Skinvisible, Inc.

Ticker: (OTCQB: SKVI)

Research Report

as of July 30th, 2024

Sector: Pharmaceutical
Industry: Drug Delivery
Website: Skinvisible.com

Speculative Buy:6 Month Target Range $2.00 - $3.00

Key Statistics

Source: Yahoo Finance

Price *7/30/2024*	.67
52 Week High	.75
52 Week Low	.05
Avg. Vol (*3 m*)	2,680
Market Cap *(Interday)M*	3.27
Price/Sales *(TTM)*	NA
Common Shares Outstanding *(M)*	4.89
Float*(M)*	4.36
EPS*(TTM)*	(.25)

COMPANY

Skinvisible, Inc. (SKVI:OTCQB) (the "Company" or "Skinvisible") is a pharmaceutical research and development company, incorporated in Nevada in 1998. Through its wholly owned subsidiary, Skinvisible Pharmaceuticals, Inc., the Company has developed and patented an innovative polymer skin delivery system known as Invisicare®. This technology enhances the delivery of active ingredients in transdermal and topically applied products. Skinvisible has formulated over forty topical skin products targeting the global skincare and dermatology market, over-the-counter market and other healthcare sectors, as well as a number of transdermal products targeting glucose-controlling conditions such as obesity and diabetes. The Company's business model focuses on out-licensing its patented products to established manufacturers and marketers worldwide, generating revenue through licensing fees and royalties.

Skinvisible's flagship technology, Invisicare®, offers significant advantages, including substantially releasing active ingredients both topically and transdermal, binds products to the skin, and it can improve efficacy, safety and consumer satisfaction. Recently, the Company entered new large medical markets outside of dermatology, beginning with obesity. Skinvisible's unique delivery system and patent-pending formulations to position the Company as a competitive player in the obesity market. With a focus on innovation and strategic partnerships, Skinvisible aims to monetize its investment in Invisicare® and expand its presence in the global market.

TECHNOLOGY/INTELLECTUAL PROPERTY

Skinvisible's main intellectual property is the flagship polymer delivery technology Invisicare®. Invisicare is a proprietary drug delivery which enhances the delivery of active ingredients in topical and transdermal products. This technology uses a combination of hydrophilic and hydrophobic polymers to create a complex that improves the release, stability, and binding of ingredients (finished formulas) to the skin. Invisicare® allows for sustained and controlled delivery, avoiding initial spikes and enhancing efficacy and safety. It is used in various formulations, including those for obesity, dermatology, and rare skin diseases. Transdermal delivery is achieved without the use of patches or needles. The technology has been proven to deliver active ingredients more effectively than other systems, with significant potential benefits for patient compliance and therapeutic outcomes.

Recent Highlights

- **7/11/24** The Company announced exciting data demonstrating its transdermal delivery of obesity drugs (and other glucose- controlling drugs) including a GLP-1 agonist and CB-1 receptor antagonist delivered by its proprietary Invisicare® technology; a polymer delivery vehicle that does not require a patch or needles.

- **6/24/24** Skinvisible, Inc., announced the filing of a second patent application for its groundbreaking Invisicare® technology and its transdermal delivery of obesity and glucose-controlling agents. This new application significantly broadens the scope of the Company's initial patent application.

- **5/29/24** The Company has achieved a significant milestone by officially filing a provisional patent application covering formulations that leverage the Company's proprietary delivery technology Invisicare® for the transdermal administration of obesity drugs.

