVB sunscreen was granted a patent from the United States patent office in 2013. Avobenzone is known for breaking down in the sun after only two hours – thus the requirement to reapply every 2 hours. Skinvisible's patent was granted based on Invisicare's® minimum 8 hour photo stability. For countries outside the United States, Skinvisible has additionally patented UVA/UVB sunscreens formulated with Tinosorb S.

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3. ***Increasing The Value Of Skinvisible's Pipeline:*** **Clinical Enhancement Of Pipeline**

We have a pipeline of over forty products which are available for licensing. Testing is conducted in-house generating proof of concept including release of the active ingredient as well as long term shelf life (stability). Additional studies conducted on specific products including skin sensitivity, toxicity and product efficacy are outsourced to FDA compliant laboratories. These studies are critical in attracting potential licensees. Our clinical strategy is to:

- Our clinical strategy is to find a partner for our prescription product portfolio. This would allow for a partner to seek FDA approval using the 505b2 pathway for one or more of our products.

- Launch of our DermSafe® hand sanitizer in Canada under Kintari. In 2013, we 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. 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. In 2013, we obtained the registration rights for DermSafe® in Belgium. This designation allows for the sale and/ or registration of DermSafe in most EU countries. A strategy is being developed along with a larger global strategy to bring DermSafe to the EU and. Skinvisible has also commissioned further testing of DermSafe against the (Middle East Respiratory Syndrome Coronavirus (MERS-CoV); a SARS-like virus and the avian influenza A virus, H7N9.

- We continue to look for avenues to obtain orphan drug status for our Netherton syndrome product. Netherton syndrome is a disease caused by a genetic defect which causes the skin to continually exfoliate, never forming a skin bond. This leaves the patient highly susceptible to infection and dealing with a life-long condition that has no cure. Our product has shown excellent results in lab studies blocking the enzyme that breaks down the skin and we are seeking "Orphan Drug" designation in both the US (FDA) and Europe (EMA). We have reformulated our product to better meet the demands of this very debilitating disease and are undergoing preliminary proof-of-concept investigations on Netherton syndrome.

The advantages of obtaining Orphan Drug designation is that it provides various incentives including a reduction or elimination of registration and market authorization fees, protocol assistance, and seven years of market exclusivity for the product in the US and ten years in Europe. There can be no assurances that our project will be successful.

4. ***Secure Additional Licensees:***

We are in discussions and undergoing internal discussions with various pharmaceutical companies for licenses.

To facilitate further expansion, we are seeking an exclusive license with a proven US or global based Pharmaceutical Company for our existing Rx product formulations. The licensee would be expected to pay all costs in getting FDA approval. The licensee would pay Skinvisible for the license in milestone payments as Clinical Phases are proven.

Invisicare Formulations

Our forty products have been successfully tested in-house to show proof of concept and are ready to be licensed. We continue to develop other prescription, OTC and cosmeceutical products in response to the needs of the marketplace.

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Product patent applications are immediately filed on newly developed products. FDA regulatory approvals are required for prescription products while OTC products have limited requirements. Cosmetic-type products, products without therapeutic claims and OTC products that follow the FDA monograph, are immediately available for marketing. In Canada, OTC products follow the Health Canada monograph requiring only the submission of a DIN registration.

We have over 40 products developed and available for licensing:

CONDITION / USE	**PRESCRIPTION** (PRE-CLINICAL)	**OTC / COSMECEUTICAL**
Acne	3	2
Actinic Keratosis	1	
Analgesics	1	6
Anti-Fungal	2	2
Anti-Inflammatory	4	1
Antimicrobial	1	4
Pre-Operative Skin Prep	1	
Dermatitis / Dry Skin	1	5
Netherton Syndrome	1	
Anti- Aging		4
Suncare		6
Sunless Tanning		3
TOTAL	15	33

Research and Development

Our facilities include a research and development laboratory, headed by James Roszell PhD, where we continue to enhance our current product offerings and to develop a variety of new product formulations with Invisicare for out-licensing.

Our R&D focus is centered on the following initiatives:

§ We continue to expand our product development beyond the dermatology market into other areas including women's health, orphan drugs, pain management and surgical;

§ To increase the value of our prescription products, with additional testing on our most lucrative prescription products in order to provide independent validation and verification of our product claims. We utilize FDA compliant,

independent laboratories with extensive qualifications for carrying out investigative product studies, utilizing protocols incorporating Good Lab Practice and Good Clinical Practice ("GLP/GCP") standards;

§ We have successfully developed a unique product for Netherton syndrome and are seeking orphan drug status for this product. Additional studies are required in order to receive approval as an orphan drug in the United States and Europe.

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We have also completed preliminary development of a new Invisicare technology which will provide transdermal delivery of drugs. This new transdermal delivery system will allow us to enter the very lucrative markets of hormone replacement therapy, neurological treatment, nicotine cessation and others.

Sales and Marketing Plan

Our Licensing Strategy

As stated above, we are seeking a proven US based Pharmaceutical company to license all our prescription products and for them to seek FDA approval. This would be an exclusive licensing agreement and allow management to focus on developing Kintari while our research department continues to support the Pharmaceutical Company.

Competition

Market research indicates there is reasonably limited direct competition for Invisicare and patented products in terms of performance capabilities for topically administered skin products. Many companies are seeking unique delivery systems to enhance their portfolio and purchasing companies that have delivery technology.

