July 17, 2024

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Steven Ralston, CFA
312-265-9426
sralston@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Medicus Pharma Ltd. (V.MDCX – TSX.V)

V.MDCX: Medicus Submits Updated Phase 2 Clinical Protocol. Successful Non-Brokered Private Placements of Common Shares and Convertible Notes Provide Ample Capital For Funding Phase 2 Clinical Trial.

Utilizing a financial model based on DCF methodology that uses a 10% discount rate and a terminal P/S multiple of 3.12 (based on comparable Specialty Drug Manufacturers), the indicated value of MDCX.V is **$5.35 per share**.

Financials & stock prices in $CDN unless noted otherwise.

Current Price (07/16/24)	$2.20
Valuation	**$5.35**

OUTLOOK

Medicus Pharma Ltd. (TSXV:MDCX) is focused on acquiring or partnering with life-science companies that are developing **novel therapeutics for unmet healthcare needs** that are already **in the clinical trial stage**. Management plans fast-track these specific therapies through FDA clinical trials toward commercialization.

The company's first acquisition was **SkinJect**, which has a novel, patented transdermal patch for the treatment of BCC. In early January 2024, the protocol for a Phase 2 study was submitted to the FDA for approval; comments were received in mid-February. A **complete reply was submitted in July**.

SUMMARY DATA

52-Week High	**$3.05**
52-Week Low	**$0.31**
One-Year Return (%)	**N/A**
Beta	**N/M**
Average Daily Volume (shrs.)	**4,865**
Shares Outstanding (million)	**21.69**
Market Capitalization (C$mil.)	**$47.73**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18.4**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/M**
P/E using 2024 Estimate	**N/M**
P/E using 2025 Estimate	**N/M**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Biotechnology-Drug**

ZACKS ESTIMATES

Revenue
(in millions of $CDN)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2022	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2023	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2024	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	N/M A	N/M A	N/M A	N/M A	N/M A
2022	-$0.14 A	-$0.12 A	-$0.10 A	-$0.12 A	-$0.45 A
2023	-$0.13 A	-$0.14 A	-$0.40 A	-$0.34 A	-$0.93 A
2024	-$0.11 A	-$0.11 E	-$0.08 E	-$0.08 E	-$0.38 E

Quarterly EPS may not equal annual EPS due to rounding or dilution.

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

EXECUTIVE SUMMARY

- **Medicus Pharma Ltd.** (TSXV: MDCX) is a **holding company specializing in the acquisition** life-science / biotechnology companies that are advancing novel therapies through clinical trials toward commercialization.

- Medicus Pharma completed its **first acquisition**, **SkinJect**, **Inc**., in September 2023. SkinJect holds an exclusive license to a **Dissolvable Microneedle Array drug delivery system** for basal cell carcinoma (BCC)

    - In the last SEVEN (7) months, **Medicus has significantly accelerated the** r**egulatory process for the SkinJect transdermal patch for the treatment of BCC.**

        1) In the first week of January 2024, the **protocol** for **a Phase 2 clinical study** was **submitted to the FDA** for review.

        2) In mid-February 2024, Medicus **published an abbreviated clinical study report on the SKNJCT-001 Phase 1 safety and tolerability study**, which concluded in May 2021.

        3) On March 21, 2024, Medicus Pharma **received clinical non-hold comments from the FDA**, which requested additional data to support the protocol's dosing arms and specifically the data related to dose-limiting toxicities.

        4) On July 15, 2024, Medicus Pharma announced that **a full package of information was submitted to the FDA to support the approval to conduct the Phase 2 (SKNJCT-003) clinical trial**

- Through **Private Placements of Convertible Notes and Common Shares** between May and July 2024, along with the subsequent conversion of the Convertible Notes to Common Shares, **Medicus raised over US$10 million** to **help fund research& development programs**, along with bolstering working capital. As a result, shares outstanding increased **34.3%** to **21,693,560 shares.**

- Company representatives are attending conferences to advance the awareness of the Medicus Pharma's novel non-invasive therapeutic treatment for BCC skin cancer.

    - UAE Healthcare and Life Sciences Mission (5/13-17/2024) in Dubai
    - NIDI Skin Spring Symposium (5/24-25/2024) in New York City

- The company was **listed on the TSX Venture Exchange**, and **began trading on October 11, 2023**. Subsequently, the company's common shares were listed on the Frankfurt Stock Exchange under the ticker symbol N46.

- On January 25, 2024, Medicus Pharma **filed a short-form shelf prospectus** allowing the company to offer (from time to time) up to US$50,000,000 in securities (common shares, preferred shares, warrants, debt, Units etc.) in Canada over a period of 25 months.

- On May 29, 2024, Medicus Pharma filed Form F-1 (registration statement) with the SEC relating to its proposed IPO in the United States.

- Medicus Pharma presents the opportunity to participate in the development of relatively advanced novel therapies that already have completed a clinical trial.

RECENT DEVELOPMENTS

Updated Phase 2 Clinical Protocol Submitted to FDA

On July 15, 2024, Medicus Pharma announced that **a full package of information was submitted to the FDA to support the approval for conducting a Phase 2 clinical trial (SKNJCT-003)** on the company's non-invasive treatment of basal cell carcinoma (BCC) of the skin that utilizes micro-needle arrays which contain doxorubicin. **The full package includes**:

- an **updated clinical protocol**, which now includes artificial intelligence (AI) powered software and confocal microscopy as supplementary endpoints in order to improve the assessment accuracy of the clinical study
- **supporting CMC** (Chemistry, Manufacturing and Controls) that establishes physicochemical properties and provides stability & sterility data such that the process to properly scale up the manufacturing process is relatively assured
- the **requested responses** to the non-hold comments received from the FDA in March 2024
    - the **safety data** from the Phase I safety and tolerability clinical study (SKNJCT-001) in order **to support the dosing of 100µg and 200µg** of doxorubicin hydrochloride in the microneedle array (D-MNA)
    - an **updated investigator brochure** that includes safety information from the SKNJCT-001 and SKNJCT-002 clinical studies, along with **data at each dose level** was specifically requested concerning **any adverse events** that would relate to any dose-limiting toxicities.

The full comprehensive package of information was submitted in order to support an accelerated timeline of the FDA's approval process so that the company is able to commence randomizing participants as quickly as prudently possible, potentially in the third quarter of 2024.

Private Placement of Common Shares

On July 5, 2024, Medicus Pharma announced the completion of a non-brokered **private placement of 2,922,500 common shares** issued at US$2.00 per share. **Gross proceeds were US$5,845,000**. Net proceeds were released from escrow on July 5, 2024. The net proceeds will help fund research and development programs, along with bolstering working capital.

Private Placement and Conversion of Convertible Notes

On May 3, 2024, Medicus Pharma completed a **private placement of US$5,172,500 of 10.00% Unsecured Convertible Notes** due December 31, 2025. Prior to January 1, 2025, the Notes are to be automatically converted into common shares upon completion of an IPO (initial public offering) in the United States, which occurred as of June 28, 2024. **All the Convertible Notes were converted into an aggregate of 2,586,250 shares** (US$2.00 per share). In addition, an aggregate of **31,345 shares were also issued in respect of accrued and unpaid interest** to Note holders who did not elect to receive cash interest. Approximately US$41,000 was paid in accrued and unpaid interest to holders of Notes who elected to receive cash interest.