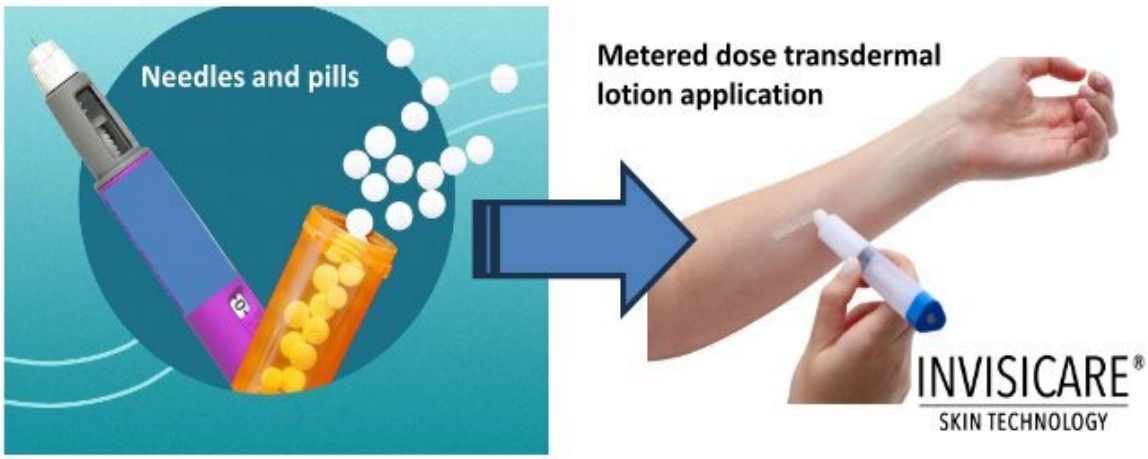
- **2/14/24** The Company is excited to share a promising update on the ongoing clinical trials conducted by its licensee, Quoin Pharmaceuticals, Inc. ("Quoin") (NASDAQ:QNRX). The trials focus on the innovative formulation "QRX003," powered by Skinvisible's Invisicare® proprietary drug delivery technology, to address the challenges of Netherton Syndrome ("NS").

The second use case is to release the active ingredient into the skin, which is used to treat skin diseases (for example, Quoin Pharmaceuticals Limited, a licensee of the Company, is currently in the final stages of FDA approval for a treatment for Netherton Syndrome; a rare genetic skin disease).

The third use case, and arguably the largest market; is the transdermal delivery of drugs through the skin into the blood stream, such as the Company's new formulations to treat obesity and diabetes. The Invisicare technology has proven successful in all three use cases.

There are currently 8 different families of the Invisicare® formulation that can be formulated with a variety of different active ingredients based on what the final product is trying to accomplish. Transdermal delivery is the new direction for the Company's developments, the benefits of which are many. With oral delivery (pills), there are often side effects associated with digestion, such as bloating, nausea, or diarrhea. The "first-pass" through the liver with an oral medication also substantially reduces the bioavailability of the drug being delivered.

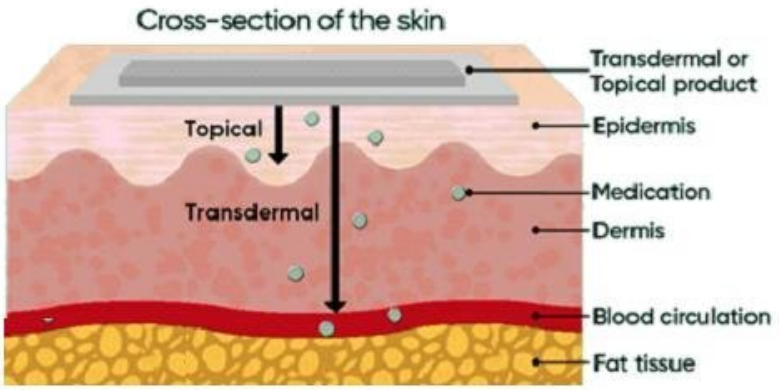
Another delivery method is through injections. Injections are uncomfortable and reduce patient compliance, and also sometimes introduce injection site complications. In comparison, Skinvisible's transdermal delivery avoids first-pass, delivering the drug directly into the bloodstream and thereby potentially reducing or eliminating the side-effects of oral delivery. There are no needles or patches; Skinvisible's formulations are applied via a metered dose applicator of the lotion to the skin. Skinvisible is also able to accomplish a sustained even release over time, avoiding the initial spike of the active agent after a patient takes medication.