Some of the companies involved in developing delivery technology are listed below. However, none of these competitors offer the same advantages of Invisicare principally the “long-term staying power” and the ability to control the release of active ingredients on the skin.

- GSK through its subsidiary, Stiefel Laboratories Inc., purchased Connetics Corporation for approximately $640 million in the fall of 2006. (Subsequently in 2009, Stiefel, with $900 million in sales, was purchased by GlaxoSmithKline for $3.9 billion – at 4 times revenue). Connetics has a patented foam delivery technology.

- Foamix Ltd is a drug development company with its head office in Israel. It has developed five platforms which use a foam delivery technology and is used in products like Rogaine®.

- A.P. Pharma sold its acne and actinic keratosis products made with its patented Microsponge® delivery system to two companies for a reported $30 million; Johnson & Johnson purchased the Retin-A Micro® product line, with revenues of $110 million in the US in 2006 and sanofi-aventis purchased Carac®, a product

used to treat actinic keratosis, with $11 million in sales in 2001.

Government Regulation

Cosmetic and Skin Care Regulation

Depending upon product claims and formulation, skin care products may be regulated as cosmetics, drugs, devices, or combination cosmetics and drugs. We currently only market cosmetic skin care products and are evaluating entry into the pharmaceutical market. The FDA has authority to regulate cosmetics marketed in the United States under the FDCA and the Fair Packaging and Labeling Act ("FPLA") and implementing regulations. The Federal Trade Commission (the "FTC") regulates the advertising of cosmetics under the FTCA.

The FDCA prohibits the marketing of adulterated and misbranded cosmetics. Cosmetic ingredients must also comply with the FDA's ingredient, quality, and labeling requirements and the FTC's requirements pertaining to truthful and non-misleading advertising. Cosmetic products and ingredients, with the exception of color additives, are not required to have FDA premarket approval. Manufacturers of cosmetics are also not required to register their establishments, file data on ingredients, or report cosmetic-related injuries to the FDA.

We will be responsible for substantiating the safety and product claims of the cosmetic products and ingredients before marketing. The FDA or FTC may disagree with our characterization of one or more of the skin care products as a cosmetic or the product claims. This could result in a variety of enforcement actions which could require the reformulation or relabeling of our products, the submission of information in support of the product claims or the safety and effectiveness of our products, or more punitive action, all of which could have a material adverse effect

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on our business. If the FDA determines we have failed to comply with applicable requirements under the FDCA or FPLA, it can impose a variety of enforcement actions from public warning letters, injunctions, consent decrees, and civil penalties to seizure of our products, total or partial shutdown of our production, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us. If the FTC determines we have failed to substantiate our claims, it can pursue a variety of actions including disgorgement of profits, injunction from further violative conduct, and consent decrees.

Orphan Drug Designation

We are seeking "Orphan Drug" designation in both the US and Europe for a product to treat a rare skin condition called Netherton syndrome. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a New Drug Application, or NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to seven years of orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity (superior efficacy, safety, or a major contribution to patient care). Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication. We have not received orphan drug status for any of our products.

Under European Union medicines laws, the criteria for designating a product as an "orphan medicine" are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of marketing exclusivity, except under certain limited circumstances comparable to United States law. During this period of marketing exclusivity, no "similar" product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

Domestic State and Local Government Regulation

Some states and local governments in the United States regulate the labeling, operation, sale, and distribution of our skin care products. To the extent additional state or local laws apply, we intend to comply with them.

Foreign Government Regulation

In general, we will need to comply with the government regulations of each individual country in which our products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. The level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for us. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. As a result it is possible that we may not be permitted to sell our products in foreign markets or expand our business into one or more foreign jurisdictions.

Environmental Laws

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

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Employees

We currently have four employees, including our sole officer Terry Howlett.

Subsidiaries

We conduct our operations through our wholly-owned subsidiaries, Skinvisible Pharmaceuticals, Inc. and Kintari USA Inc.

Item 2. Properties

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. We signed an addendum to our lease on November 9, 2015, which extends the term until February 28, 2017. Rent is $2,858 per month plus all applicable CAM charges.

Skinvisible Pharmaceuticals, Inc., our wholly-owned 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. Mine Safety Disclosures

Not Applicable

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PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is quoted under the symbol "SKVI" on the OTCQB operated by OTC Markets Group, Inc.

Only a limited market exists for our securities. There is no assurance that a regular trading market will develop, or if developed, that it will be sustained. Therefore, a shareholder may be unable to resell his securities in our company.

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 OTCQB. 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, 2015		
Quarter Ended	High $	Low $
December 31, 2015	0.042	0.023
September 30, 2015	0.049	0.015
June 30, 2015	0.052	0.025
March 31, 2015	0.06	0.038

Fiscal Year Ending December 31, 2014		
Quarter Ended	High $	Low $
December 31, 2014	0.09	0.035
September 30, 2014	0.0524	0.0337
June 30, 2014	0.045	0.0155
March 31, 2014	0.022	0.0135

On April 6 2016, the last sales price per share of our common stock on the OTCQB was $0.02.

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 standardized risk disclosure document prepared by the SEC, that: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation of such duties or other requirements of the securities laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and the significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form, including language, type size and format, as the SEC shall require by rule or regulation.

The broker-dealer also must provide, prior to effecting any transaction in a penny stock, the customer with (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) a monthly account statement showing the market value of each penny stock held in the customer's account.

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In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written de