Significant Equity Holder

215 Capital Togo PHL Fund I, LP (of Philadelphia, PA) beneficially **owns 4.0 million shares of Medicus Pharma** Ltd, **approximately 18.4% of the company's shares outstanding**. The shares were acquired pursuant to the equity and convertible note private placements. 215 Capital's cost is roughly US$8.0 million (or CDN$10,949,600 at a USD/CAD exchange rate of 1.3687).

Recent Financial Filings

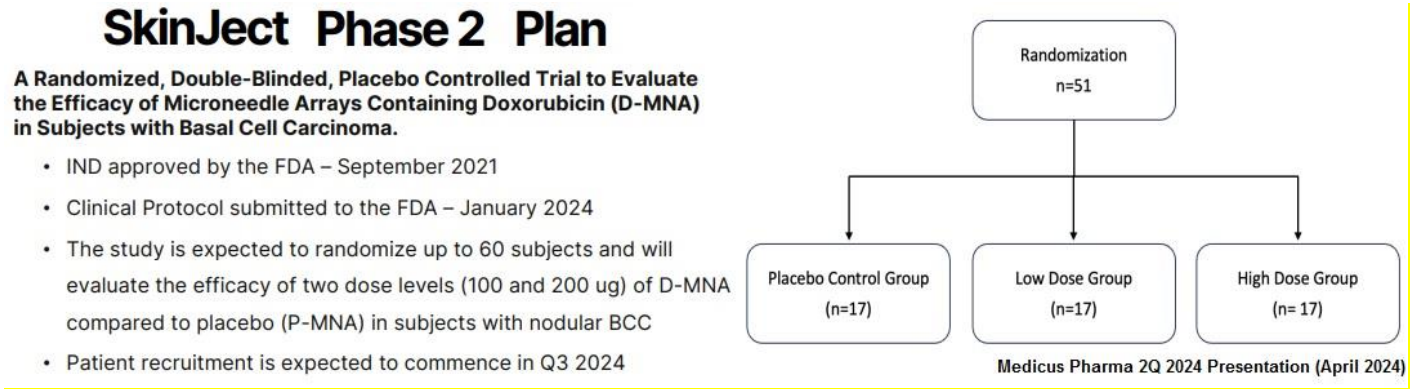
On April 30, 2024, Medicus Pharma filed audited Consolidated **Annual Financial Statements** for the year ending December 31, 2023, long with a Management's Discussion and Analysis (**MDA**), which are available on SEDAR+.

Then, on May 30, 2024, Medicus Pharma Ltd filed Consolidated Quarterly Financial Statements and the MDA for the **first quarter of 2024** ending March 31, 2024.

UPCOMING PHASE 2 CLINICAL TRIAL of SkinJect PATCH

In its effort to **fast track the clinical development program** for the **SkinJect D-MNA patch**, in the first week of January 2024, Medicus Pharma submitted a clinical protocol (**SKNJCT-003**) to the FDA for a Phase 2 clinical trial on its non-invasive treatment of **nodular BCC** of the skin. In July 2024, an **updated clinical protocol** was submitted to the FDA, which included artificial intelligence (AI) powered software and confocal microscopy as supplementary endpoints in order to improve the assessment accuracy of the clinical study

The proposed protocol is a randomized, double-blinded, placebo-controlled clinical study. **Up to 60 patients with nodular BCC** of the skin are planned to be enrolled, and the efficacy of two dose levels (**100µg** and **200µg** of doxorubicin hydrochloride) will be evaluated compared to the placebo control group (three groups in total). The participants will be randomly and equally placed in one of three groups: the placebo-controlled group, a low-dose group (100µg) and a high-dose group (200µg). The SKNJCT-003 protocol follows the FDA guidelines for fast-tracking the approval process.



The **FDA commented on protocol around March 20th**, with **requests for additional data** to support the protocol's dosing arms and specifically the data related to dose-limiting toxicities. These non-hold comments did not contain any clinical comments (such as suggested revisions or amendments related to the proposed protocol). Nor did the comments include a deadline.
In order to maintain the new, higher level of momentum in the regulatory process, **management submitted a full submission**, which **provided the information/data requested** by the FDA, **AND**

also contained stability data concerning CMC (Chemistry, Manufacturing and Controls) of the product that is being manufactured for the Phase 2 trial.

FIRST HALF 2024 TIMELINE FOR PHASE 2 CLINICAL TRIAL of SkinJect PATCH

On January 3, 2024, Medicus Pharma announced that the company had **submitted** its **Phase 2 IND clinical protocol to the U.S. FDA** for the non-invasive treatment of BCC of the skin. The proposed protocol (**SKNJCT-003**) is a randomized, double-blinded, placebo-controlled clinical study. Up to 60 patients with nodular BCC of the skin will be enrolled, and the efficacy of two dose levels (100µg and 200µg of doxorubicin hydrochloride) will be evaluated compared to the placebo control group. The participants will be randomly and equally placed in one of three groups: the placebo-controlled group, a low-dose group (100µg) and a high-dose group (200µg).

On January 25, 2024, Medicus Pharma filed a **short-form shelf prospectus in Canada** which allows the company to offer (from time to time) up to US$50,000,000 in securities (common shares, preferred shares, warrants, debt, Units etc.) over a 25-month period. The filing of a shelf prospectus is a common method to raise capital for public companies from large-cap to micro-cap in order to maintain financial flexibility.

In mid-February 2024, the company **published an abbreviated clinical study report for the Phase I safety and tolerability study** (SKNJCT-001 aka NCT03646188), which studied 13 participants across five dose levels (25 µg, 50 µg, 100 µg, 200 µg and placebo). The micro-array needles containing doxorubicin (D-MNA) was found to be **safe and well-tolerated across all dose levels**. There were not any dose-limiting toxicities (DLTs) or serious adverse events (SAE). Two (2) participants reported pain at the application site, which were classified as Other Adverse Events. The **maximum tolerated dose was at 200 ug**, the highest dose which was administered in the study to one (1) participant. The six participants demonstrating complete responses exhibited nodular subtype of BCC.

The study also described the **efficacy of D-MNA** with **six participants, all with nodular BCC, experiencing complete responses** (disappearance of BCC at the last study visit). The application of the microneedle array on the other seven (7) patients did not adequately penetrate the skin, and therefore, only mild dissolution was achieved.

The clinical study report is available at: https://clinicaltrials.gov/study/NCT03646188?tab=results.

On March 21, 2024, Medicus Pharma **received clinical non-hold comments from the FDA**, which included two requests:

1) the **data** from the Phase I clinical study (SKNJCT-001) in order **to support the dosing of 100µg and 200µg** of doxorubicin hydrochloride in the microneedle array and

2) an **updated investigator brochure** that includes information from the SKNJCT-001 and SKNJCT-002 clinical studies, along with **data at each dose level** was specifically requested concerning **any adverse events** that would relate to any dose-limiting toxicities.

OVERVIEW

Medicus Pharma Ltd. (TSXV:MDCX) is a **holding company in the healthcare sector** focused on acquiring or partnering with life-science / biotechnology companies, and then advancing specific therapies through FDA-approved clinical trials toward commercialization. Prospective target companies are being identified by the Directors and management through a collaborative process that **seeks out novel pharmaceutical compounds, treatments and/or delivery systems** that already have progressed to the clinical stage.

Management is agnostic to the particular healthcare field that the therapeutic medical treatment addresses, but rather concentrates on the level of innovation and the degree to which the therapy has been de-risked through the clinical study process. The company accelerates the advancement of these prospective therapies through higher level clinical trials. On an ongoing basis, the Directors and management actively explore for additional candidates in order to expand the company's therapy development pipeline.