The Company has over 20 patents for different uses of the technology that it can leverage to generate revenue. Most prominent are the two patent applications submitted in Q2 of this year for the treatment of obesity and glucose-controlling actives. Other product patents include acne (US Patent 9,149,490), cationic (US Patent 8,735,422), and sunscreen (US Patent 8,128,913). Each composition is comprised of an active medical ingredient (ex. Obesity drug, acne medicine or sun protection) and with a skin binding polymer component.

STRATEGY

In May of 2024, Skinvisible broke into the global obesity treatment market by filing a provisional patent application for a transdermal obesity medication delivery method. This was followed by a second provisional expanded patent application in June of 2024 encompassing all key glucose-controlling agents and conditions.



Advantages of transdermal obesity treatment include avoiding the gastrointestinal tract and liver, potentially reducing side effects by avoiding first-pass, optimizing the amount of active ingredient reaching systemic circulation and increasing patient compliance due to the absence of needles and pills. Skinvisible's transdermal formulations aim to improve therapeutic outcomes and enhance patient adherence, emphasizing ease of application and potential benefits in therapeutic effectiveness, reduces side-effects and manufacturing efficiency. **In addition, transdermal applications could also be suitable for maintenance dosing**, where another product using Invisicare® would be introduced after the main treatment has undergone completion just to maintain long term results for the patient, which would introduce additional recurring revenues.

The global obesity treatment market is extremely large and growing, with many pharmaceutical and biotech companies trying to develop treatments and medications. Skinvisible could serve as the platform that provides the drug delivery method through licensing or even through an acquisition by a company in the space.

The management is currently committed to developing relationships and licensing its obesity treatment and is confident that the Company's new patent will open up doors, with the potential to earn very large licensing fees.

LICENSEE

Up until recently, Skinvisible's focus has been the skin care and dermatology market, with over 30 dermatology products developed. The management is intensifying its efforts to increase licensing opportunities for the Company's intellectual property and patented prescription and over-the-counter products.

The most noteworthy licensing agreement currently in place is with Quoin Pharmaceuticals, Limited (NASDAQ: QNRX) for a series of rare skin diseases with an initial focus of Netherton syndrome, a rare genetic disorder, affecting the skin, hair, and immune system from birth, causing symptoms like red, scaly skin, fragile hair, and immune reactions such as eczema and asthma.

Skinvisible engaged in an Exclusive License Agreement with Quoin on October 17, 2019. This agreement granted Quoin rights to certain products. In return, Quoin paid Skinvisible a $1 million upfront license fee. **Additionally, Quoin is committed to making a milestone payment of $5 million upon achieving FDA regulatory approval which is targeted to be completed in 2025**. Skinvisible will also receive a single-digit royalty percentage on sales following US or EU approval, whichever comes first, and 25% of sublicensing royalty revenues. The product is already sub-licensed in 60 countries.

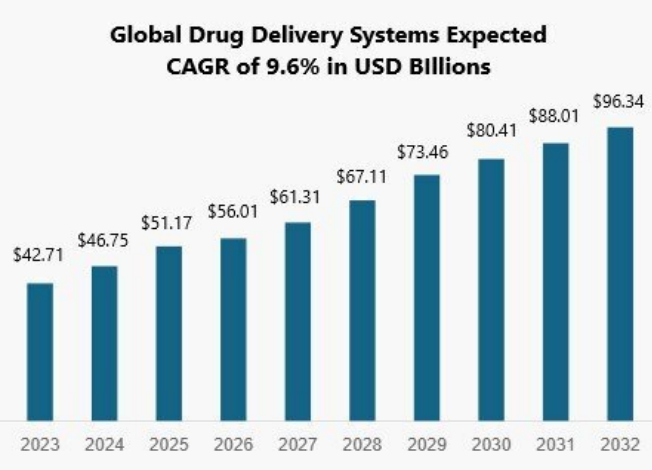
On February 4th, 2024, Skinvisible, Inc. reported significant advancements in the clinical trials conducted by its licensee, Quoin Pharmaceuticals, Inc., focusing on the Invisicare® based formulation QRX003 for Netherton Syndrome. QRX003 is a topical lotion utilizing Invisicare® and, includes a broad-spectrum serine protease inhibitor. It works by mimicking the function of the protein LEKTI, aimed at reducing excessive skin shedding seen in Netherton syndrome patients while enhancing the integrity of the weakened skin barrier. The trials, operating under an open Investigational New Drug application, have shown positive initial data and a favorable safety profile, prompting an optimization plan that includes expanding trial sizes and adjusting dosing frequency. Protocol amendments aim to enhance data quality and potentially expedite regulatory approvals. Quoin anticipates these changes will bolster QRX003's path to becoming the first approved treatment for this condition.

QRX003 is a topical lotion utilizing the Invisicare® based formulation for Netherton Syndrome

In summary, Skinvisible is aggressively pursuing a partnership or licensee in the obesity treatment market with its new patent, while simultaneously continuing to monetize its large, accumulated depository of intellectual property in the dermatology space. The license agreement with Quoin Pharmaceuticals, Inc. is anticipated to yield a $5 million fee in 2025 and a lucrative source of royalty revenues upon FDA approval.

MARKET

According to a July 1st, 2024, report by Fortune Business Insights, the global drug delivery systems market size was valued at $42.71 billion in 2023 and is expected to grow at a CAGR of 9.6% reaching $96.34 billion by 2032 from $46.23 billion in 2024. One of the key growth factors identified in the report is strategic collaborations and development and introduction of new products. New technologies with improved safety and user-friendly features are expected to fuel the industry's growth. Other growth factors include a surging prevalence of chronic diseases and rising awareness and adoption of advanced delivery systems.



OBESITY SECTOR

According to a May 7th, 2024, article, **Morgan Stanley research is now expecting the global market size for obesity drugs to reach $105 billion by 2030, constituting a 15-fold increase from $6 billion in 2023**. Obesity drugs are a disruptor on a scale rarely matched in the pharmaceutical industry. Growing evidence of improved outcomes of these drugs fuel the demand, and continuous investment by drugmakers into supply chains allows the companies to keep up with the demand. Obesity drugs could have a ripple effect through a large portion of the healthcare sector as obesity is responsible for the majority of diabetes cases and can be linked to more than 200 other chronic diseases. Morgan Stanley estimates that as much as 9% of the U.S. population could be taking obesity drugs by 2035. Goldman Sachs Research also forecasts that the global anti-obesity medications market could reach $100 billion by 2030, citing similar factors fueling the growth.

The booming market has led to big rallies for the stocks of leading obesity drug manufacturers, most notably **Novo Nordisk A/S (NVO:NYSE)** ($581 billion market cap), the producer of Ozempic and Wegovy, and **Eli Lilly and Company (LLY:NYSE)** ($774 billion market cap), the producer of Mounjaro and Zepbound. The success of its obesity drugs made Novo Nordisk the most valuable company in Europe. Novo underwent a significant reorganization of its research division in 2018 after years of slow innovation and overreliance on insulin sales, and emerged as one of the dominant stock market success stories of the 2020s. The shares rose by over 220% since the FDA approval of Wegovy for chronic weight management in June of 2021. Eli Lilly's Zepbound received FDA approval for obesity treatment in November of 2023. Eli Lilly's shares rose by almost 90% in the past 12 months.

The hot obesity market is attracting the attention of investors and other pharmaceutical companies. This launched a series of acquisitions, both from large pharmaceutical companies attempting to enter the market with their own drugs, as well as established players like Novo Nordisk and Eli Lilly attempting to secure their leadership position. The lucrative industry led to exceptionally large valuations. In July of 2023, Eli Lilly signed a deal to acquire Versanis, a private clinical-stage biopharmaceutical company, for up to $1.93 billion (comprised of an upfront payment and additional payments upon achievement of certain milestones). Versanis's lead asset, bimagrub, has the potential to further reduce fat mass while preserving muscle mass and may lead to better outcomes for obesity patients. In August of 2023, Novo Nordisk acquired Inversago Pharma for up to $1.075 billion, aiming to enhance its clinical development pipeline in obesity and related disorders.