SkinJect

The first company under the Medicus Pharma holding company umbrella is **SkinJect**, which holds an exclusive license to a patented **drug delivery system** (a patch with dissolvable microneedle arrays capable of delivering **chemotherapeutic agents**) that is being advanced **for the treatment** of cancers. Currently, the microneedle arrays (MNAs) are infused with **doxorubicin**, and these arrays will noninvasively deliver the agent in the vicinity of the basal cell layer. The initial target of the clinical studies is the most common form of skin cancer, **basal cell carcinoma**.

SkinJect, now a wholly-owned subsidiary of Medicus Pharma, was acquired through a Business Combination (via a reverse takeover transaction) that closed on September 29, 2023. A concurrent private placement of subscription receipts provided Medicus Pharma with approximately US$5.1 million in gross proceeds, which is principally earmarked for R&D, professional fees and corporate expenses.

In October 2018, Investigational New Drug (**IND**) application **122448** was submitted to the FDA, which approved a Phase I study of the SkinJect patch for the treatment of basal cell carcinoma through a Study May Proceed letter issued in November 2018. A 13-patient **Phase I safety and tolerability study was completed in May 2021**, which demonstrated that the SkinJect patch is safe and well-tolerated.

On September 29, 2023, the **Business Combination** between Medicus Pharma (f/k/a Interactive Capital Partners Corp.) and SkinJect, Inc. **closed**. A **concurrent private placement** of subscription

receipts provided approximately **US$5.1 million in gross proceeds**, which is principally earmarked for R&D, professional fees and corporate expenses.

On October 12, 2023, Medicus Pharma Ltd. incorporated a subsidiary, Medicus Pharma Inc., in the state of Delaware.

Medicus Pharma Listed on the TSX Venture Exchange

Medicus Pharma Ltd. was listed on the TSX Venture Exchange, and began trading on October 11, 2023. The final non-offering prospectus was filed on SEDAR on October 11, 2023.

The listing on the TSX-V represented a significant milestone for the company by adding liquidity, financing opportunities and investor awareness of management's mission to advance innovative medical therapies through the FDA approval process.

Medicus Pharma Listed on the Frankfurt Stock Exchange

On January 18, 2024, the company's common shares were listed on the Frankfurt Stock Exchange under the ticker symbol N46 (identification number A3ES6P).

SKINJECT

Founded in 2013, SkinJect Inc. was formed as a developmental-stage biotechnology life sciences company focused on commercializing a novel drug delivery therapy for skin cancer utilizing a microneedle patch developed by Dr. Louis D. Falo at the University of Pittsburgh and Professor O. Burak Ozdoganlar at Carnegie Mellon University, both of which serve as advisors to Medicus Pharma. The technology for the SkinJect microneedle patch was formally licensed from the University of Pittsburgh in August 2016.

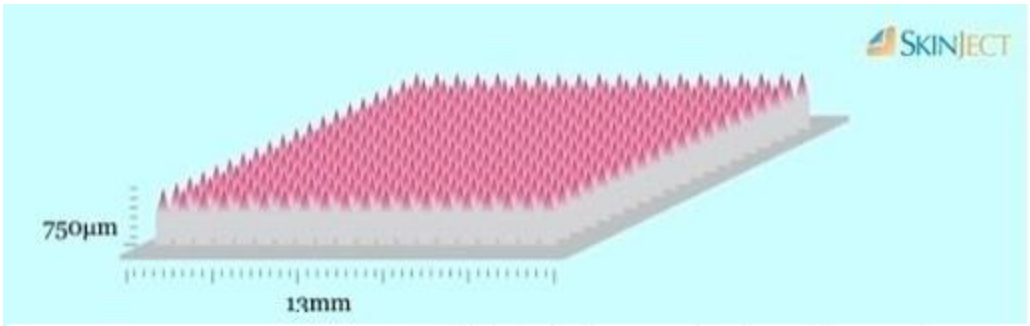
Medicus Pharma Ltd. (fka Interactive Capital Partners Corp.) entered into a letter of intent with SkinJect, Inc., effective April 17, 2023, for a reverse takeover transaction

Medicus Pharma Ltd. acquired SkinJect, Inc. **on September 29**, **2023** through a Business Combination via a reverse takeover transaction. The process was initiated through the signing of a Letter of Intent with SkinJect (effective April 17, 2023). Concurrent with the Business Combination, Medicus completed a private placement of subscription receipts that raised approximately US$5.1 million. SkinJect is now a wholly-owned subsidiary of Medicus Pharma.

The SkinJect Microneedle Patch

The SkinJect microneedle patch is a promising novel approach for treating non-melanoma skin cancers. The **initial treatment target** of the SkinJect drug delivery system is **basal cell carcinoma (BCC)** with squamous cell carcinoma (SCC) anticipated to be the subsequent target.

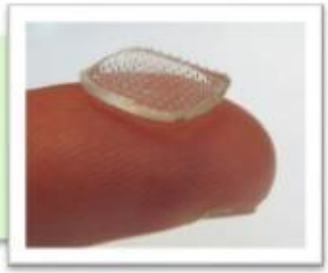
The SkinJect patch is approximately 15mm x 15mm in size and consists of 13mm x 13 mm array of 400 dissolvable microneedles, each of which is approximately 750 microns (aka 0.75mm) in length. The microneedles are composed of buffered carboxymethyl cellulose, in which is deposited a cargo load of a chemotherapeutic agent, doxorubicin hydrochloride.



skinjectpatch.com - a Medicus Pharma Company

Thumb-sized array of dissolvable microneedles that

- ✓ deliver a chemotherapeutic agent (doxorubicin)
- ✓ kill an existing skin cancer and
- ✓ induce a memory immune response to prevent cancer re-occurrence



Medicus Pharma Presentation April 2024

When applied to the skin, the microneedles are designed to penetrate the skin down to the interstitial fluid lying between the basal cell layer & the dermis and thereafter, to dissolve within 30 minutes, transdermally delivering a defined quantity of doxorubicin to the BCC lesion. The doxorubicin induces apoptosis (a programmed cell death) by causing an immune system reaction.

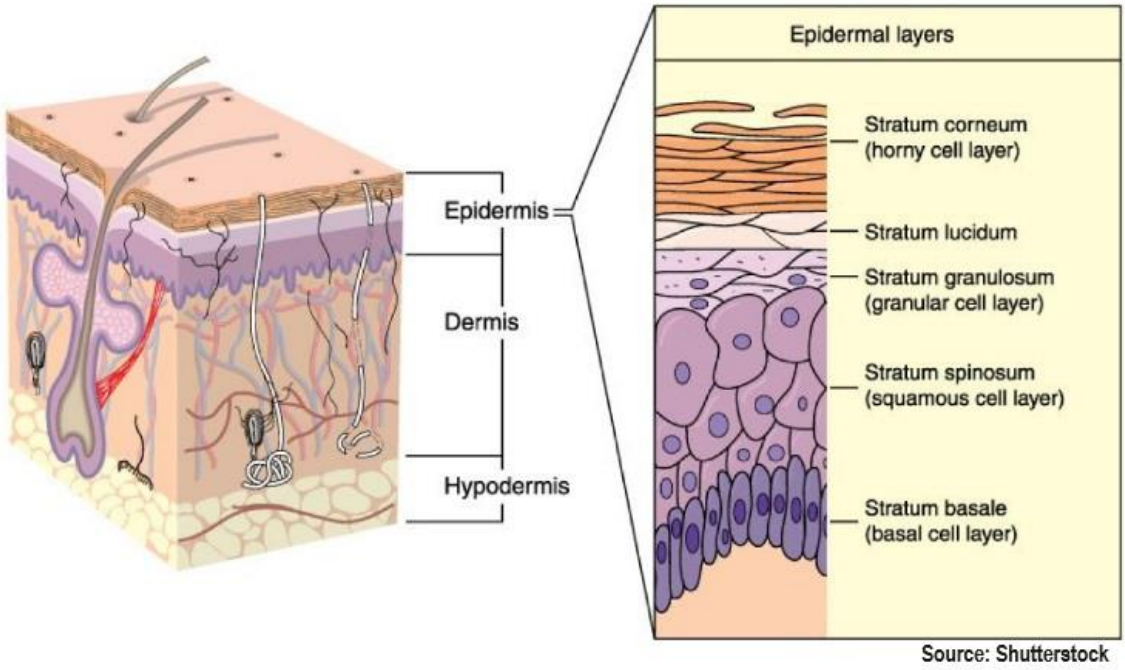
Both the healthcare-grade buffered carboxymethyl **cellulose** that forms the microneedles **and doxorubicin** (the chemotherapy cargo) are **approved by the FDA for human use**.