The acquisition includes Inversago's lead asset, INV-202, an oral CB1 inverse agonist currently in phase 2 trials for diabetic kidney disease, with potential applications in obesity treatment. Swiss pharmaceutical giant **F. Hoffmann-La Roche AG (known as Roche) (ROG.SW)** (220 CHF billion market cap) acquired obesity drug developer Carmot Therapeutics for $2.7 billion in December of 2023, aiming to compete with leading weight-loss drug makers Novo Nordisk and Eli Lilly. At the time of the deal announcement, Carmot's promising drug candidate, CT-388, a dual GLP-1/GIP receptor agonist, was set to enter Phase II trials after encouraging initial results.

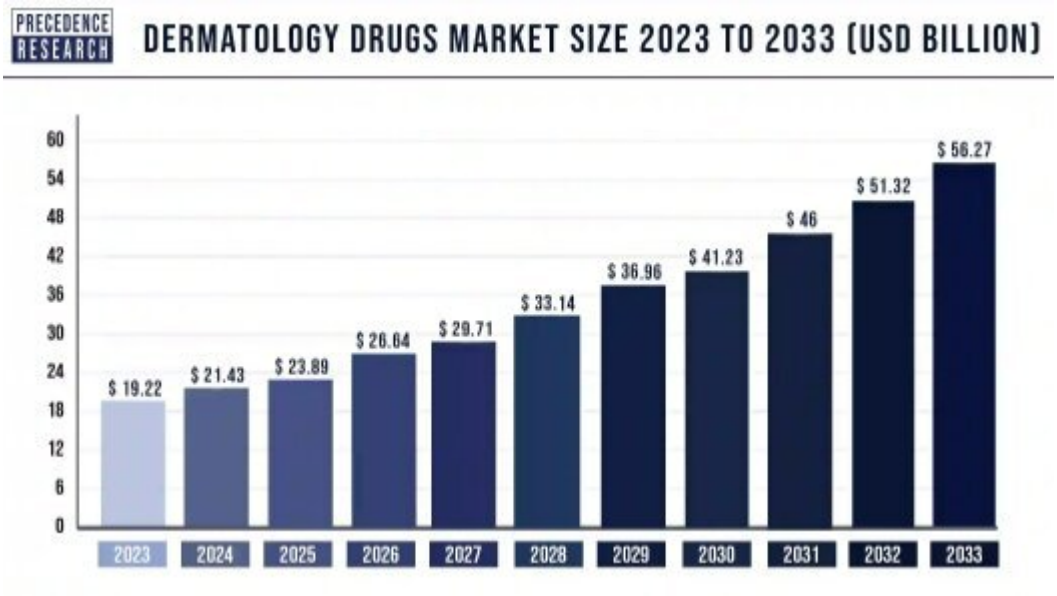
In June of 2024, **Pfizer (PFE:NYSE)** ($170 billion market cap) partnered with Flagship Pioneering's ProFound Therapeutics to develop new obesity drugs, marking its first public move to gain external resources in the competitive obesity market. The collaboration aims to leverage ProFound's platform to discover novel proteins for therapeutics, with Pfizer advancing the research programs.

In early May, major drug company **Amgen Inc. (AMGN:NASDAQ)** ($180 billion market cap) announced that they were entering the obesity market. Following the announcement Amgen's market capitalization swelled by $20 billion, a surge that reflects intense investor interest in emerging weight loss medicines. **Viking Therapeutics, Inc. (VKTX:NASDAQ)** ($7.13 billion market cap) announced in late July 2024 that it is advancing its experimental weight loss injection, VK2735, into a phase three trial earlier than expected, potentially launching the drug by 2029. The injection, which targets GLP-1 and GIP hormones, showed promising results in a phase two trial, with patients losing up to 14.7% of their body weight. The stock jumped nearly 30% following the announcement.

As evidenced by the deal activity, big pharma is willing to pay high premiums for pharmaceutical research companies in the obesity space, Skinvisible is aggressively pursuing a licensee for its obesity formulations. The most common obesity drugs currently in the market are delivered either by injection or orally and have many side effects. For example, common Ozempic side effects may include nausea, diarrhea, stomach (abdominal) pain, vomiting, and constipation. By avoiding the first pass, Skinvisible is able to dramatically reduce or eliminate many of the complications associated with injections or oral delivery. As the market becomes more and more inundated with obesity products, product differentiation increases in importance. By providing a transdermal delivery solution, **Skinvisible's technology could be very valuable for the pharmaceutical or biotech companies attempting to gain market share in obesity treatment.**

DERMATOLOGY MARKET

According to a March 2024 report by Precedence Research, the global dermatology drugs market was valued at $19.22 billion in 2023, and is projected to reach $56.27 billion by 2033, growing at a CAGR of 11.32% during the forecast period. Skinvisible could leverage its product experience in areas like sunscreen to secure new licensing deals. Some of the big sunscreen brands include Neutrogena, owned by **Johnson & Johnson (JNJ: NYSE)** ($376 billion market cap), Coppertone, owned by **Beiersdorf (BEI.DE)** (30.7 EUR billion market cap), and CeraVe, owned by **L'Oréal (OR: Euronext Paris)** (213 EUR billion market cap).



MARKET SUMMARY

Skinvisible operates in large, rapidly expanding markets, with the obesity sector presenting a particularly compelling opportunity. For investors, Skinvisible's position offers multiple avenues for potential returns: substantial revenue growth from market expansion, an innovation premium for addressing a critical health issue, increased M&A potential given the sector's attractiveness, and portfolio diversification into a resilient healthcare subsector. The obesity market's characteristics of rapid growth, heightened investor focus, and potential for premium pricing align well with Skinvisible's strategic focus and technological capabilities, potentially offering stakeholders a unique opportunity to capitalize on this lucrative sector.

MANAGEMENT

Terry Howlett - President & Chief Executive Officer

Mr. Howlett founded Skinvisible in 1998 and has served as the President and Chief Executive Officer since. He has over 35 years of experience in emerging growth companies, especially in financing new ventures, market initialization, and business management. His other experience includes being President and Co-Founder of Ovation Science Inc. (CSE: OVAT), a topical and transdermal CBD/cannabis products company, and founding Presley Laboratories, direct sales cosmetic and skin care products company. Mr. Howlett is adept at strategic planning and business growth, especially in the context of emerging and publicly traded start-up companies.

David St. James - Director

Mr. David St. James, an inventor and businessman from Las Vegas, Nevada, has made significant contributions to the automotive industry, including the invention of turbochargers and superchargers used in production vehicles and Formula 1. He has also worked in product development, service, and repair. Since July 2014, he has been the President and a Director of Homeland Resources Ltd., and since August 2014, the Vice President and a Director of Nouveau Ventures Inc. Previously, he served as the President of XLR Medical Corporation from January 2009 to January 2012.

James A. Roszell - Ph.D, Chemist

Dr. James Roszell, a chemist with over 35 years of experience, has been with Skinvisible since 1998, focusing on research and development of their patented technology and polymer delivery systems. He obtained his PH.D. in chemistry from The University of Memphis. Since then, he has authored multiple patents for Skinvisible. Before Skinvisible, Dr. Roszell was a research chemist in the Cancer Research Laboratory in the V.A. Hospital in Memphis, TN. and a research chemist in the Respiratory Carcinogenesis Program at the V.A. Hospital, Tampa, FL. Dr. Roszell has been the Director of Research and Development for, Supertech Products and Biochemical Industries where he ensured regulatory compliance and quality control. His extensive background spans chemical, pharmaceutical, environmental, and clinical laboratories, making his expertise crucial to Skinvisible's innovations.