Brief Primer on Skin Cancer

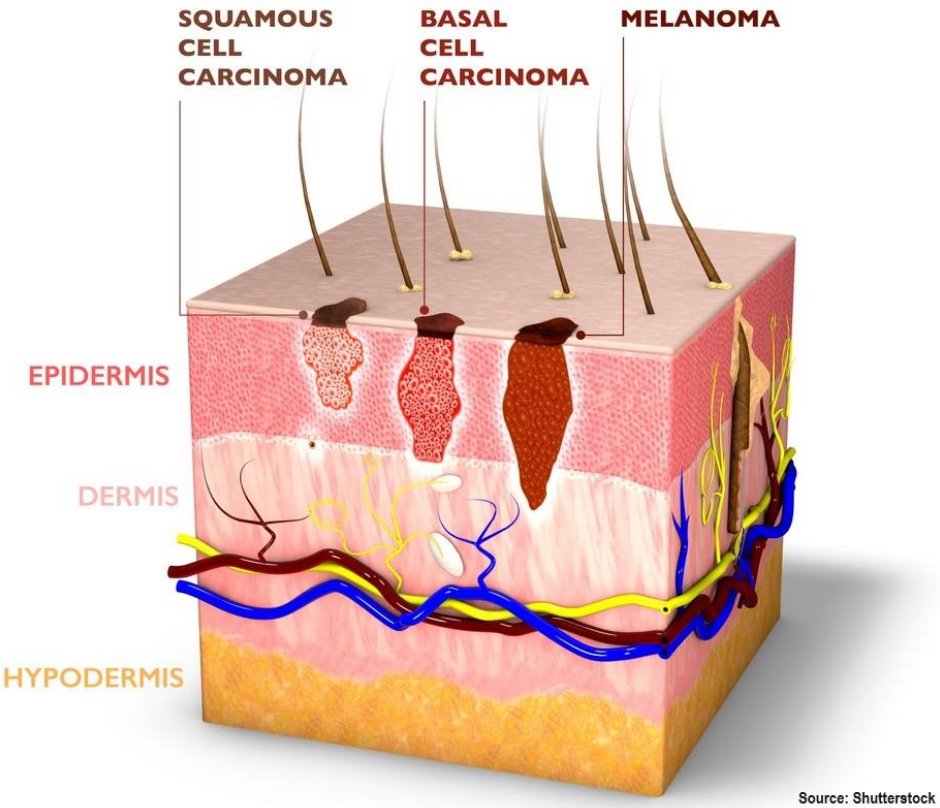
Human skin is composed the three main layers: epidermis, dermis and hypodermis, the latter also being known as subcutis or subcutaneous tissue. The epidermis, the uppermost layer, is comprised of several strata.

Basal cell carcinoma (BCC) originates from the **basal cell layer** (*stratum basale*), which is situated in the lowest area of the epidermis. BCC tends to grow to up to the surface of the skin causing bumps and/or lesions. BCC can also invade the upper area of the dermis transversing boundary between the epidermis and the dermis, known as the Dermo-Epidermal Junction (DEJ) or basement membrane. **Interstitial fluid** resides in this area. It is critical that the dissolvable microneedle arrays be inserted in such a way that the microneedles make contact with the interstitial fluid.

Squamous cell carcinoma (SCC) originates from within the **squamous cell layer** (*stratum spinosum*). When squamous cells grow in an uncontrolled manner, they can develop into SCC.



Typically, BCC and SCC are not life-threatening. However, if left untreated, these skin cancers can grow locally, becoming wider on the surface and deeper into the epidermis. In rare aggressive cases, basal cell carcinoma can metastasize to other areas of the body and become life-threatening.



Basal cell carcinoma is the most common form of skin cancer, and SCC is the second most common. Exposure to ultraviolet light, especially from the sun, is the highest risk factor for the development of these two types of skin cancer.

SkinJect - Method of Action

Doxorubicin (the cancer chemotherapeutic agent used to destroy cancerous basal cells) has a very potent cytotoxic effect on cells since it induces local cell apoptosis. Though doxorubicin is FDA-approved for human use, systematic exposure when administered by injection (intramuscularly or subcutaneously) entails risks due to the life-threatening toxic side effects of cell necrosis, particularly as related to cardiotoxicity, thrombocytopenia, myelosuppression and nephrotoxicity.

However, when **delivered by dissolvable microneedle arrays in small amounts transdermally**, the result is a **release of doxorubicin into a specific targeted area** (the lower part of epidermis and upper area of the dermis). Consequently, a higher local concentration is **delivered within a micro-environment** in the vicinity of the basal cell layer affected by BCC. This delivery process **improves both the effectiveness** of the chemotherapeutic agent **and the safety profile** (by minimizing and/or avoiding systemic exposure to the cytotoxic agent).

A variety of designs of microneedle arrays have been developed in order to provide a method of delivering therapeutic compounds transdermally; the categories include solid, hollow, coated, hydrogel-forming and dissolving microneedles. Transdermal drug delivery with microneedle arrays can evade some issues related to topical, oral and systemic delivery methods, such as topical creams, pills/tablets/capsules and hypodermic needles, respectively.

Dissolving microneedles appear to provide higher therapeutic agent loading than other methods by delivering higher local concentrations of the required drugs for treatment to the target area within the skin layers, thereby enhancing the level of absorption in the target area and reducing systemic side effects, including potential drug interactions.