Doreen McMorran - Vice President, Business Development

Ms. McMorran has extensive experience in the medical and pharmaceutical sectors, specializing in strategic planning, sales, and marketing. She has worked with international dermatology and skincare companies such as Procter & Gamble, Johnson & Johnson, and Novartis. She holds a Bachelor of Commerce (Honours) degree from the University of Manitoba and Certified Business Strategist from the University of British Columbia. Previously she spent six years at Astra Pharma. Additionally, she has held senior management roles in various healthcare companies, focusing on business development, sales, marketing, and operations including Co-Founder of Ovation Science Inc. (CSE: OVAT), a topical and transdermal CBD/cannabis products company.

FINANCIALS

For the three months ended March 31, 2024, the Company reported revenues of $5,000 and a net loss of $290,372, or $0.06 per share, consisting of $123,489 in selling general and administrative expenses, $166,408 in interest expenses, and other smaller expenses including depreciation and amortization, and loss on change in derivative liability. Total net cash used in operating activities for the three months ended March 31, 2024, was $12,291. The Company generated $22,500 through proceeds on convertible notes payable.

For the year ended December 31, 2023, Skinvisible reported an operating loss $490,375 and a net loss of $2,382,440. The Company generated $20,000 in revenues, primarily as a result of licensing fees, generating a 100% gross profit margin in 2023 and 98% gross profit margin in 2022. This is due to the licensing nature of the business model and a limited number of employees (currently 3, including management).Skinvisible, Inc.‘s balance sheet as of March 31, 2024, shows the Company has total assets of $153,403, which include $30,689 in current assets and $122,714 in patents and trademarks. This does not include the potential new obesity / glucose-controlling patent. Liabilities outweigh the assets, with total liabilities amounting to $9,466,818. These include current liabilities such as accounts payable and accrued liabilities totaling $532,888, accrued interest payable amounting to $2,729,328, loans from related parties totaling $3,000, loans payable of $433,600, convertible notes payable totaling $376,275, and a derivative liability of $19,324.

Additionally, there are convertible notes payable consisting of $40,000 face value 9% secured notes and $22,500 face value 10% secured notes, both offering conversion options. On January 31, 2023, the Company restructured accrued salaries, vacation, and convertible notes for its two officers. The total outstanding notes of $4,220,209, accrued salaries of $1,062,000, and accrued vacation of $90,193 were converted into unsecured convertible promissory notes. These notes, due in five years with a 10% interest rate, can be converted into common stock at $0.10 per share, with warrants to purchase one share for every two shares issued at $0.15 per share for three years

As of March 31, 2024, and December 31, 2023, the note balance remained $5,372,402. If the conversion rights are exercised in the future the company's shareholder deficit would significantly decrease. Secured debt includes $433,600 in 9% notes payable secured by US Patent rights granted for the Company's Sunscreen Products: US patent number #8,128,913, currently past due and in default (the secured debt holders do not have a claim on any of the other Skinvisible intellectual property). The investors have not made any claims against the company regarding the secured debt. The stockholders' deficit stands at $9,313,415, reflecting an accumulated deficit of $39,670,860. The Company has been operating at a loss for an extended period, raising concerns about its ability to continue as a going concern without securing additional funding or achieving profitable operations. However, the company's burn rate remains manageable and there is a plan to raise additional capital in the near term.

The Company is navigating a transitional phase, with strategic developments positioning it for future growth. While current operations have resulted in on-going losses, the Company maintains a prudent approach to cash management, keeping expenses well-controlled. Additionally, the Company has developed a strategic plan to address its financial situation, including a near-term initiative to raise capital. While challenges remain, these proactive steps suggest the Company is actively working towards improving its financial position and long-term viability.

The management is highly optimistic that the licensee Quion will receive FDA regulatory approval in 2025, which will result in a $5 million payment to Skinvisible and a royalty revenue stream. This payment would immediately significantly improve the Company's balance sheet, and the approval would start a potentially lucrative future revenue stream. Furthermore, the hot deal market in obesity could help Skinvisible secure a highly lucrative contract for the Company's obesity formulations possibly by Q4 2024.

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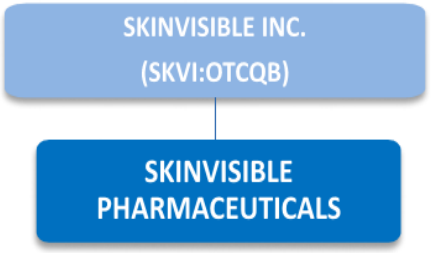

SUMMARY AND OUTLOOK

Due to the large monetary potential, Skinvisible's primary focus is the continued successful development of its obesity formulations, patent applications and securing a partnership or licensee for these obesity formulations. The management is reaching out to major pharmaceutical and biotech companies that are either currently in the obesity treatment space or want to break into the market with a new differentiated product.

Any potential license deal with a major pharmaceutical company would be worth many millions of dollars upfront with additional ongoing royalties based on a successful outcome.

The Company plans to raise interim capital in the near term for its working capital needs. It also anticipates the $5 million milestone payment from Quion in 2025 to reduce its debt and continue with its developments in other lucrative markets. **Given the huge potential of the Company's intellectual property in the obesity market and the obesity's market size, rate of expansion, and the anticipated milestone payments, the Company's shares appear to be very attractive for speculative and risk-oriented investors.**

Corporate Contact Information

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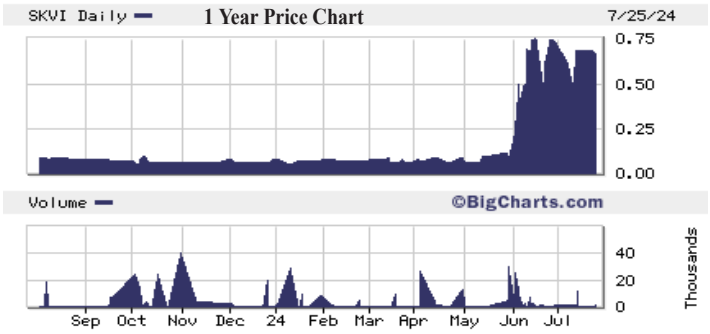

All figures below are quoted in US Dollars and in Thousands

Income Statement	FY 12/31/22	FY 12/31/23	3M 3/31/24
Revenue	$ 279	20	5
Gross Profit	$ 274	20	5
Oper Loss/income	$ (238)	(490)	(123)
Net Loss/Income	$ (1,225)	(2,382)	(290)

Balance Sheet	FY 12/31/22	FY 12/31/23	3M 3/31/24
Current Assets	$ 109	35	31
Total Assets	$ 247	163	153
Total Liabilities	$ 6,887	9,186	9,467
Total Shareholder's Deficit	$ (6,641)	(9,023)	(9,313)

Cash Flow Statement	FY 12/31/22	FY 12/31/23	3M 3/31/24
Operating Cash Flow	45	(77)	(12)
Investing Cash Flow	(3)	(9)	0
Financing Cash Flow	(27)	6	20
Cash at end of period	81	1	8

Analysts whose efforts contributed to this report.

Alan Stone BS, MBA, Managing Director and CEO, WallStreet Research™. Alan has been active in the investment management and securities industry for over 40 years. He was a top analyst and fund manager at leading investment firms on Wall Street including Prudential Capital, Merril Lynch Asset Management, and Ladenburg Thalmann before acquiring WallStreet Research™. Alan holds a BS degree in Economics and Finance from the University of Pennsylvania's Wharton School and an MBA in Finance and Investments from New York University's Graduate School of Business, and has completed advanced studies at the London School of Economics and UCLA.

Marcus Lecky, BS Finance from Florida International University, Miami. Marcus has been an Associate Analyst with Wallstreet Research for 4 years.

Mark L Vega, CTO. Mark gained his experience in the investment community working as a technical advisor to investment bankers, brokers and traders. Prior to working with WallStreet Research, Mr. Vega served as the CTO responsible for the overall technical advancement of several publicly traded companies in the energy, telecom, video and advertising sectors.

ADDITIONAL DISCLOSURES

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