Phase I Trial of SkinJect Patch

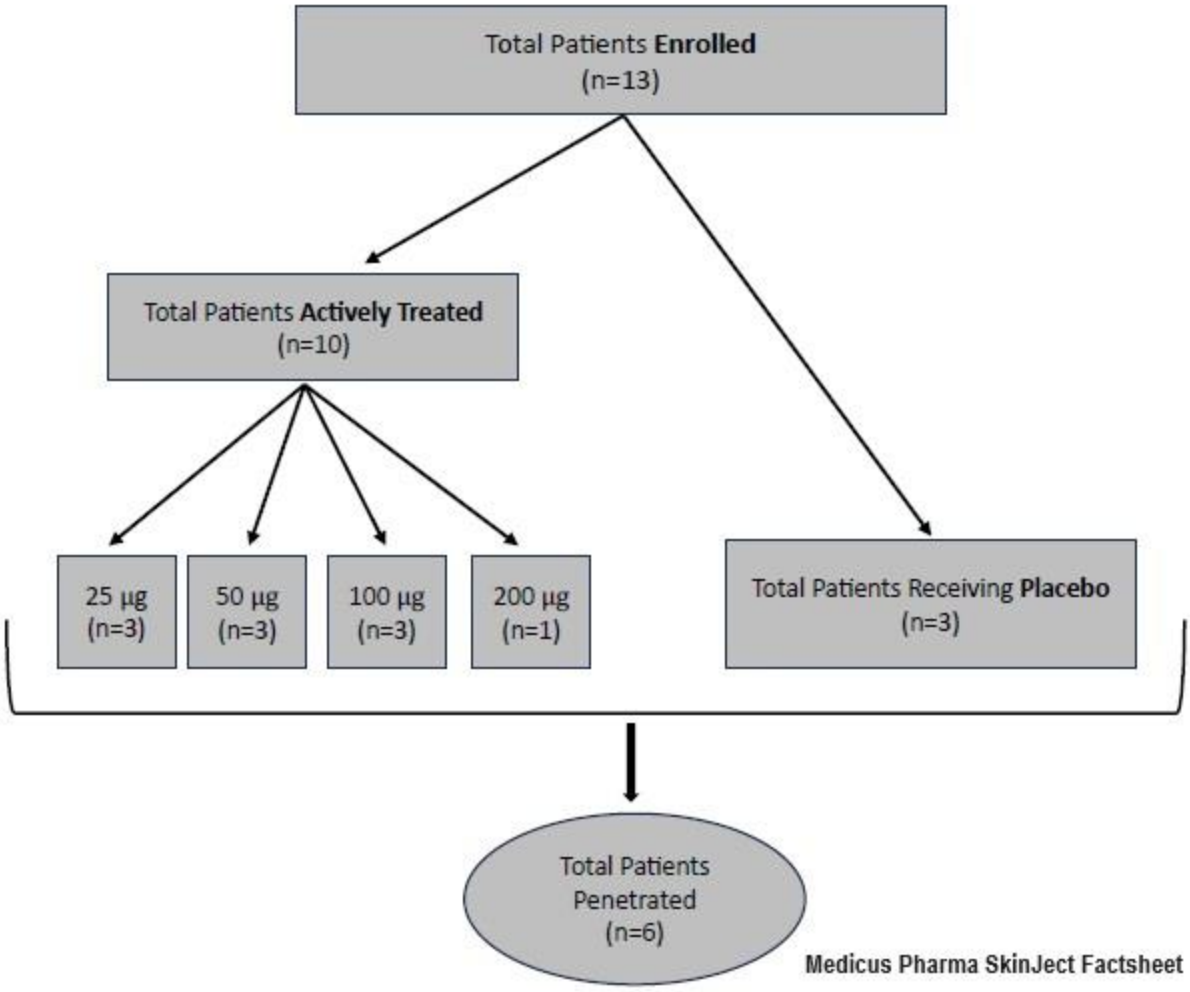
A Phase I clinical trial entitled ***An Open-Label Dose Escalation Trial to Evaluate Dose Limiting Toxicity, Maximum Tolerated Dose, Safety, and Tolerability of Microneedle Arrays containing Doxorubicin in Participants with Basal Cell Carcinoma*** was governed by the **SKNJCT-001 protocol.**

The Phase I clinical study was a **dose escalation trial** of tip-loaded, 15mm x 15 mm microneedle arrays that delivered doxorubicin (D-MNA) to the basal cell layer with the tips penetrating the interstitial fluid that resides in the area of the Dermo-Epidermal Junction. The Part I trial followed a 3+3 dose escalation design with each dose cohort composed of three (3) participants. The three (3) dose cohorts (25 µg, 50 µg, 100 µg of doxorubicin hydrochloride), along with a placebo group (n=3) and a single patient dosed with 200 µg, were studied in order to determine the highest safe and tolerable dose (**Dose Limiting Toxicity** aka DLT) and to define a **Maximum Tolerated Dose (**MTD). Other factors that could affect the rate and extent of array dissolution were evaluated including the anatomic location of the patch, the age of the patient, duration of exposure to the skin and the method of application of the MNA to the skin.

The Phase I study's protocol included a screening visit, three weekly treatment visits over a two-week interval and an end of treatment visit, along with three follow-up visits. The microneedle arrays were pressed into the skin at the site of a lesion, secured to the skin with a bandage and removed after 30 minutes.

There were 13 patients enrolled into the Phase I clinical study; but, only **six (6) patients were properly penetrated** (their ages ranged from 55 to 83). The application of the microneedle array on the other seven (7) patients did not adequately penetrate the skin, and therefore, only mild

dissolution was achieved. Consequently, there was an insufficient delivery of doxorubicin to the target tissue in those seven (7) patients.



The Phase I results suggest that the SkinJect patch is **safe** and **well tolerated** across dose levels between 25 µg and 200 µg due to the following results:

- All patients that completed the study did not have any drug-related serious adverse events.
- Concerning the assessment of Dose-Limiting Toxicity (DLT), the primary study endpoint, no patient reached the protocol's DLT at any treatment assessment.

In addition, in testament to the efficacy of the SkinJect patch, histopathologic assessments showed that all six subjects who were properly penetrated exhibited no residual BCC after the last follow-up visit that occurred four weeks after the treatments.

The Phase I safety and tolerability study was conducted at the Center for Clinical and Cosmetic Research in Aventura, Florida and concluded on May 4, 2021. The costs associated with the execution of the Phase I study was approximately US$1.7 million.

Continuation of Phase I Trial of SkinJect Patch

Given that only six of the 13 patients enrolled in the initial Phase I trial were properly penetrated by the application of the microneedle array, a follow-on study on healthy, older volunteers was designed to ensure that the application of the array consistently resulted in:

1) the adequate penetration of the skin, such that the MNA is in contact with subject's dermal interstitial fluid during the entire period of time that the microneedle array is applied
2) the dissolution of the microneedles results in the delivery of the cargo in a consistent and satisfactory manner

The follow-on study was entitled ***A Trial to Evaluate the Performance of Placebo Microneedle Arrays in Healthy Human Volunteers*** was carried out under the existing 122448 IND. The trial was governed by the **SKNJCT-002 protocol**, which was submitted to the FDA in June 2021 and subsequently approved.

SKNJCT-002 (Part 1) Protocol

Study Title	Study design	Dosing regimen	Study population	FVFP†	Planned enrolment	Expected Subject exposure
A Trial to Evaluate the Performance of Placebo Microneedle Arrays in Healthy Human Volunteers	Placebo microneedle training phase in healthy subjects,	Part I: 5 placebo arrays, one each applied to 5 anatomic locations	Part I: Men and women aged 50-70	Part I: 24 September 2021	Part I: Up to 12 subjects (6 subj/site)	5 arrays applied once to up to 12‡ subjects.

†FVFP = first visit first patient
‡Enrollment paused at 8 placebo subjects

Medicus Pharma (Interactive Capital) Prospectus dated Sept. 18, 2023 page 63

The study's protocol included inserting P-MNAs (**Placebo**-Micro-Needle Arrays) **on five (5) anatomic locations** of 12 **healthy older volunteers** (six at the Florida site and six at the New York City site). The procedure of **inserting** the microneedle arrays into the skin **and taping** the MNA in place was to be **observed in real time** with a Dino-Lite Digital Microscope being utilized to determine the degree and extent of dissolution of the microneedles during the procedure.

Subject enrollment began in late September 2021 at the first site in Florida with the FVFP (first visit first patient) on September 24th. Clinical work at the Florida site concluded in early March 2022. Then, in September 2022, enrollment began at a second site located in New York City. After treating the 7th subject, the study was paused in that same month, when it was decided to identify the cause of the **inconsistent outcomes** and suboptimal success rate for the proper penetration and dissolution of the microneedles.

Ultimately, the cause for the variability of outcomes was identified. It was concluded that, in all probability, the erratic outcomes from the application of the microneedles could be resolved by providing **robust training for site personnel** on the techniques necessary for the proper application of MNAs. The training requires 1) that the **principal investigators** master the art of applying MNAs to **older subjects** and then 2) that their alternative agents (designates) also be properly trained to accomplish the same, specifically

- That each microneedle array is **pressed firmly, but quickly, into the skin** such that the microneedles adequately penetrate the epidermis to an extent that the tips come in contact with dermal interstitial fluid and
- That the MNA patch be **secured to the skin with a bandage** such that constant contact with dermal interstitial fluid is ensured for the duration of the 30 minute treatment

BASAL CELL CARCINOMA (BCC) MARKET

The Patient Market

Basal cell carcinoma is the most common type of skin cancer. A paper published by the National Institutes of Health in October 2017 entitled *Skin Cancer Epidemics in the Elderly as An Emerging Issue in Geriatric Oncology* stated that **BCC accounts for approximately 70% of all skin cancer** cases with SCC accounting for approximately another 20%.[i] The American Cancer Society cited an estimate that eight (8) out of ten (10) skin cancers were diagnosed as BCCs in the U.S during 2012,[ii] which is the most recent statistics available other than from paid services. It is clear that **basal cell carcinoma is the most diagnosed form of non-melanoma skin cancers in the U.S**.

Looking at the BCC market alone, every year an estimated **3.6 million cases** of BCC are diagnosed in the U.S., according to the Skin Cancer Foundation.[iii] To some extent, this is confirmed by the National Council on Skin Cancer Prevention, which states that **5.4 million new cases of BCC** and SCC are diagnosed in the U.S. annually.[iv] **Management believes there are over 5 million cases of basal cell carcinoma in the U.S. annually**, which is projected to grow to approximately 10 million cases by 2030.

The actual number of cases is unknown because cases of BCC and SCC are not required to be reported to cancer registries. We speculate that this lack of reporting may stem from the combination of the size of the market and the low metastatic potential attributed to these epitheliomas due to the low death rate of these characteristically non-malignant forms of skin cancer. A study in 2012 confirms that the registration of all cases of nonmelanoma skin cancer (NMSC) "is likely not correct because NMSC is considered a negligible health problem with low risks of mortality and morbidity."[v]

However, given the statistics gathered by major public and private organizations, along with prognostications from other than from paid services, we estimate that approximately **4.5 million new cases of basal cell carcinoma are diagnosed in the U.S. annually**. According to the Skin Cancer Foundation, one in five Americans will be diagnosed with skin cancer by the age of 70.[vi]

SKINJECT PATENTS

The **SkinJect Microneedle patch** is protected by several patents in the U.S. All are assigned to the University of Pittsburgh and Carnegie Mellon University with the inventors of the drug delivery technology being Dr. Louis D. Falo, Jr., Geza Erdos, PhD Professor O. Burak Ozdoganlar.

U.S. Patent US2014/8834423 B2 entitled ***Dissolvable Microneedle Arrays for Transdermal Insertion***. The patent was granted and published on September 16, 2014.

U.S. Patent US2016/0136407 A1 entitled ***Microneedle Arrays for Cancer Therapy Applications***. The patent was published on May 19, 2016 and issued on November 6, 2016.

U.S. Patent US2018/9944019 B2 entitled ***Tip-Loaded Microneedle Arrays for Transdermal Insertion***. The patent was granted and published on April 17, /2018 with a term through December 2034.

U.S. Patent US2023/11744927 B2 entitled ***Dissolvable Microneedle Arrays for Transdermal Insertion to Human Skin***. The patent was issued on September 5, 2023 with a term through April 2040. This patent is related to patent US2014/8834423 B2 cited above.

SKINJECT LICENSE AGREEMENT

On August 9, 2016, SkinJect announced that the company had secured **exclusive, worldwide development and commercial rights** of the **patented dissolvable microneedle arrays for transdermal insertion** (including the technology and also current & future intellectual property rights) through a **license agreement** concerning relevant patents from the University of Pittsburgh and the Carnegie Mellon University. All the patents and patents pending are categorized under two internal University Reference Numbers 02006 and 02688 that encompass four (4) patents in the U.S., along with patents in Canada, Mexico, Australia, India, China, Brazil, Hong Kong, the European Union, Israel, Japan and Singapore. The license agreement was amended in February 2020. SkinJect, Inc. is now a wholly-owned subsidiary of Medicus Pharma Ltd.

The **applicable anti-cancer drug agents** include, but are **not limited to, doxorubicin**. On the other hand, the targets of the treatment encompass all cancers and pre-cancerous lesions, but specifically **exclude in-transit melanoma**.

SkinJect (and its parent company) has the **right to enter into sublicensing agreements** with prior written approval by the University of Pittsburgh.

The University of Pittsburgh and the Carnegie Mellon University reserved the nonexclusive (royalty-free) right to exercise patent rights for non-commercial education and research purposes

VALUATION

The Therapeutic Treatment Market

There are various **therapeutic treatments** depending on the diagnosis of one of the 26 different BCC subtypes. The potential treatments can be broadly categorized into two types: **surgical** (Mohs surgery, Electrodessication & Curettage aka EDC and standard surgical excision) and **non-surgical treatments** (e.g. topical chemotherapeutic agents, photodynamic therapy, cryotherapy, laser therapy, radiation and systemic medications). Surgery accounts for approximately 51% of the global BCC treatment market in terms of value.[vii]

Though invasive and painful, Mohs micrographic surgery (MMS) is the gold standard for treating BCC. Due to the specificity of tissue removal, MMS affords the lowest recurrence rate of the many treatment modalities for BCC at 1% in comparison to 7.5% for cryotherapy, 7.7%, 7.7% for EDC, 8.7% for radiation therapy and 10.1% for surgical excision.[viii]

The cost of Mohs surgery depends the BCC's location on the body and the complexity involved, particularly if deeper tissues need to be accessed and/or if a skin graft is required. In general, the price range is between US$1,000 and US$5,000.According to a study conducted in 2022, the average cost of Mohs surgery is US$1,400 and with reconstruction US$3,534.[ix] The target market of SkinJect includes some cases currently undergoing Mohs surgery Management estimates that the insurance reimbursement in United States is between US$1,500 to US$2,000, which is consistent with the US$1,400 above, which was a negotiated rate for a Veterans hospital, and certainly will be in the range given the inflation rate in the healthcare industry, along with the projected time required to receive FDA approval. Management projects that the SkinJect treatment should cost below $1,000, probably in the US$500-to-$600 range. **If approved, the SkinJect patch would be a very price competitive alternative procedure for the treatment for non-complex nodular BCC** when compared with Mohs micrographic surgery. Also, the SkinJect patch would be, to some extent,

competitive with non-surgical treatments, including topical creams in the management of nodular basal cell carcinoma.

We constructed a Discounted Cash Flow model, generally using the average of published estimates from governmental, industry and private research firms. The number of BCC cases in the U.S. is expected to be around 3.67 million in 2024 and increasing at an 8.6% CAGR over the next seven years. Approximately 70% of those cases will be nodular in nature. Furthermore, it is assumed that 20% of the roughly 850,000 Mohs surgeries performed annually are complex and not appropriate for a D-MNA insertion. The price of SkinJect patch is assumed to start at $500 and increase at the healthcare rate of inflation of 8%. We assume an initial small rate of acceptance of the patch in 2026 with interest ramping up to 1.5% market share in 2030, which would equate to US$30 million in revenues, still being less than 10% of the value of the imiquimod topical cream market.

Utilizing a financial model based on DCF methodology, which forecasts out to 2031 and uses a 10% discount rate (based on CAPM), and a terminal P/S multiple of 3.12 (based on Specialty Drug Manufacturers that focus on developing and commercializing novel therapeutics for unmet healthcare needs), the indicated value of MDCX.V is **CDN$5.35 per share**.

Medicus Pharma Ltd

DCF Model

	2024	2025	2026	2027	2028
Revenues	0	0	202,844	671,250	4,113,406
Cash costs	5,647,687	5,817,118	5,991,631	6,171,380	6,356,521
R&D costs	1,343,530	1,383,836	1,425,351	1,468,112	1,512,155
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%
Free Cash Flow after R&D costs	(6,991,217)	(7,200,954)	(7,214,139)	(6,968,241)	(3,755,270)

Discount Rate	10.0%	
NPV	489,200	
Terminal Value	134,144,859	
Cash From Option Exercises	232,000	
Cash From Warrant Exercise	0	
Probability	80.0%	
Total Sum of Parts	107,892,847	
Debt	0	1Q:2024
Cash	10,542,405	1Q:2024
Current Shares	21,693,560	
Option & Warrant Shares	400,000	
Diluted Shares	22,093,560	1Q:2024

Total NPV	118,435,252
Share Price	$5.36

Large Capitalization Industry Comparables	Ticker	Forward P/E	Mkt Cap ($billion)	TTM Price/ Book	TTM Price/ Sales	TTM EV/ EBITDA
Industry Mean		**12.31**	**2.40**	**3.84**	**3.12**	**9.17**
Industry Median		10.24	1.58	3.15	2.48	6.65
Alkermes plc	ALKS	10.24	3.96	3.15	2.48	6.31
Lantheus Holdings, Inc.	LNTH	17.79	4.41	8.54	6.39	12.52
Pacira BioSciences, Inc.	PCRX	7.96	0.99	1.11	1.67	6.65
Supernus Pharmaceuticals, Inc.	SUPN	20.16	1.58	1.70	2.63	16.57
Collegium Pharmaceutical, Inc.	COLL	5.39	1.04	4.68	2.44	3.80

Our valuation is based on the company's potential in in the U.S. market, which is estimated to be approximately $6.7 billion. The global market is substantially larger, with some of the major markets being Germany, France, Italy, Spain, the U.K., Japan and China. Management believes the global market size for annual treatment of BCC is more than $20 billion.

RISKS

- As with almost all evolving life-science / biotechnology companies advancing specific therapies toward commercialization, Medicus Pharma is an early-stage enterprise that has yet to generate cash flow from operations to fund management's initiatives, particularly R&D activities and clinical trials. However, the company has been able to fund its operations and initiatives to date.

- As with many life science / biotech companies, Medicus is advancing a novel healthcare technology with associated regulatory risks and the uncertainty of market acceptance

- In order to commercialize the SkinJect patch, Medicus may need to establish production facilities, sales & marketing teams and other operational and distribution support capabilities, all of which entail execution risks. However, part of management's business strategy includes the possibility of aligning with a strategic collaborating partner that helps the company advance the development process that would defray or transfer these execution risks to another entity. Concerning M&A, if a compelling offer arises, then Board would respond in a manner that is in the best interest of the shareholders.

- The company's success is highly dependent on the management team, particularly CEO Dr. Raza Bokhari, the driving force behind the creation of the company and its strategy. The loss of Dr. Bokhari could have material adverse effect on Medicus Pharma.

- With the company's stock having been recently listed on the TSX Venture Exchange in October 2023, trading volume has been light, which represents a low level of liquidity.

BALANCE SHEETS

Medicus Pharma Ltd.					
(Canadian Dollars)	SkinJect Inc. 2022	Interactive Capital 2022	Medicus Pharma 3Q 2023	Medicus Pharma 2023	Medicus Pharma 1Q 2024
Period ending	12/31/2022	12/31/2022	9/30/2023	12/31/2023	3/31/2024
ASSETS					
Cash and cash equivalents	267,652	729	5,107,945	1,719,338	542,405
Prepaid expenses	15,000	-	219	173,719	112,076
Other current assets	-	-	-	-	-
Total Current Assets	**282,652**	**729**	**5,108,164**	**1,893,057**	**654,481**
Right-of-use assets (net)	-	-	-	-	330,748
Intangible assets	-	-	-	-	-
TOTAL ASSETS	**282,652**	**729**	**5,108,164**	**1,893,057**	**985,229**
Accounts payable & accrued liabilities	99,794	431,601	1,601,179	781,609	1,229,684
Lease obligations	-	-	-	-	71,123
Note payable	150,000	8,500	-	-	-
Convertible promissory notes	1,381,499	-	-	-	-
Derivative liability	774,074	-	-	-	-
Preferred share liability	10,075,317	-	-	-	-
Total Current Liabilities	**12,480,684**	**440,101**	**1,601,179**	**781,609**	**1,300,807**
Long-term debt	-	-	-	-	-
Lease obligations	-	-	-	-	294,669
Non-Current Liabilities	**0**	**0**	**0**	**0**	**294,669**
TOTAL LIABILITIES	**12,480,684**	**440,101**	**1,601,179**	**781,609**	**1,595,476**
SHAREHOLDERS' EQUITY					
Common stock	194,538	989,942	19,835,839	19,835,839	19,835,839
Contributed surplus	-	78,941	-	146,671	216,497
Accumulated deficit	(12,392,570)	(1,508,255)	(16,328,854)	(18,871,062)	(20,662,583)
Total Stockholders' Equity	**(12,198,032)**	**(439,372)**	**3,506,985**	**1,111,448**	**(610,247)**
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	**282,652**	**729**	**5,108,164**	**1,893,057**	**985,229**
Shares outstanding	6,434,000	7,249,999	16,153,465	16,153,465	16,153,465

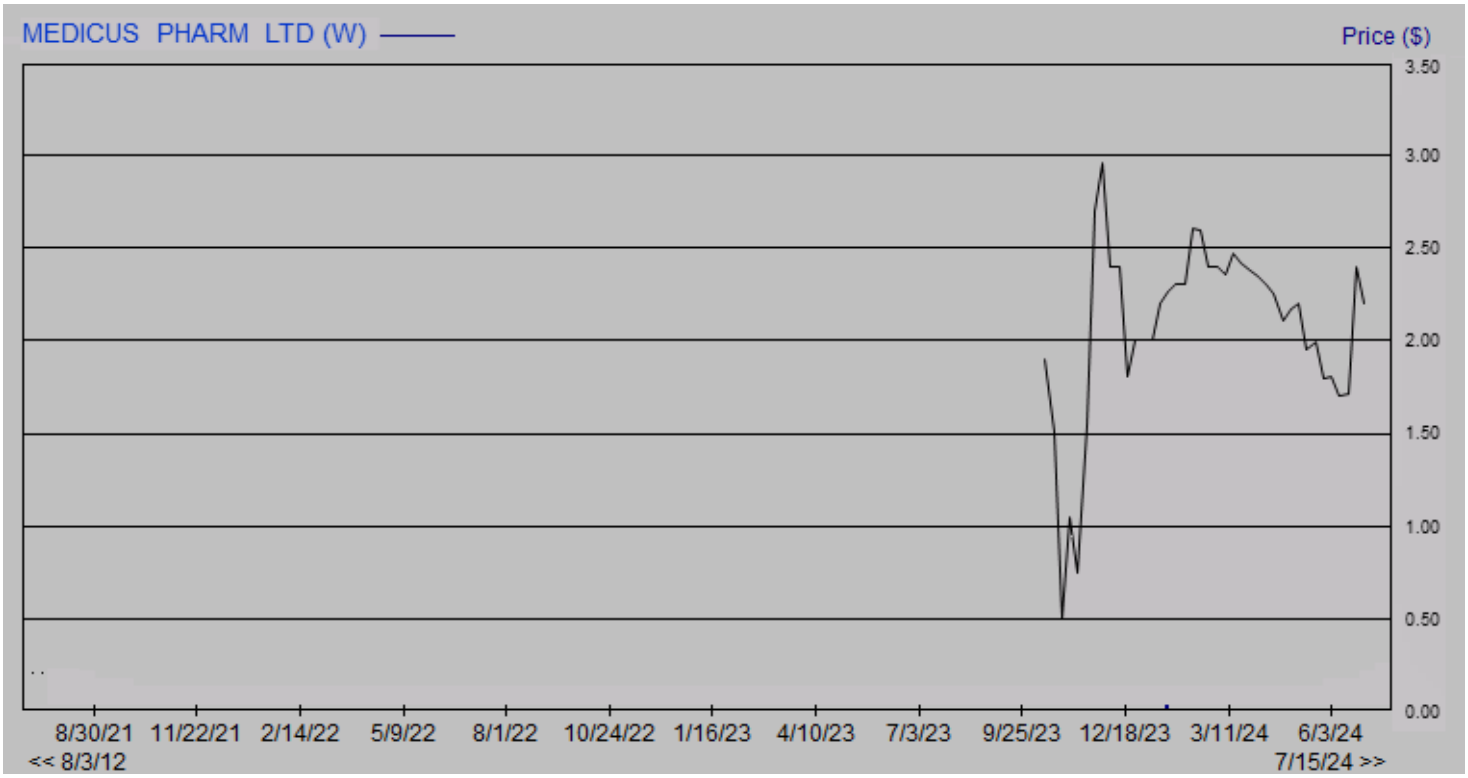
ANNUAL INCOME STATEMENTS

Medicus Pharma Ltd.			
Income Statement in $CDN, except share data) Period ending	2022 12/31/2022	2023 12/31/2023	2024 E 12/31/2024
Total Revenues	**0**	**0**	**0**
Expenses			
General and administrative	332,032	2,366,202	5,647,687
Research and development	646,384	193,578	1,343,530
Professional fees	-	-	-
Depreciation	-	-	107,310
Share-based compensation	-	146,671	292,126
Total Operating Expenses	**978,416**	**2,706,451**	**7,390,653**
Gain (Loss) Before Other Expenses	**(978,416)**	**(2,706,451)**	**(7,390,653)**
Interest expense, net	713,966	500,579	(129,242)
Gain (loss) on settlement of debts	-	-	-
Listing expense	-	3,271,462	-
Other expenses	-	-	-
Total Other Expenses	**713,966**	**3,772,041**	**(129,242)**
Net Gain (Loss)	**(1,692,382)**	**(6,478,492)**	**(7,261,411)**
Basic and diluted loss per share	**(0.45)**	**(0.93)**	**(0.38)**
Wgted. Avg. Shares Out. - diluted	3,769,800	6,959,018	18,923,513

QUARTERLY INCOME STATEMENTS

Medicus Pharma Ltd.					
Income Statement	**1Q 2024**	**2Q E 2024**	**3Q E 2024**	**4Q E 2024**	**Estimate 2024**
(in $US except share and per share data)	**3/31/2024**	**6/30/2024**	**9/30/2024**	**12/31/2024**	**12/31/2024**
Total Revenues	**0**	**0**	**0**	**0**	**0**
Expenses					
General and administrative	1,370,263	1,397,668	1,425,622	1,454,134	5,647,687
Research and development	316,388	329,044	342,205	355,893	1,343,530
Professional fees	-	-	-	-	-
Depreciation	26,036	26,557	27,088	27,630	107,310
Share-based compensation	69,826	71,921	74,078	76,301	292,126
Total Operating Expenses	**1,782,513**	**1,825,189**	**1,868,993**	**1,913,958**	**7,390,653**
Gain (Loss) Before Other Expenses	**(1,782,513)**	**(1,825,189)**	**(1,868,993)**	**(1,913,958)**	**(7,390,653)**
Interest expense, net	9,008	12,000	(60,250)	(90,000)	(129,242)
Gain (loss) on settlement of debts	-	-	-	-	-
Listing expense	-	-	-	-	-
Other expenses	-	-	-	-	-
Total Other Expenses	**9,008**	**12,000**	**(60,250)**	**(90,000)**	**(129,242)**
Net Gain (Loss)	**(1,791,521)**	**(1,837,189)**	**(1,808,743)**	**(1,823,958)**	**(7,261,411)**
Basic and diluted loss per share	**(0.11)**	**(0.11)**	**(0.08)**	**(0.08)**	**(0.38)**
Wgted. Avg. Shares Out. - diluted	16,153,465	16,153,465	21,693,560	21,693,560	18,923,513

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Steven Ralston, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover.

SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.

---

[i] Garcovich S, Colloca G, Sollena P, Andrea B, Balducci L, Cho WC, Bernabei R, Peris K. Skin Cancer Epidemics in the Elderly as An Emerging Issue in Geriatric Oncology. Aging Dis. 2017 Oct 1;8(5):643-661. doi: 10.14336/AD.2017.0503. PMID: 28966807; PMCID: PMC5614327. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5614327/

[ii] Key Statistics for Basal and Squamous Cell Skin Cancers, American Cancer Society, https://www.cancer.org/cancer/types/basal-and-squamous-cell-skin-cancer/about/key-statistics.html & https://www.uptodate.com/contents/epidemiology-pathogenesis-clinical-features-and-diagnosis-of-basal-cell-carcinoma

[iii] Basal Cell Carcinoma- Market Insight, Epidemiology And Market Forecast – 2032, DelveInsight https://www.delveinsight.com/report-store/basal-cell-carcinoma-basal-cell-epithelioma-market

[iv] National Council on Skin Cancer Prevention, https://skincancerprevention.org/

[v] Epidemiology and Economic Burden of Nonmelanoma Skin Cancer, November 2004, pp 419-422 https://doi.org/10.1016/j.fsc.2012.07.004

[vi] Skin Cancer Facts & Statistics, Skin Cancer Foundation, https://www.skincancer.org/skin-cancer-information/skin-cancer-facts/

[vii] Coherent Market Insights, November 2021 https://www.coherentmarketinsights.com/market-insight/basal-cell-carcinoma-market-4794

[viii] Emily P. et al, Cost effectiveness of Mohs micrographic surgery: review of the literature, October 2009, https://pubmed.ncbi.nlm.nih.gov/19852120/

[ix] Liu, Sophia MD, Cost Analysis of Mohs vs Total Surgical Excision, *Plastic and Reconstructive Surgery*, April 2022, p37, https://journals.lww.com/prsgo/fulltext/2022/04001/pc5__cost_analysis_of_mohs_vs_total_surgical.73.aspx